



PHARMACY AND POISONS BOARD

MINISTRY OF HEALTH

**GUIDELINES FOR SCHEDULING OF HEALTH PRODUCTS
AND TECHNOLOGIES**

January 2023

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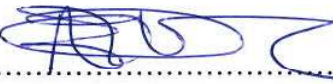
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ABBREVIATIONS

| | |
|-------------|---|
| API | Active Pharmaceutical Ingredient |
| FDC | Fixed Dose Combination |
| GSL | General Sales List |
| HCPs | Healthcare Practitioners |
| IVDs | In- Vitro Medical Diagnostics |
| NCEs | New Chemical Entity |
| NMRA | National Medicines Regulatory Authority |
| MAH | Marketing Authorization Holder |
| OTC | Over the Counter |
| PO | Pharmacy Only |
| PoM | Prescription Only Medicines |
| PPB | Pharmacy and Poisons Board |
| SRA | Stringent Regulatory Authority |
| ToRs | Terms of Reference |

GLOSSARY

Applicant a person that applies to the Board for scheduling of a medical product or health technology.

Alternative Medicine a term that describes medical treatments that are used instead of conventional therapies.

Authorized Prescriber refers to a duly qualified healthcare provider authorized by the law or regulation to prescribe medicines.

Board means the Pharmacy and Poisons Board, or the acronym “PPB” established by Cap 244 of the Kenyan Law;

Borderline products are products having combined characteristics of medicines along with foods, medical devices or cosmetics.

Controlled drug or substance means any narcotic drug, psychotropic substance or precursor chemical made available for use but require controlled access due to their potential of causing physical or psychological dependence or manufacture of drugs with similar characteristics.

Disinfectant A chemical or compound that eliminates many or all pathogenic micro-organisms in inanimate objects.

Dispense means the supply of a medicinal product or poison by a duly qualified pharmaceutical technologist or a pharmacist on or in accordance with a prescription duly given by an authorized healthcare provider recognized by law.

Enrolled pharmaceutical technologist means a holder of a diploma in pharmacy from a training institution recognized by the Pharmacy and Poisons Board and whose name appears on the Roll;

Food supplements a product other than tobacco intended to supplement the diet and shall include all of the following characteristics;

- i. Contains concentrated source of one or more of the following: vitamins, minerals, amino acids, essential oils, natural substances of plants or animal origin, enzymes, substances with nutritional or physiological functions or contains any combination of these.
- ii. Is intended to be taken orally in the form of tablet, capsule, powder, soft gel, granules or liquids.

- iii. Is not presented for use as a conventional food or as a sole item of a meal of the diet.
- iv. Is labelled as a food supplement.

Health products includes human and veterinary medicines, medical products, medicinal substances, nutraceuticals vaccines, diagnostics, medical devices, blood products, traditional, complementary and alternative medicine, therapeutic feeds and nutritional formulations, medical cosmetics, and related products.

Health technology means the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life.

Herbal Products any labelled preparation in pharmaceutical dosage form that contains one or more substances of natural origin as active ingredients

General Shop a licensed retail/ wholesale outlet where goods and services are offered including general sale health products and technologies.

General Sale Health Products means any health products and/or health technologies or chemical listed under schedule one whose use does not require the direction or prescription by a health care provider and can be bought, stored and handled in licensed general shops, supermarkets including sale on e-commerce platforms.

Marketing Authorization means an official approval of medicines and health technologies products to be marketed or distributed in Kenya.

Medical Cosmetics are substances or preparations that contains the qualities of a pharmaceutical product designed for cleansing, perfuming, soothing, treating, preventing or alleviating disease or symptoms of a pathological condition or that affect the structure or function of the human body.

Medical Devices means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article:

- a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes(s) of:

Diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury,

Investigation, replacement, modification, or support of the anatomy or of a physiological process,

Supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Narcotic drugs mean any of the substances natural or Synthetic referred to in the Single Convention on Narcotic drugs of 1961.

Pharmacovigilance means the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions, and includes the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem;

Registered pharmacist means a holder of a degree in pharmacy from a university recognized by the Board and whose name is entered in the register;

Post Market Surveillance means the practice of monitoring the safety and quality of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance

Pharmacy means premises approved by the Board for the storing, dispensing and distribution of Health products and/or health technologies and related substances and which is under the control of a of a registered pharmacist or enrolled pharmaceutical technologist including e-Pharmacy;

Pharmacy Only Health Products means health products and technologies that are available only over the counter from licensed pharmacy premises including

online pharmacies to be dispensed only by a pharmacist or pharmaceutical technologist without a prescription.

Prescription means a lawful written direction or order by an authorized prescriber for the preparation and dispensing of a health product and /or health technology by a registered pharmacist or enrolled Pharmaceutical Technologist;

Prescription Only Health Products refer to any health products and or technologies available from licensed pharmacy premises to be dispensed only by a pharmacist or pharmaceutical technologist only upon a prescription given by a dully qualified and authorized prescriber.

Psychotropic Substances mean any substance natural or Synthetic or any natural material, or any salt or preparation of such substance or material referred to in the Convention of Psychotropic Substances of 1971 intended for medical and scientific purposes;

Radiopharmaceutical means radioactive isotopes which are used as diagnostic and therapeutic agents.

Risk defined as the possibility that a harmful event (death, injury or loss) arising from exposure to a chemical or physical agent may occur under specific conditions.

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Special thanks are extended to Dr. Peter Karimi Ndirangu, the chairperson of the ad hoc committee on scheduling and the committee members for drafting these guidelines.

I also acknowledge the Pharmacy and Poison Board Management for their tireless efforts in coordination and planning during development of this guideline.

1.0 PREFACE

This guideline is intended to provide guidance to applicants and stakeholders on the scheduling of health products and technologies submitted for registration. The guideline represents the Pharmacy and Poisons Board current thinking on control and access of health products and considers the country's obligations in the context of Universal Health Coverage, promotion of self-care and international agreements.

The overall objective of this guideline is to enhance regulated control and access of the medical products and health technologies in order to assure of their quality, safety and efficacy and also to protect the general public. The guideline will be regularly reviewed so as to ensure continued consistency with any changes in the applicable standards.

I would like to thank all the stakeholders who contributed to the successful development of the guideline.

Dr. Fred M. Siyoi

Chief Executive Office

2.0 INTRODUCTION

Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority (NMRA) for Kenya mandated to regulate Practice of Pharmacy Profession, health Products and Technologies. The Board seeks to ensure, quality, safety and efficacy of health products and technologies available in the Kenya Market. Additionally, the Board aims to ensure that information passed to medical professionals and the general public by marketing authorization holders (MAHs) is accurate and factual so as to avoid misinformation geared towards promotion of certain products or to gain advantage over other products.

Scheduling is a national classification system that controls how health products and technologies are made available to the public. One of the key functions of the Board is scheduling and rescheduling of Health products and Technologies according to the level of regulatory control required, need for their availability and the protection of public health.

The key considerations that shall guide scheduling and rescheduling include; risk to harm, accessibility, therapeutic index, abuse potential, inappropriate use, precaution, community harm, precedence, efficacy, availability of medicines with similar active ingredient, legal control, manufacturing, labelling, pack sizes, dosage forms, items in the essential medicines list and Levels of prescribing.

In order to control access, a product can be moved from one schedule to another through rescheduling.

2.1 LEGAL MANDATE

The Constitution of Kenya, 2010, under Articles 35 and 43 (1) guarantees the citizens of Kenya the right to access information and to the highest attainable standard of health. These guidelines shall be read in conjunction with Pharmacy and Poisons Board Act, Cap 244 Laws of Kenya and the Health Act 2019, Kenya

Essential medicines List, 2019, Narcotics and Psychotropic substances Act and the regulations thereunder.

The Ministry of Health in response to the ever-changing environment and constitutional reforms in the country adopted Sessional Paper No 4 of 2012 on the National Pharmaceutical Policy in order to craft the policy direction to inform reform in the pharmaceutical sector in order to ensure equitable access to quality essential health products and technologies for all Kenyans.

In order to achieve the foregoing, this objective envisioned in the policy, pharmaceutical regulation is required to adhere to the provision and come up with a scheduling system that allows for different levels of regulatory control over pharmacologically active substances, whether in the form of active pharmaceutical ingredients, excipients, naturally-occurring products or extracts thereof, or finished pharmaceutical products (medicines), medical devices and accessories which will be reviewed, regularly updated and enforced.

The Pharmacy and Poisons Act, Cap 244 Laws of Kenya (“the Act”) governs the scheduling of health products in Kenya. Under Section 3(a) of the Act, the Board is empowered to formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products.

The Board, specifically under section 25 (1) and (3) of the Act, is mandated to prepare a list of the substances which are to be treated as poisons and submitted to the Cabinet Secretary for approval. The list shall be divided into two parts; Part 1 and Part II which are to be further classified into schedules according to the risk of harm and the level of access control.

The Board therefore prepares these guidelines in order to establish criteria on which to schedule and or reschedule medical products and recommend the same to the Cabinet Secretary.

These guidelines are consistent with the Narcotic Drugs and Psychotropic Substances (Control) Act 1994, which relies on the provisions of the Pharmacy and Poisons Act to inform licit control of narcotics and psychotropics in line with the International Drug Control Conventions to which Kenya is a signet

2.2 SCOPE

This guideline applies to scheduling and rescheduling of both existing and novel health products and technologies. These includes health products, medicinal substances vaccines, diagnostics, medical devices, blood products, traditional and alternative medicines, therapeutic feeds, nutritional formulations, cosmetics and borderline health products.

2.3 OBJECTIVE

- a) Delineate appropriate levels of control for health products and/or health technologies based on their safety, efficacy, benefits and risks, and consumer understanding of products.
- b) Establish a list of products per schedule and application criteria to be used.
- c) Provide information and guidance on the criteria and factors to be considered during scheduling and rescheduling.

3.0 PRINCIPLES OF SCHEDULING

The decision to categorize health products and technologies into different schedules shall be based on risk and benefit profile, in relation to the therapeutic indications for its use and the requirements for professional advice and/or supervision of its use or ability to appropriately self-select.

Other factors to be considered include but not limited to; need for access of a health product, potential for abuse, evidence for the toxicity, need for medical diagnosis, monitoring and medical management by a healthcare professional and the proposed indication for the product.

Health products and technologies may be listed in one or more of the eight schedules based on dosage, formulation, labelling, packaging and presentation, route of administration, strength, indication, or a combination of these factors among other considerations in the interest of the public.

4.0 SCHEDULING OF COMBINATION PRODUCTS

Scheduling of combination products shall consider the existing schedules for individual molecules. Where the active ingredients do not belong to the same schedule, the molecule that is more restrictive applies to the product.

5.0 PRINCIPLES FOR RESCHEDULING

Rescheduling of health products and technologies shall be based on scientific evidence that supports change in schedule. The evidence shall demonstrate that benefit-risk profile of the product would not change in favour of risk if existing regulatory controls are altered. Some of the principles to be considered during down-scheduling include;

- a) Medicine is appropriate for self-care or for the prevention or management of an important widespread public health problem.
- b) A product should have a well-defined place in therapy
- c) Current controls unnecessarily limit patient access to the product, and create a disproportionate level of control relative to benefit: risk assessment of broader access; or lead to ineffective medicine use and/or result in inefficient use of other health system resources including practitioner skills and time.

- d) Rescheduling would result in important benefits to the patient and society at large e.g., improved access, clinical outcomes, public health, consumer involvement and economic benefits.
- e) Rescheduled product should meet more than 60% of the scheduling factors of the target (new) schedule.
- f) The product in question is licensed and has been in use in Kenya
- g) Where applicable, public participation and or stakeholder involvement has been undertaken. Where a Pharmacy or Prescription only health product is being rescheduled to general sales, public participation will be required; where the switch is from Prescription to Pharmacy only, stakeholder consultation will be required.
- h) Product pack size limits total number of doses that patients can access under the down scheduling regime.
- i) The product label provides adequate patient information for rescheduled use.
- j) MAH provides patient information leaflets, medication guides as necessary
- k) MAH retains responsibility for the safety of the product; commits to monitor product use and product safety under the new schedule.
- l) Applicant institutes safeguards to prevent accidental misuse and drug abuse.
- m) A national training Program is in place to support drug prescribing, administration and patient -monitoring under the down-scheduling regime.
- n) A referral system is in place to support safe patient- care under the down-scheduling regime.

6.0 EXPERT COMMITTEE ON HEALTH PRODUCTS SCHEDULING (ECHS)

An expert committee shall be established by the Board to advise and make recommendations on scheduling of health products and technologies based on

risk benefit analysis. The committee shall endeavour to keep up to date with new scientific developments, requirements, procedures and policies in line with best international practices.

The membership, and terms of reference (ToRs) for the expert Committee are set out in **Annex 1**

7.0 APPLICATION FOR SCHEDULING AND RESCHEDULING

An application to schedule or reschedule a health product shall be addressed to the office of the Chief Executive Officer in the prescribed format.

Application can be initiated by individual, organizations, law enforcement agencies or relevant institutions with justifiable scientific information. The Board may also initiate rescheduling of a substance in line with the latest available information including safety, efficacy and potential for abuse and misuse.

To apply for rescheduling, the applicant shall attach all supporting evidence and justification based on a thorough benefit risk analysis for purposes of optimal control. There shall be two types of applications to be considered by the Board;

- a) Applications for scheduling of new health products and technologies
- b) Application for rescheduling of health products and technologies already listed or registered.

Application format and flow chart are hereto attached as **Annex II**.

7.1 SUMMARY OF SCHEDULES

| Schedules | Name | Sub Schedules |
|------------------|-------------------------------|---|
| Schedule 1 | General Sales Health Products | i. General Sales Medicines ii. General Sales Complementary and Alternative Medicines |

| | | |
|------------|--|--|
| | | iii. General Sales Borderline products |
| Schedule 2 | Pharmacy Only Health Products | <ul style="list-style-type: none"> i. Pharmacy Only Medicines ii. Pharmacy Only Complementary and Alternative Medicines iii. Pharmacy Only Cosmetic and related substances iv. Pharmacy only borderline products |
| Schedule 3 | Prescription Only Health Products | <ul style="list-style-type: none"> i. Prescription Only Medicines ii. Prescription Only Complementary and Alternative Medicines |
| Schedule 4 | Controlled Substances | |
| Schedule 5 | Chemicals and Poisons | <ul style="list-style-type: none"> i. Regulated Explosives ii. Regulated Poisons iii. Reportable/ Common use Poisons iv. Non-Explosive Poisons |
| Schedule 6 | Prohibited Products | <ul style="list-style-type: none"> i. Prohibited Pharmaceutical products ii. Prohibited Chemical products iii. Prohibited Cosmetic products |
| Schedule 7 | Pharmaceutical Raw Materials | <ul style="list-style-type: none"> i. Pharmaceutical Active Ingredients ii. Pharmaceutical Excipients |
| Schedule 8 | Medical Devices and In-vitro Diagnostics | <ul style="list-style-type: none"> i. Medical Devices ii. In- vitro Diagnostics |

8.0 SCHEDULE I: GENERAL SALES HEALTH PRODUCTS

Health Products in this category shall be available for self-selection by the public in licensed pharmacies and retail outlets such as supermarkets, general shops or kiosks. They are categorized into four sub schedules as;

- i. General sales borderline products
- ii. General sales medicines
- iii. General sales complementary and alternative medicines
- iv. General sales medical cosmetics and related substances

8.1 Assessment criteria for General Sales Health Products

- a) Use may not require the direction, intervention or authorization of a healthcare professional but is aimed at promoting self-care.
- b) Safe and effective use of the medicine can be achieved through labelling in English and/or Kiswahili including pictograms where necessary in accordance to prevailing PPB labelling requirements for general sale medicines.
- c) Labelling and advertising shall advise that the product is for short term management of signs and symptoms.
- d) Safe and effective use of the medicine can be achieved through Patient Information leaflet in English and Kiswahili which shall be in line with PPB PIL requirements and shall include at a minimum dosing regimen, maximum daily dosage, safe and effective indications, contraindications, precautions, adverse drug reactions and warnings.
- e) The Products shall be used for a specified duration of time, sold in final primary pack, shall not be repacked or relabelled.
- f) The product must not contain a substance known to be addictive or cause dependence;
- g) The health hazard, risk of misuse and the need for special precautions in handling are minimal, and the availability of the product without professional supervision does not pose risk to health of the public.
- h) Product in this category shall not include products formulated for eye preparations, ear preparations, suppositories, pessaries and parenteral administration.

- i) Risk-benefit profile of a product will be confirmed by the PPB department of pharmacovigilance and post marketing surveillance.
- j) The products may be displayed and advertised to the general public and healthcare professionals upon authorization by the Board.
- k) The products are for relief of symptoms of self-diagnosed or self-limiting ailments that can easily be recognized and are unlikely to be confused with serious diseases or conditions.
- l) Antiseptics and disinfectants shall contain low risk ingredients, make no specific claims relating to mycobacterium, fungi spores or viruses and shall not be meant for use in healthcare setting but limited to low level activity against bacteria.

In addition to the above, borderline and complementary herbal /ayurvedic medicines;

- a) shall either be listed or registered
- b) shall have combined characteristics of general sales medicines along with foods, medical devices or cosmetics
- c) should have plausible efficacy based on evidence of long-standing use and experience
- d) shall include traditional medicines that are freshly prepared by traditional health practitioner for an individual patient with fresh or dried raw materials, with a short shelf life
- e) shall comprise of traditional medicines currently used in the community that are prepared in advance and composed of crude raw plant materials.

8.2 Restrictions to general sale cosmetics

The products in this category shall exclude the following;

- a) Products used by attaching to or by spreading on teeth for whitening or by smearing on teeth for cleaning which contains more than 3% of hydrogen peroxide.

- b) Toothpastes containing higher than 1,500 ppm of fluorine or 0.75% of hydrogen peroxide.
- c) Hair-dying products containing 2, 4-diaminoanisole and its sulphate.
- d) Mouth freshener containing more than 0.75% of hydrogen peroxide

The General sale list is hereto attached as **Annex III**.

9.0 SCHEDULE 2: PHARMACY ONLY HEALTH PRODUCTS

Health Products in this category shall only be dispensed or supplied from a licensed pharmacy outlet and or an online pharmacy and they shall not be available for self-selection. They are categorized into four sub schedules as;

- a) Pharmacy Only borderline products
- b) Pharmacy Only Medicines
- c) Pharmacy Only Complementary and Alternative Medicines
- d) Pharmacy Only medical Cosmetics and Related Substances

9.1 Assessment criteria for pharmacy only health products

Health Products shall require more restrictions/control as compared to the products in general sales category:

- a) Input from a pharmacy professional may be sought for safe and effective use before. This may include diagnosis; medication use counselling and monitoring therapy.
- b) The risk profile of the medicinal product is identifiable, predictable and well defined. They may include; adverse effects, drug interaction, contra indications, misuse, abuse or illicit use.
- c) Shall have combined characteristics of pharmacy only medicines along with foods, medical devices or cosmetics.

Medical prescription may not be required because: -

- a) Requirement for medical prescription delays or restricts access to a timely and effective essential or emergency care.

- b) Public health interest is best served by making the product available without medical prescription.
- c) A nursing or medical professional is not required to administer the treatment.
- d) The patient can identify the signs and symptoms of a condition to be treated by a medical product but the correct choice should be verified and item supplied
- e) These products may be used for prevention of physiological disturbances, prophylaxis against disease and injury and reduction of disease complications
- f) The product is not likely to result in intolerable side effects and or unexpected adverse reactions, dependence or other negative outcomes.
- g) The Products shall have a comprehensive appropriate product information leaflet in English and Kiswahili which shall be in line with PPB label/PIL requirements
- h) The product shall require a supplementary pharmacy label during dispensing that contains at a minimum; date, patient name and dosage
- i) Appropriate patient records, follow up and referral may be required to be carried out by the pharmacy professional.
- j) A product may not be included in this category if its indications would mask symptoms or delay diagnosis of a serious condition.
- k) Products may be advertised and promoted to the general public and healthcare providers within the premises of licensed pharmacies and or healthcare facilities as per the guideline on advertisement and promotion
- l) Risk-benefit profile of a product will be confirmed by the PPB department of pharmacovigilance and post marketing surveillance.
- m) Antiseptics shall include products used in healthcare settings on human skin for medical purposes or pre-surgical procedures and that contain medicinal substances such as cetrimide

- n) Disinfectants shall include products that are dispensed through fogging applications/automated airborne systems, and make specific claims relating to viruses, tuberculosis, mycobacterium or fungi.
- o) Complementary and Alternative Products in this schedule may be used for promotion of health and wellness so long as;
- p) They are isolated pure compounds obtained from traditional medicines following scientific research
- q) They Include standardized plant extracts prepared in advance and supported by scientific research

9.2 Assessment criteria for pharmacy only medical cosmetics

- a) Medical cosmetics and related substances shall be sold as Pharmacy Only.
- b) should have both cosmetic and pharmacological activity
- c) shall require premarketing approval by the Board
- d) Shall require declaration of all the ingredients and their concentrations.
- e) shall require professional input for safe and effective use by the consumer
- f) usage shall be for a specified duration of time
- g) Should conform to the labelling requirements outlined in the cosmetic products registration guidelines.
- h) They may be advertised and promoted to healthcare providers upon approval by the Board.

The pharmacy only list is hereto attached as **Annex IV**.

10.0 SCHEDULE 3: PRESCRIPTION ONLY HEALTH PRODUCTS

Health Products in this category shall be dispensed or supplied from a licensed pharmacy under the supervision of an authorized pharmacy professional to the

consumer on and in accordance with a prescription given by a duly authorized healthcare provider.

They are categorized into three sub schedules as;

- a) Prescription Only Medicines;
- b) Prescription Only Complementary and Alternative Medicines;
- c) Prescription Only medical cosmetics and related substances;

10.1 Assessment Criteria for Prescription Only Health Products

- a) The inappropriate uses of the health products and or health technologies are likely to contribute to severe harm such as adverse drug reactions, toxicity, treatment failure, development of resistant strains of microorganisms.
- b) Close monitoring is required during treatment by a qualified healthcare provider for effectiveness and safety of the product.
- c) All new molecules or combination registered for use in Kenya for the first five (5) years unless otherwise justified
- d) All investigational products used in clinical trials and products for compassionate use.
- e) Prescribing and dispensing records shall be retained for a period of two (2) years.
- f) Medication use counselling shall be provided during prescribing and dispensing.
- g) The PPB department of pharmacovigilance and post marketing surveillance profile will confirm the Risk benefit profile of the products. Products may require special prescription forms (hard copy/electronic) that will be used by different levels of authorized prescribers.
- h) Products shall require close monitoring of supply chain to ensure that only authorized persons can handle them.

- i) Health products in this schedule shall not be advertised to the general public but may be detailed or promoted to healthcare providers upon approval by the board.
- j) These products have a low potential for dependence.
- k) Limited quantities can be found in authorized health institutions and research laboratories as may be prescribed by the Board from time to time.
- l) The prescription only list is hereto attached as **Annex V**.

11.0 SCHEDULE 4: CONTROLLED SUBSTANCES

These are substances that have the potential to cause both psychological and physical dependence.

These products shall be dispensed or supplied from a licensed pharmacy premise under the supervision of an authorized pharmacy professional to the consumer or to certified healthcare provider as well as education and research institutions on a valid prescription.

11.1 Classes of controlled substances

They are categorized into five classes; V, IV, III, II, and I based on increasing potential for abuse and dependency.

- a) Class I drugs; Have a high potential for abuse. They have no currently accepted medical use in the treatment of diseases but may be used for research purposes. There is a lack of accepted safety for use of these drugs.
- b) Class II drugs or other substances; Have a high potential for abuse. They have accepted medical uses in treatment of diseases but with severe restrictions. Abuse of these agents may lead to severe psychological or physical dependence.

- c) Class III drugs or other substances; Have less potential for abuse than the drugs or other substances in classes I and II. They have accepted medical uses and abuse may lead to moderate or low physical or high psychological dependence.
- d) Class IV drugs or other substances; Have a low potential for abuse relative to the drugs or other substances in class III. They have accepted medical uses and abuse may lead to limited physical or psychological dependence relative to the agents in class III.
- e) Class V drugs or other substances; Have a low potential for abuse relative to the drugs or other substances in class IV. They have accepted medical uses and abuse may lead to limited physical or psychological dependence relative to the drugs or other substances in class IV.

11.2 Assessment criteria for controlled substances

- a) Use leads to craving of higher doses and lack thereof precipitates withdrawal signs and symptoms. This eventually causes the victims to depend on the product for psychological satisfaction and physical activities.
- b) They may cause social disharmony due to changed behaviour of the victims
- c) Access shall be restricted through high level control of the entire supply chain.

The controlled substances list is hereto attached as **Annex VI**.

12.0 SCHEDULE 5: POISONS, CHEMICALS AND REAGENTS

Schedule VI shall comprise of non-medicinal poisons, chemicals and reagents whose possession and access should be controlled because of the potential for misuse that can lead to physical hazards, toxicity or terrorism.

They are categorized into five parts in their order of decreasing risk;

- a) Regulated explosive precursors

- b) Regulated poisons
- c) Reportable explosive precursors
- d) Reportable / common use poisons
- e) Other Laboratory Chemicals

12.1 Assessment criteria for poisons, chemicals and reagents

- a) The products are not intended for use in human beings through any route of administration
- b) Their level of risk is dependent on many factors including concentration of the chemicals in a product, complexity of a product and amount of the product.
- c) The risk of causing harm by explosive precursor chemicals and poisons can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
- d) Regulated poisons and regulated precursors shall bear a warning that; *'Acquisition, possession or use by the general public is restricted'*.
- e) Additional labelling shall include the terms **'CAUTION'** for low risk, **'POISON'** for medium risk chemicals, **'SPECIAL PRECAUTIONS'** for high-risk chemicals and appropriate safety symbols for hazardous products.
- f) Chemicals and Poisons shall be manufactured, imported, distributed and handled by wholesalers and retailers licensed by the Board (PPB).
- g) Shall only be supplied to authorized quality control laboratories, training institutions, manufacturers, research institutions as well as horticultural, agricultural and mining entities for activities within their approved scope of operations.

12.2 Regulated explosive precursors

A regulated explosive precursor refers to chemical substance which can be made into an explosive with relative ease by mixing or blending with other substances, or by simple chemical processing. The majority of these chemicals is used for

legitimate purposes but could potentially be misused for the illicit manufacture of homemade or improvised explosives.

Relatively small amounts of these chemicals can be sufficient to manufacture explosives. The records of the sale shall be kept, stating the;

- a) Date of the supply,
- b) Name and address of the purchaser;
- c) Name and quantity of the regulated explosive precursor supplied;
- d) Stated purpose of the purchase and signature of purchaser.

The records must be retained for at least three (3) years.

12.3 Regulated poisons

- a) These substances refer to chemical weapons that can be used to cause harm or terrorism.
- b) They can cause severe harm or death to human beings even in low amounts if ingested, breathed in, injected into the body or absorbed through the skin.
- c) The records of the sale shall be kept, stating the date of the supply, the name and address of the purchaser; the name and quantity of the regulated explosive precursor supplied; the stated purpose of the purchase and signature of purchaser. The records must be retained for at least three (3) years.

12.4 Reportable explosive precursors

- a) These substances may be used for illicit manufacture of explosives.
- b) The ease of illicit manufacture of explosive from these chemicals and level of risk is less than that of class V (a).
- c) In addition to professional use, the products are used in common consumer products within a vast supply chain.

- d) Suspicious transactions, significant disappearances and thefts of these poisons shall be reported to the Board

12.5 Reportable poisons

- a) Reportable poisons are commonly used poisons and can be supplied to purchasers if the purchase is not suspicious.
- b) Suspicious transactions, significant disappearances and thefts of these poisons shall be reported to the Board

12.6 Other laboratory chemicals

- a) The schedule shall include all non-medicinal chemicals, poisons and reagents not listed in schedule 5 (a)-(d)
- b) They shall be supplied to licensed institutions such as training institutions, quality control laboratories, research institutions and manufacturers within their approved scope of operations.

The chemicals and poisons list are hereto attached as **Annex VII**.

13.0 SCHEDULE 6: PROHIBITED PRODUCTS

They shall be classified into three major categories:

- a) Prohibited Pharmaceutical products
- b) Prohibited Chemical products
- c) Prohibited Cosmetic products

13.1 Prohibited Pharmaceutical products

Prohibited pharmaceutical products shall be categorized into three groups;

- a) Banned,
- b) Severely restricted
- c) Non-approved

- a) **Banned products:** These are products that have been withdrawn from use and/or sale in one or more countries by order of the competent national authority or the manufacturer having regard to its safety in relation to its intended use.
- b) **Severely restricted:** A product containing a substance;
 - i. That is controlled more rigorously than is provided for under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances or that is subjected to analogous control at the national level before it has been considered for international scheduling
 - ii. That may be incorporated in pharmaceutical dosage forms only within the specific limits determined by statute;
 - iii. That is approved by a competent national authority and is subsequently subjected to restrictions that exclude its use in a substantial proportion of the potential target population of patients having regard to its safety.
 - iv. That from the outset has been severely restricted in its indications having regard to the known balance of safety and efficacy is excluded.
- c) **Non-approved:** A product that has been formally submitted for registration by a manufacturer to a national competent authority and which has been rejected on grounds of safety.

13.2 Prohibited Chemical and cosmetic products

Prohibited chemical and cosmetic products shall be listed as;

- a) **Banned:** A product that has been prohibited for all uses nationally or internationally by government regulatory or international authority action because of health or environmental reasons.

- b) **Withdrawn:** A product formerly in commerce that has been withdrawn for all uses nationally or internationally by final voluntary action of the manufacturer because of health or environmental reasons.
- c) **Severely restricted:** A product for which virtually all uses have been prohibited nationally or internationally by government regulatory or international authority action because of health or environmental reasons, but for which certain specific uses remain authorized.

13.3 Assessment Criteria for prohibited health products

- a) The potential health risk does not include potential for abuse, diversion into illicit products or other factors which would warrant inclusion in Schedule IV
- b) The schedule shall contain all those substances that are contained in lists updated through international conventions for which Kenya is a signatory.

13.4 Authorized outlets for Prohibited pharmaceutical products

- a) Banned products – not to be kept by any outlet
- b) Severely restricted – can be kept by pharmacy or hospital outlets with a special approval to handle the same from the Cabinet Secretary. Since it is restricted for wider population, approved outlet should demonstrate ability to avoid use in wide population and ensure health and environmental safety.
- c) Non-approved - not to be kept by any outlet

13.5 Authorized outlets for Prohibited Chemicals and Cosmetics

- a) Banned chemical/cosmetic products – not to be kept by any outlet
- b) Withdrawn chemical/cosmetic products - not to be kept by any outlet
- c) Severely restricted chemical/cosmetic products – to be kept by outlet upon special approval by the Cabinet Secretary. since it is restricted

for wider population, approved outlet to demonstrate ability to avoid use in wide population for safety.

The prohibited list of products is hereto attached as **Annex VIII**.

14.0 SCHEDULE 7: PHARMACEUTICAL RAW MATERIALS

These are raw materials that are used in the manufacture of medicines for human and animal use. They are categorized as;

- a) Active pharmaceutical Ingredients (APIs)
- b) Pharmaceutical Excipients

14.1 Active Pharmaceutical Ingredients (API)

These are substances or mixture of substances intended to be used in the manufacture of medicinal substances and that, when used in the production of medicinal substance, becomes an active ingredient in the medicinal substance.

For purpose of this guideline, active pharmaceutical ingredients are categorized into three;

- a) APIs with no potential for abuse and addiction
- b) Controlled APIs
- c) Controlled precursor chemicals

a) API with no potential for abuse and addiction

APIs under this class are those excluded from schedule 4 (a) and (b)

Assessment criteria for APIs with no potential for abuse

These substances;

- a) Do not cause addiction or dependence;
- b) Health hazard, risk of misuse and the need for special precautions handling are minimal.
- c) Are used in the manufacture of finished products in schedules 1, 2 and 3.

- d) Are sold and distributed in bulk packaging. If repackaging activities are undertaken, approval by the Board shall be required.
- e) Are labelled with all the details in the bulk packaging and in accordance with applicable WHO guidelines on repackaging.
- f) Shall require close monitoring of supply chain, including import, wholesale, distribution, to ensure that only authorized persons can handle them.

b) Controlled APIs

They shall be treated according to rules applicable to the schedules IV. Controlled APIs shall either be of addictive nature such as narcotics and psychotropic substances or those with potential for abuse in competitive sports such as erythropoietin and nandrolone.

For purposes of this guideline, controlled APIs are further classified into;

- a) **Least controlled APIs:** These drug substances that;
 - i. Have a low potential for abuse.
 - ii. They are a currently accepted for medical use in Kenya and
 - iii. Abuse of the drug substance may lead to limited physical or psychological dependence.
- b) **Strictly controlled APIs:** These are substances that;
 - i. Have a high potential for abuse,
 - ii. Have accepted medical use in Kenya
 - iii. May lead to severe psychological or physical dependence
- c) **Highly controlled APIs.** These substances;
 - i. Have a high potential for abuse.
 - ii. Have no currently accepted medical use in Kenya
 - iii. Lack adequate safety data to support medical use.

- d) **Restricted veterinary APIs.** These substances;
 - i. are used in the manufacture of finished veterinary medicines.
 - ii. have a narrow therapeutic window
 - iii. require restricted access and use by authorized persons

- e) **APIs with potential for illicit use in sporting activities.**

These drug substances have therapeutic use but can be subject of abuse to enhance bodily performance by athletes and other sports persons and may represent an actual or potential health risk to the athlete such as nicotine and related substances including substances used in e-cigarettes.

- f) **APIs used in manufacture of medical cosmetics.**

This refers to active ingredients used in the formulation of special cosmetic products as defined under schedule II and III.

Assessment criteria for controlled APIs:

These substances;

- a) Shall require close monitoring of supply chain, including import, wholesale/distribution, to ensure that only authorized persons can handle them
- b) Have potential to cause addiction or dependence
- c) Are used in the manufacture of finished products in schedules 1, II, and III
- d) Shall be labelled with all the details in the bulk packaging and in accordance with applicable WHO guidelines on repackaging.
- e) Are sold and distributed in bulk packaging. If repackaging activities are undertaken, approval by the Board shall be required.

c) Controlled precursor chemicals

Controlled precursor chemicals are any substance which;

- a) Can be used in any of the chemical processes involved in the production, manufacture or preparation of narcotic drugs, psychotropic substances or substances having a similar effect;
- b) Incorporates its molecular structure into the final product making it essential for those processes; and
- c) Broadened to encompass all chemicals that are controlled under the United Nations convention against illicit traffic of narcotic drugs and psychotropic substances, 1988.
- d) These substances are classified by the international narcotic control board (INCB) into table I and table II products. Generally, table I chemicals are more critical to the production of controlled substances than are those in table ii, therefore provisions concerning these substances are more rigorous.

Assessment criteria for controlled precursor chemicals

- a) Controlled precursors require a high level of control through prohibition or restriction on manufacture, supply, distribution, possession and use to reduce abuse, misuse, and diversion into illicit activities.
- b) Controlled precursors are labelled with details of batch attributes including manufacturing date, expiry / retest date and batch number
- c) Controlled precursors shall require close monitoring of supply chain, including import, wholesale/distribution, to ensure that only authorized person can handle them
- d) Notification to Pharmacy and Poisons Board by operators of suspicious transaction in precursors is required
- e) All operators dealing with substances in table I shall require licensing from the Pharmacy and Poisons Board

Authorized handlers of APIs and precursor chemicals:

Authorized handlers shall comprise of;

- a) Authorized dealers such as manufacturers of finished pharmaceutical
- b) Persons engaged in research activities
- c) Manufacturers and suppliers of APIs and precursor chemicals
- d) Persons engaged in licensed cultivation of plant derived controlled APIs

For purposes of good regulation of APIs, licensure shall be issued to;

- a) Manufacturers license for APIs
- b) Manufacturers license for Precursor chemicals
- c) Wholesale dealers license – for vendors and suppliers
- d) Cultivation license for plant derived controlled APIs
- e) License for research activities involving the use of controlled APIs

Special conditions shall be attached to the issued licenses depending on the type and risk profile of the APIs and precursor chemicals handled. The licenses are subject to periodic returns of consumption to the Pharmacy and Poisons Board. Controlled precursor chemicals that have other general uses shall be exempted based on volume and concentration. All exemptions shall be entered into precursor chemicals register by vendors.

14.2 PHARMACEUTICAL EXCIPIENTS

They are substances that are included in the pharmaceutical dosage forms not for their direct therapeutic actions but to aid the manufacturing process to protect, support or enhance stability, bioavailability, or patient acceptability.

Pharmacopeial grade excipients have a long history of use and safety profile are included in official monographs while novel excipients are new and have a higher

risk profile, and they shall be subjected to stricter controls until their safety profile is established.

Licensure for excipients shall take into consideration whether they are novel or pharmacopeial. For purposes of this guideline, pharmaceutical excipients are classified into two categories;

- a) General excipients (low risk) and
- b) Special excipients (moderate to high risk)

14.2.1 General excipients

They are routinely and widely used in the pharmaceutical sector and they do not require special warning and labelling requirements. General excipients shall be handled by the following:

- a) Authorized dealers such as manufacturers of finished pharmaceutical product and other products
- b) Persons engaged in research activities
- c) Manufacturers and wholesalers of excipient

14.2.2 Special excipients

These are excipients that shall have labelling requirements indicating their risks and storage requirements that require appropriate handling by qualified personnel. For purposes of this schedule, special excipients are classified into;

- a) Pharmaceutical grade excipients
- b) Research grade excipients

Pharmaceutical grade excipients shall be subjected to the stricter regulatory requirements. The manufacturers and suppliers of special excipients shall ensure the excipients are of good quality and safety profile. Some special excipients may fall under active pharmaceutical ingredients in which case the stricter requirements shall apply.

For purposes of good regulation of special excipients for pharmaceutical use, licensure shall apply to;

- a) Manufacturer's license
- b) Wholesale dealers license for vendors and suppliers

Special conditions shall be attached to the issued licenses depending on the type and risk profile of the excipients handled.

The pharmaceutical raw material list is hereto attached as **Annex IX**.

15.0 SCHEDULE 8: MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

These are instruments and reagents that are used in assisting diagnosis, prevention, monitoring, treatment or alleviation of diseases. They are categorized into two sub schedules;

- a) Medical Devices
- b) In-Vitro Diagnostics Medical Device (IVD-MD)

15.1 Risk based classification of Medical Devices and IVDs

Medical Devices and In-vitro diagnostics shall be scheduled following the risk-based classification of Class A, Class B, Class C, and Class D. The inherent risk of a medical device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design manufacture and use.

Class A

- a) Lower risk as compared to class B
- b) Devices has no invasive or require only sporadic contact with the body
- c) Class includes loaded and unloaded medication delivery devices
- d) Devices contain, carry, deliver, leach or emit potentially harmful materials into the environment.

- e) Procedures to be performed require medical prescription or assistance.
- f) Applicant to provide a certificate of quality, certificate of origin and proof that manufacturer has a certified quality management system.

Class B

- a) Lower risk as compared to class C
- b) Devices are minimally invasive or require only sporadic contact with the body
- c) Class includes loaded and unloaded medication delivery devices
- d) Devices contain, carry, deliver, leach or emit potentially harmful materials into the environment.
- e) Procedures to be performed require medical prescription or assistance.
- f) Applicant to provide a certificate of quality, certificate of origin and proof that manufacturer has a certified quality management system.

Class C

- a) Lower risk as compared to class D
- b) Devices are invasive or require prolonged contact with a part of the body
- c) Devices contain, carry, deliver, leach or emit potentially harmful materials into the environment.
- d) Procedures to be performed require assessment, medical prescription or assistance.
- e) Applicant to provide a certificate of quality, certificate of origin
- f) Manufacturer has a certified quality management system.

Class D

- a) Devices that have the highest level of risk to the patient, user or environment.
- b) Device is implanted into the body or is otherwise highly invasive
- c) Device interferes or modulates physiological function
- d) Device requires specialized training to operate, calibrate and use
- e) Device is based on a novel technology
- f) Operated by a trained healthcare professional or used by a patient or caregiver under the supervision of a trained health care professional.
- g) Devices produce or emit radioactive or carcinogenic materials.
- h) Devices used to support life in critically-ill patients.
- i) Applicants to provide proof of registration by a strict regulatory authority, evidence of clinical testing, a certificate of quality, users' manual, and repair manual.
- j) Applicant to collect and share safety data post -licensing
- k) Intended use or indication is a specialized procedure ordinarily performed by a trained health care professional.

15.2 Medical Devices

For purposes of use and handling of control of sale, medical devices shall be scheduled as;

- a) General sales medical devices
- b) Over the counter medical devices
- c) Prescription only medical devices

a) General Sales Medical Devices

These are low risk health products that may be supplied or handled by licensed pharmacies, retail outlets, authorized dealers, laboratories and hospitals.

Selection criteria for general sales medical devices

- a) The degree of risk and harm is low
- b) Sale and use do not require specialized knowledge, consumers can self-select the appropriate medical device for their own use
- c) Device is non-invasive or require only sporadic contact with the body
- d) Class A characteristics of classification shall be applied, excluding invasive and active medical devices
- e) They can be advertised to the general public

b) OTC Medical Devices

These are medium risk products that may be supplied or handled by licensed pharmacies, authorized dealers, laboratories and hospitals

Selection criteria of OTC medical devices

- a) Operation of the device require a trained healthcare professional and use by the patient or caregiver should be under the supervision of a trained health care
- b) The degree of risk and harm is medium
- c) Both Class A and B active medical devices maybe included
- d) They may be advertised to the general public following approval by the Board

c) Prescription Only Medical Devices

These are high risk health products that shall be supplied and or dispensed by an authorized healthcare provider on a valid prescription in licensed pharmacies and hospitals.

Selection criteria for prescription only medical devices

- a) Shall be sold by authorized wholesaler dealers, licensed hospitals and pharmacies

- b) Sale and use of the device or diagnostic require medical use counselling
- c) Procedures to be performed require medical prescription or assistance
- d) The degree of risk and harm is very high
- e) Shall follow risk classification of Class C and D medical devices
- f) They will only be advertised to the healthcare providers

The medical device list is herein attached as **Annex X**.

15.3 IN-VITRO DIAGNOSTICS MEDICAL DEVICE (IVD-MD)

For purposes of use, handling and control of sale, In-Vitro Diagnostics shall be scheduled as;

- a) Over the Counter (OTC) Invitro Diagnostics
- b) Prescription Only Invitro Diagnostics

a) OTC Invitro Diagnostics

These are high risk invitro diagnostics that shall be supplied or handled by licensed pharmacies, authorized dealers, laboratories and hospitals.

Assessment criteria for OTC IVDs

- a) Shall be sold and handled by licensed pharmacies, Laboratories, Hospitals and other authorized dealers and wholesalers.
- b) Operation of the device or diagnostics by a patient/caregiver requires guidance of a trained health care provider.
- c) The degree of risk and harm is moderate
- d) Both Class A and B characteristics of classification of IVD shall be applied.
- e) They can only be advertised to the Healthcare Providers

b) Prescription Only IVDs

These are high risk health invitro diagnostics that shall be supplied and or dispensed by an authorized healthcare provider on a valid prescription in licensed pharmacies and hospitals.

Assessment criteria for POM IVDs

- a) Shall be dispensed by an authorized healthcare provider on a valid prescription in licensed pharmacies and Hospitals
- b) Shall be sold by authorized wholesaler dealers, licensed hospitals and pharmacies
- c) Sale and use of the diagnostic require medical professional counselling and guidance
- d) Procedures to be performed require medical prescription and assistance
- e) The degree of risk and harm is very high
- f) Class C & D characteristics of classification of Invitro diagnostics shall be applied
- g) Includes all types of assays, such as first-line assays, confirmatory assays and supplemental assays.
- h) They can only be advertised to the Healthcare Professionals

The In-vitro diagnostic list is herein attached as **Annex XI**

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17.0 CONTRIBUTORS

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18.0 ANNEXES

Annex I:



MINISTRY OF HEALTH PHARMACY AND POISONS BOARD

Terms of Reference for Expert Committee on Scheduling of Health Products and Technologies

1.0 INTRODUCTION

The Board has developed guidelines for scheduling to provide for different levels of regulatory control over health products and technologies. It's envisaged that the guideline will provide information and guidance on the criteria and factors to be considered during application leading to controlled access.

2.0 PURPOSE

The purpose of this expert Committee is to provide advice to the Board on the scheduling of health products and technologies.

3.0 MEMBERSHIP OF THE COMMITTEE

The Committee shall comprise of nine members with specific scientific, medical, or clinical expertise, as well as appropriate consumer health issues

relating to Health Products and Technologies. However subject matter experts may be co-opted by the Board on a need basis.

4.0 SECRETARIAT OF THE COMMITTEE

The department responsible for scheduling shall be the secretariat of the committee.

5.0 ROLES OF THE COMMITTEE

The committee shall provide technical expertise to the Board regarding scheduling and rescheduling of health products and technologies which shall include;

- a) Making recommendations to the Board on the classification of Health Products and Technologies.
- b) Evaluating and providing guidance regarding scheduling and rescheduling of the products.
- c) Recommending the removal of the products from the schedules.
- d) Advice the Board on the appropriate information regarding scheduling and rescheduling that requires to be disseminated to stakeholders including the public.
- e) Any other relevant responsibility that may be delegated by the Board.

6.0 QUORUM OF THE MEETING

The committee meeting shall be held according to Pharmacy and Poisons Board rules and procedures. The quorum of the meeting shall be not less than five members.

7.0 CONDUCT IN MEETINGS

The committee shall conduct its business Face-to-face and or virtually at least four times a year. However, ad hoc meetings may be held depending on the need. The decision by the committee shall be through consensus. In case of a tie, the chairperson or designate shall have the veto power. The members

shall be notified of an impending meeting fourteen days prior through email and telephone calls.

8.0 REMUNERATION OF MEMBERS

Members shall be remunerated in accordance with the existing Pharmacy and Poisons Board financial rules and regulations.

9.0 CONFIDENTIALITY AND CONFLICT OF INTEREST

All members shall be expected to declare and sign a conflict of interest and maintain confidentiality.

10.0 TENURE OF SERVICE

The committee members shall serve for a two-year renewable once contract from the time of appointment.

11.0 TERMINATION OF MEMBERSHIP

A person may cease to be a member under the following circumstances;

- a) Through written notice of resignation
- b) Termination of the contract by the Board due to misconduct
- c) Failure to attend three consecutive meetings without justifiable reasons

12.0 AMENDMENT OF THE TERMS OF REFERENCE (TORS)

These terms of reference may be amended from time to time by the Board

Annex II

1.0 APPLICATION AND REVIEW PROCEDURE

- a. Applications for scheduling or rescheduling shall be made to the CEO in the manner and format prescribed by the Board.
- b. When an application is accepted, an acknowledgment of receipt will be issued with a reference number for each application. This reference number shall be used to effect payment and must be quoted in all correspondence concerning the application in the future.
- c. The application shall be screened for completeness prior to acceptance based on the submission checklist and according to the applicable procedures.
- d. The application shall be evaluated by the committee. The committee may request additional information from the applicant to facilitate decision making
- e. If the application is successful, the Board shall issue a regulatory notice to the applicant and the public.
- f. If the application is not successful the applicant shall be informed of the reasons and he/she can appeal to the Board.

2.0 APPLICATION FLOW CHART

The application and review process shall be as per the flow chart in **Fig 1**

3.0 FORMAT OF APPLICATION

Application documents shall be arranged in the following format;

- 1. COVER/TITLE PAGE**
- 2. DECLARATION BY APPLICANT**
- 3. TABLE OF CONTENTS**
- 4. SUMMARY**
- 5. BODY OF APPLICATION**
 - 5.1 Purpose of application**
 - 5.2 General background**

5.2.1 Current Regulatory Status

5.2.2 International Regulatory Status

5.3 Introduction of the data upon which the application is based.

5.4 Technical Information

5.4.1 Physio-chemical properties of the active pharmaceutical ingredient

5.4.2 Pharmacology

5.4.3 Clinical Data

5.4.4 Toxicology

5.4.5 Safety Reports

5.4.6 Occupational health and Safety Information

5.4.7 Pharmaceutical Aspects

5.4.8 Monitoring of the Public Health Impact

5.5 Proposal

5.6 Discussion

5.7 Proposed Indication for use

5.8 Product Information and Presentation

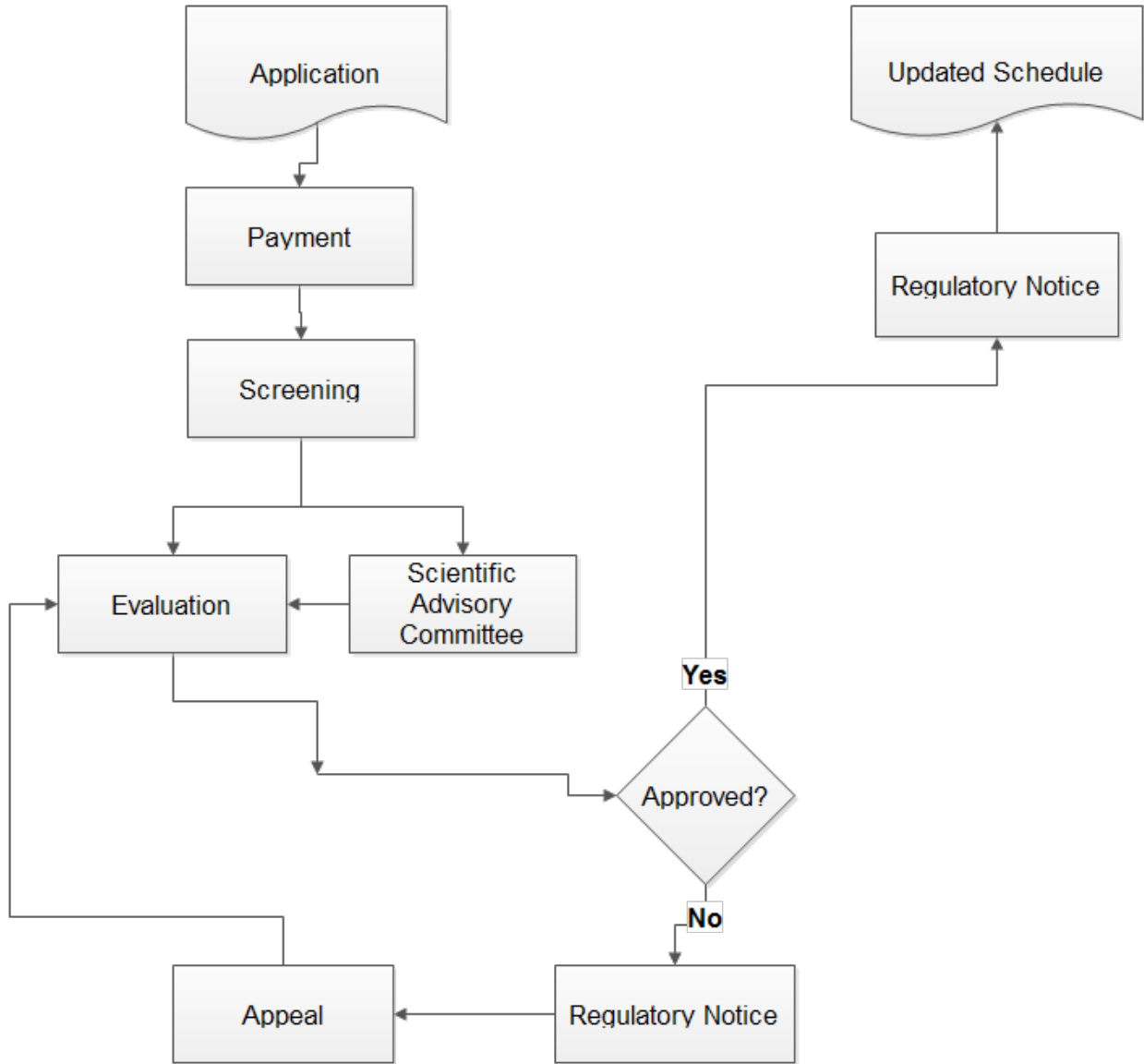
6. OTHER RELEVANT INFORMATION

7. BIBLIOGRAPHY

8. COPIES OF REFERENCED MATERIALS

9. APPENDICES IF REQUIRED

Fig 1. Application Flow Chart



4.0 REGULATORY ACTIONS

Appropriate Regulatory actions shall be applied to persons/organizations who contravene these schedules in accordance with PPB procedures.

Such sanctions may include:

- a) Demand for appropriate corrective actions
- b) Warning letter;
- c) Black listing of non-compliant entities
- d) Refusal to issue import and/ or export permit for the medical product and Health Technology in question
- e) Suspension of the applications under review
- f) Deregistration/delisting of the concerned HPTs
- g) Product recall and withdrawal
- h) Prosecution in liaison with other government agencies

Annex III: General Sales

| | CLASS | ATC CODE | THERAPEUTIC CLASS | INN | DOSAGE FORM | Comments |
|---|----------------------------------|-----------------|--------------------------|---|--------------------|--|
| 1 | Analgesics and antipyretics | N02BE | Anilides | Paracetamol | Tablets | Sold in final primary pack, shall not be repacked or relabelled. |
| 2 | Psychostimulants | N06BC01 | Xanthine derivatives | Caffeine & combinations. | Tablet, Powder | In combinations and shall not exceed 0.4g |
| 3 | Drugs for acid related disorders | A02AA | Magnesium compounds | Magnesium carbonate Magnesium oxide Magnesium peroxide Magnesium hydroxide Magnesium silicate Combinations | Tablets Powders | Sold in final primary pack, shall not be repacked or relabelled. |
| | | A02AB | Aluminium compounds | Aluminium oxide Aluminium phosphate | Tablets Powders | Sold in final primary pack, shall not be repacked or relabelled. |

| | | | | | | |
|---|--------------------|-----------------|--|--|--------------------|---|
| | | | | Dihydroxialuminium sodium carbonate Aluminium glycinate | | |
| | | A02AC | Calcium compounds | Calcium silicate Combinations | Tablets Powders | Sold in final primary pack, shall not be repacked or relabeled. |
| | | A02AD | Combinations and complexes of aluminium, calcium and magnesium compounds | Ordinary salt combinations | Tablets Powders | Sold in final primary pack, shall not be repacked or relabeled. |
| | | A02AF | Antacids with antiflatulents | Ordinary salt combinations and antiflatulents | Tablets Powders | Sold in final primary pack, shall not be repacked or relabeled. |
| 4 | Respiratory system | Throat lozenges | | Lozenges | Lozenges | Herbal lozenges Ordinary lozenges with no specific therapeutic claim |
| 5 | Vitamins | A11 | Ascorbic acid Multivitamin formulations | Tablets Capsules | Gummies Powders | formulations with composition below RDA, levels |

| | | | | | | |
|---|-----------------------------------|-----------------|--|---|---------|--|
| 6 | Minerals | A12 | Mineral supplements below RDA levels | Tablets Capsules, Gummies | Powders | supplements below RDA levels |
| 7 | Emollients and protective D02A | D02AA | Silicone products | lotion, cream, ointment | | This group comprises all types of emollients and protective; with no specific therapeutic effect or use, and also, preparations for use in wounds, which are not classified in D09 |
| | | D02AB | Zinc products | | | |
| | | D02AC | Soft paraffin and fat products | | | |
| | | D02AD | Liquid plasters | | | |
| | | D02AE 01, 51 | Carbamide products | | | |
| 8 | Protectives against UV radiation | D02BA | Protectives against UV radiation for topical use | Amino benzoic acid Octinoxate (<i>others-Dioxybenzone</i> <i>Oxybenzone</i> <i>Micronised titanium oxide</i> <i>Sulisobenzone</i>) | | Primary sunscreens with SPF less than 30 Some secondary sunscreens (e.g. sunbathing and moisturising skin care products) with an SPF less than 30 |
| | | D02BB | Protective against UV-radiation for systemic use | Betacarotene Afamelanotide | | |

| | | | | | |
|---|-------------------------------|-------|-------------------------------------|---|--|
| 9 | Antiseptics and disinfectants | D08AX | Other antiseptics and disinfectants | Hydrogen peroxide Propanol Isopropanol Sodium hypochlorite Ethanol Propanol, combinations Chloroxylenol Chlorhexidine Cetrimide | limited to low level activity against bacteria (e.g. kills 99.9% of bacteria) and they are not for use in health care settings |
|---|-------------------------------|-------|-------------------------------------|---|--|

General sales complementary and alternative medicines

| | Common name | Botanical name | Indication |
|----|------------------|---|--|
| 1. | Almond oil | <i>Prunus dulcis</i> (Miller) seeds | Minor skin conditions, cuts, wounds. |
| 2. | Articulin-F | <i>Winthania somnifera</i> , <i>Boswellia serrata</i> , <i>Curcuma longa</i> | anti-inflammatory antimicrobial effect |
| 3. | Bletilla rhizome | <i>Bletilla striata</i> | for arresting bleeding with astringent action, Topical use for ulcers, sores, swelling & chapped skin |
| 4. | Cardamon seeds | <i>Semen cardamoni</i> | Carminative, stimulant |
| 5. | Castor oil | <i>Ricinus communis</i> | Domestic purgative, food poisoning, in intestinal examination |
| 6. | Cayenne pepper | <i>Capsicum frutescens</i> L. | Used as Rubefacient, vasostimulant |
| 7. | Chamomile | <i>Chamaemelum nobile</i> L. | For dyspepsia, poultice |

| | | | |
|-----|--------------------------------|---|--|
| 8. | Cinnamon | Cinnamomum cassia Blue (Bark) | Diaphoretic, circulatory stimulant |
| 9. | Dryopteris root or Shield fern | <i>Dryopteris crassirhizoma</i> | antioxidant & immunomodulatory activities |
| 10. | Evening Primose oil | <i>Oenothera biennis/ O. larmarkiana</i> | Treatment of atopic eczema and premenstrual syndrome |
| 11. | Fenugreek | <i>Trigonella foenum-graecum</i> L. | Antidiabetic, cholesterol-lowering, antipyretic, antiulcer and anticancer |
| 12. | Fresh ginger rhizome | <i>Zingiber officinale</i> | anti-inflammatory, antiemetic, nausea |
| 13. | Garlic bulb | <i>Allium sativum</i> | Diabetes, rheumatism, flatulence & fevers |
| 14. | Ginger | <i>Zingiber officinale</i> | Prophylaxis of the nausea and vomiting of motion sickness |
| 15. | Ginseng root | <i>Panax ginseng</i> | Improves memory, male erectile dysfunction & to boost immunity, a tonic and sedative |
| 16. | Hibiscus | <i>Hibiscus sabdariffa</i> L. | Astringent, diuretic effect and antioxidant |
| 17. | Indian gosberry | <i>Emblica officinalis</i> (Amla) | Antifungal activity, antioxidant and anti-inflammatory |
| 18. | Lycopene | <i>Lycopersicon esculentum</i> | Antioxidant, protective against myocardial infarction (MI), eye health |
| 19. | Neem | <i>Azadirachta indica</i> (Neem) | skin ulcers, gingivitis & fever |
| 20. | Olives | <i>Olea europea</i> | Cardiovascular health, cancer prevention |
| 21. | Peppermint | <i>Mentha piperita</i> <i>Mentha balsamea</i> wild | Cooling sensation on the skin, muscle pain, nerve pain, itching |
| 22. | Picrorhiza kurroa rhizome | <i>Picrorhiza kurroa</i> | Liver problems & allergy |

| | | | |
|-----|---|---|---|
| 23. | Pomegranate bark | <i>Cortex granati</i> | antioxidant & immunomodulatory activities |
| 24. | Pumpkin seeds | Semen cucurbitae (<i>Curcubita pepo</i>) | antioxidant & protective against cancer of the prostate and colon |
| 25. | Purple sunflower | <i>Echinacea spp.</i> | common cold, coughs, bronchitis & upper respiratory infection |
| 26. | Rabbit tobacco | <i>Gnaphalium obtusifolium</i> | Internally for treatment of throat ulcers, chest complaints intestinal& respiratory catarrh; externally for bruises |
| 27. | Rooibos tea | <i>Asplathusa linearis</i> | Antioxidant, anti-inflammatory |
| 28. | Rosemary oil | <i>Rosmarinus officinalis/ Aetheroleum Rosmarini</i> | Carminative, spasmolytic |
| 29. | Sage | <i>Salvia officinalis L.</i> | Antiseptic, astringent |
| 30. | Saw palmetto | <i>Serenoa repens</i> | loss of hair in men; improved urinary function |
| 31. | stinging nettle | <i>Urtica dioica</i> and other <i>Urtica</i> spp. | Adjuvant treatment of rheumatic conditions |
| 32. | Theomine | <i>Camellia sinesis</i> | Relaxant and memory enhancement |
| 33. | Trikatu (black pepper, long pepper, ginger) | <i>Piper nigrum</i> , <i>piper longum</i> , <i>Zingiber officinalis</i> | antipyretic & anti- diarrheal |
| 34. | Turmeric | <i>Curcuma longa</i> | healing wounds, liver disorder, jaundice & blood purifier |
| 35. | Evening primrose oil | <i>Oenothera biennis L.</i> ; <i>Oenothera lamarckiana L.</i> | Skin disorders and minor wounds |
| 36. | Garlic | <i>Allium sativum L.</i> | Cough and cold, Circulatory disorders |

| | | | |
|-----|--------------------------------------|--|---|
| 37. | Fenugreek | Trigonella foenum-graecum L. | Loss of appetite, Skin disorders and minor wounds |
| 38. | Eucalyptus leaf | Eucalyptus globulus Labill. | Cough and cold |
| 39. | Eucalyptus Oil (as a formulation) | Eucalyptus globulus Labill.; Eucalyptus polybractea R.T. Baker; Eucalyptus smithii R.T. Baker. | Pain and inflammation, Cough and cold |
| 40. | Green tea | Camellia sinensis (L.) Kuntze | Fatigue and weakness |
| 41. | Javanese turmeric | Curcuma xanthorrhiza Roxb. (C. xanthorrhiza D. Dietrich). | Gastrointestinal disorders |
| 42. | Thyme oil | Thymus vulgaris L.; Thymus zygis L. | Cough and cold |
| 43. | Pale Coneflower Root | Echinacea pallida (Nutt.) Nutt. | Cough and cold |
| 44. | Ivy leaf | Hedera helix L. | Cough and cold |
| 45. | Soya | Glycine max (L.) Merr. | Mosquito repellent, lowering of LDL |
| 46. | Vanilla essential oil. | Vanilla fragrans / Vanilla planifolia | Antioxidant |
| 47. | Zangqingguo | Fructus Chebulae | Neuronal damage, antimicrobial. |

Annex IV: Pharmacy Only Medicines

| | CLASS | ATC CODE | THERAPEUTIC CLASS | INN | DOSAGE FORM |
|---|--|-----------------|------------------------------|--|--------------------------------|
| | Alimentary tract and metabolism | | | | |
| 1 | Drugs for acid related disorders | A02AF | Antacids with antiflatulents | Simethicone, Dimethicone, Ordinary salt combinations with antiflatulents | Syrup Suspension Tablets |
| | | A02BX | Anti-ulcerative | Sucralfate, Bismuth Subcitrate, Bismuth Subnitrate, Alginic Acid | |
| | | A02BA | H2 Receptor antagonists | Cimetidine, Ranitidine, Famotidine, Nizatidine, Roxatidine, Niperitidine | |
| | | A02BC | Proton Pump inhibitors | Omeprazole, Esomeprazole, Lansoprazole, Pantoprazole, Rabeprazole, Dexlansoprazole, | |

| | | | | | |
|---|-----------------------------------|-------|---|--|--|
| | | | | Dexrabeprazole, | |
| 2 | Anthelmintic | P02CA | Antinematodal benzimidazoles | Mebendazole, Albendazole | Oral suspensions Tablets |
| 3 | Anti-diarrhoeal | A07BA | Charcoal preparations | Medicinal charcoal | Tablets |
| | | A07BC | Other intestinal adsorbents | Pectin, Kaolin, Attapulgate, Diosmectite, Crospovidone | Capsules Suspension |
| | | A07CA | Oral rehydration salt formulations | ORS | |
| | | A07DA | Antipropulsives | Diphenoxylate, loperamide, loperamide oxide, | |
| | Drugs for functional GI disorders | A03FA | Propulsives | Metoclopramide Domperidone | Tablets Capsules Suspension |
| | | A03BB | Belladonna alkaloids | Butylscopolamine | |
| | | A03DB | Belladonna and derivatives combined with analgesics | Butylscopolamine and analgesics | |
| | | A03AA | Synthetic anticholinergics | Mebeverine | |
| | Drugs for constipation | A06AA | Softeners/emollients | liquid paraffin docusate sodium liquid paraffin combinations | Syrups suspensions Tablets Capsules |

| | | | | | |
|---|---------------------------------|-------|---------------------------------|---|-----------------------------------|
| | | A06AB | Contact laxatives | Bisacodyl, Castor Oil, Senna Glycosides, Cascara, Sodium picosulphate | |
| | | A06AC | Bulk forming laxatives | Ispaghulla, Psylla Seeds, Sterculia, Linseed, Methycellulose, Wheat Fibre Triticum, Polycarbophil Calcium | |
| | | A06AD | Osmotic laxatives | Magnesium (Oxide, Sulphate, Peroxide, Citrate) Lactulose Lactitol Sodium Sulfate, Mannitol Sorbitol Oidium Tartarate Macrogol | |
| | | A06AX | Others | glycerol | |
| 4 | Antidiarrheal microorganisms | A07FA | Antidiarrheal microorganisms | Lactic acid producing microorganisms, Lactic acid | Powders Tablets Suspensions |

| | | | | | |
|---|---------------------------------|-------|------------------------------------|---|---|
| | | | | <p>Saccharomyces Boulardi</p> <p>Lactobacillus Rhamnosus</p> <p>Lactobacillus Acidophilus</p> <p>Bifidobacterium Bifidum</p> <p>Bifidobacterium Animalis subsp. lactis</p> <p>Lactobacillus Reuteri</p> <p>Streptococcus Thermophiles</p> <p>Bacillus Subtilis</p> <p>Bacillus Clausii</p> <p>Lactobacillus Plantarum</p> <p>Lactobacillus Casei</p> <p>Lactobacillus Delbrueckii subsp. Bulgaricus</p> | Capsules |
| 5 | Electrolytes with carbohydrates | A07CA | Oral rehydration salt formulations | ORS | Powders suspension |
| 6 | Mineral supplements | A12AA | Calcium | Calcium phosphate, calcium carbonate, calcium lactate, calcium glucoheptonate | Tablets Syrup Suspension |
| | | A12CB | Zinc | Zinc sulphate | Capsules |
| 8 | Vitamins | A11AA | Multivitamins with minerals | <p>Multivitamins and iron</p> <p>Multivitamins and calcium</p> <p>Multivitamins and trace elements</p> | Tablets Syrup Suspension Capsules |
| | | A11AB | Multivitamins plain | Plain multivitamins | |
| | | A11GB | Ascorbic acid combination | Ascorbic acid and calcium | |

| | | | | | |
|----|-----------|-------|--|--|---|
| | | A11EC | Vitamin B complex with minerals | Vitamin B complex with minerals | |
| | | A11DB | Vitamin B1 in combination with B6 and or B12 | Vitamin B1 in combination with B6 and or B12 | |
| | | B03BB | Folic acid and derivatives | Folic acid | |
| 9 | Calcium | A12AA | Calcium | Calcium phosphate Calcium gluconate Calcium gluconate Calcium carbonate Calcium lactate Calcium lactate gluconate Calcium chloride Calcium glycerylphosphate Calcium citrate lysine complex Calcium glucoheptonate Calcium pangamate Calcium citrate Calcium (different salts in combination) Calcium laevulate | Powders for oral use, Tablets Suspensions Capsules |
| | | A12AX | Calcium combinations with vitamin D and/or other drugs | Calcium combinations with vitamin D and/or other drugs | Powders for oral use, Tablets Suspensions Capsules |
| 10 | Potassium | A12BA | Potassium | Potassium chloride Potassium citrate Potassium hydrogentartrate Potassium hydrogencarbonate Potassium gluconate | Powders for oral use Tablets Suspensions Capsules |

| | | | | | |
|----|---------------------------|-------|------------------------|---|--|
| | | | | Potassium (different salts in combination) Potassium chloride combinations | |
| 11 | Other mineral supplements | A12CB | Zinc | Zinc sulfate Zinc gluconate Zinc protein complex | Powders for oral use Tablets Suspensions Capsules |
| | | A12CC | Magnesium | Magnesium chloride Magnesium sulfate Magnesium gluconate Magnesium citrate Magnesium aspartate Magnesium lactate Magnesium levulinate Magnesium pidolate Magnesium orotate Magnesium oxide Magnesium (different salts in combination) | Powders for oral use Tablets Suspensions Capsules |
| | | A12CD | Fluoride | Sodium fluoride Sodium monofluorophosphate Fluoride combinations | Powders for oral use Tablets Suspensions Capsules |
| | | A12CE | Selenium | Sodium selenate Sodium selenite | Powders for oral use Tablets Suspensions |
| | | A12CX | Other mineral products | Other mineral products | Powders for oral use Tablets Suspensions |
| 12 | Tonics | A13A | Tonics | Tonics | Oral liquids suspensions |

| Dermatologicals | | | | | |
|------------------------|--------------|-------|---------------------------------------|--|--|
| 13 | Anti fungals | D01AA | Antibiotics | Nystatin Griseofulvin Natamycin Pecilocin Pyrrolnitrin Hachimycin Pecilocin Mepatricin Pyrolnitrin Combinations | Topical antifungal creams Shampoos |
| | | D01AC | Imidazole and Triazole derivatives | Clotrimazole, Miconazole, Itraconazole, Voriconazole, Posoconazole, Isavuconazole, Econazole Isoconazole, Ketoconazole, Bifonazole, Sertaconazole, Fluconazole, Omoconazole, | |

| | | | | | |
|--|--|-------|-----------------------------------|---|--|
| | | | | Flutrimazole, Fenticonazole, Chlormidazole Eberconazole Luliconazole Oxiconazole Efinaconazole Sulconazole | |
| | | D01AE | Other antifungals for topical use | Bromochlorosalicylanide Methylrosaniline Tribromometacresol Undecylenic acid Polynoxyllin 2-(4-chlorphenoxy)-ethanol Chlorphenesin Ticlatone Sulbentine Ethylhydroxybenzoate Haloprogin Salicylic acid Ethylhydroxybenzoate Selenium sulfide Ciclopirox Terbinafine Amorolfine Dimazole Tolnaftate Tolciclate Flucytosine Naftifine Butenafine Undecylenic acid, combination | |

| | | | | | |
|----|---------------------------------------|-------------|---|---|-----------------------------|
| | | D01BA | Antifungals for systemic use | Griseofulvin, Terbinafine | |
| 14 | Emollients and protective D02A | D02AA | Silicone products | This group comprises all types of emollients and protective; With specific therapeutic effect or use, and are not classified in D09 | Lotion Cream Ointment |
| | | D02AB | Zinc products | | |
| | | D02AC | Soft paraffin and fat products | | |
| | | D02AD | Liquid plasters | | |
| | | D02AE01, 51 | Carbamide products | | |
| 15 | Dermatological Corticosteroids | D07AA | Plain (weak)corticosteroids Potent group 1 | Methylprednisolone Hydrocortisone Prednisolone | Lotion Cream Ointment |
| | | D07AB | Plain Moderately Potent group 2 | Clobetasone, Hydrocortisone butyrate, Flumetasone Fluocortin Fluperealone Fluorometholone Fluprednidene Desonide Hydrocortisone buteprate Dexamethasone Clocortolone Triamicinolone, | Lotion Cream Ointment |

| | | | | | |
|--|--|-------|---|--|-----------------------------|
| | | | | Aclometasone Combinations | |
| | | D07AC | Corticosteroids, Potent group 3 | Betamethasone Fluclorolone Desoximetasone Fluocinolone Fluocortolone Diflucortolone Fludroxycortide Fluocinonide Budesonide Diflorasone Amcinonide Halometasone Mometasone Methylprednisolone aceponate Beclometasone Hydrocortisone aceponate Fluticasone Prednicarbate Difluprednate Ulobetasol | |
| | | D07BC | Potent corticosteroids combination with antiseptics | Betamethasone and antiseptics Fluocinolone acetonide and antiseptics Fluocortolone and antiseptics | Lotion Cream Ointment |

| | | | | | |
|--|--|----------------------------------|---|--|-----------------------------|
| | | | | Diflucortolone and antiseptics | |
| | | D07CB | Moderately potent corticosteroids combinations with antibiotics | Triamcinolone Fluprednidene Fluorometholone Dexamethasone Flumetasnoe | Lotion Cream Ointment |
| | | D07CA | Weak corticosteroids combinations with antibiotics | Hydrocortisone Methylprednisolone prednisolone | Lotion Cream Ointment |
| | | D07CC | Potent corticosteroids combinations with antibiotics | Betamethasone Fluocinolone acetonide Fludroxycortilide Beclometasone Fluocinonide Fluocortolone | Lotion Cream Ointment |
| | | D07XA D07XB D07XC D07XD | Corticosteroids with other combinations | Weak corticosteroids Moderately potent corticosteroids Potent corticosteroids | |
| | | D07BA | Weak corticosteroids with antiseptics | Prednisolone and antiseptics Hydrocortisone and antiseptics | Lotion Cream Ointment |
| | | D07BB | Moderately potent corticosteroids with antiseptics | Flumetasone and antiseptics Desonide and antiseptics Triamcinolone butyrate antiseptics | Lotion Cream Ointment |

| | | | | | |
|----|---|-------|---|--|-----------------------------|
| | | D07CA | Weak corticosteroids with antibiotics | Hydrocortisone with antibiotics Methylprednisolone with antibiotics Prednisolone with antibiotics | Lotion Cream Ointment |
| 16 | Protectives against UV radiation | D02BA | Protectives against UV radiation for topical use <i>(primary and secondary sunscreens with SPF more than 30)</i> | Aminobenzoic acid Octinoxate <i>(others-Dioxybenzone Oxybenzone Micronised titanium oxide Sulisobenzone)</i> | Lotion Cream Ointment |
| | | D02BB | Protective against UV-radiation for systemic use <i>(primary and secondary sunscreens with SPF more than 30)</i> | Betacarotene Afamelanotide | Lotion Cream Ointment |
| 17 | Preparations for treatment of wounds and ulcers | D03AX | Other cicatrizants | Cadexomer iodine Dextranomer Dexpanthenol Calcium pantothenate Hyaluronic acid Becaplermin Crilanomer Enoxolone Sodium chlorite Trolamine | Lotion Cream Ointment |
| | | D03AA | Cod liver ointments | Cod liver ointments | Lotion |

| | | | | | |
|----|-----------------------|-------|---|--|-----------------------------|
| | | | | | Cream Ointment |
| | | D03BA | Proteolytic enzymes | Trypsin Collagenase Bromelains Collagenase, combinations | Lotion Cream Ointment |
| 18 | Antiacne preparations | D10AA | Corticosteroids, combinations for Acne | Fluorometholone Methylprednisolone Dexamethasone | Lotion Cream Ointment |
| | | D10AB | Preparations containing sulfur | Bithionol Sulfur Tioxolone Mesulfen | Lotion Cream Ointment |
| | | D10AD | Retinoids for topical use in acne | Tretinoin Retinol Adapalene Isotretinoin Motretinde combinations | Lotion Cream Ointment |
| | | D10AE | Peroxides | Benzoyl peroxide combinations | Lotion Cream Ointment |
| | | D10AF | Antiinfectives for treatment of acne | Clindamycin Erythromycin Chloramphenicol Meclocycline | Lotion Cream Ointment |

| | | | | | |
|----|-----------------------------------|----------------|-------------------------------------|--|-----------------------------|
| | | | | Nadifloxacin Sulfacetamide Combinations | |
| | | D10AX | Other preparations for topical use | Aluminium chloride Resorcinol Azelaic acid Aluminium oxide Dapsone Combinations | Lotion Cream Ointment |
| 19 | Other dermatological preparations | D10AA D11AC | Antihidrotics Medicated shampoos | Antihidrotics Cetrimide Cadmium compounds Selenium compounds Povidone iodine Sulfur compounds Xenysalate Others | Lotion Cream Ointment |
| 20 | Chemotherapeutics for topical use | D06BA | Sulfonamides | Silver sulphadiazine Sulfathiozole Mefenide Sulfamethazole Sulfanilamide Sulfamerazine Combinations | Ointment Cream |
| | | D06BX | Others | Metronidazole Ingenol mebutate | |

| | | | | | |
|----|--|-------|---------------------------|---|--|
| | | D06BB | Antivirals | Acyclovir Penciclovir Acyclovir combinations | |
| 21 | Dermatological antibiotics D06A | D06AA | Tetracyclines | Tetracycline, demeclocycline, oxytetracycline Oxytetracycline | Creams Ointment Powder Solution |
| | | D06AX | Others | Fusidic Acid Chloramphenicol Bacitracin Neomycin Tyrothricin Mupirocin Virginiamycin Rifaximin Amikacin Retapamulin Gentamycin Mupirocin | |
| 22 | Antipsoriatics for topical use D05A | D05AA | Tars | Coal Tar | Creams Ointment Powder |
| | | D05AC | Antracens, derivatives | Dithranol Combinations | |
| | | D05AD | Psoralens for topical use | Trioxysalen Methoxsalen | |
| | | D05AX | Others | Calcipotriol, calcitriol | |

| | | | | | |
|----|--|-------|------------------------------|---|------------------------------|
| | | | | Fumaric acid Tacalcitol Tazarotene Calcipotriol combinations | |
| 23 | Antipruritic incl antihistamines, anaesthetics | D04AA | Antihistamines | Thonzylamine Mepyramine Thenalidine Tripeleennamine Chloropyramine Promethazine Tolpropamine Dimetindene Clemastine Bamipene Pheniramine Diphenhydramine Methylbromide Chlorphenoxamine | Lotion Cream Ointment |
| 24 | Antiseptics and Disinfectants | | | | |
| 25 | Antiseptics and Disinfectants | D08AA | Acridine derivatives | Ethacridine lactate Aminoacridine Euflavine | Swabs Rubs Hand washes |
| | | D08AB | Aluminium agents | Aluminium agents | Wipes |
| | | D08AC | Biguanides and aminidines | Dibrompropamidine Chlorhexidine Propamidine | Gargles Solutions |

| | | | |
|--|-------|-------------------------------|---|
| | | | Hexamidine Polihexanide Chlorhexidine combinations |
| | D08AD | Boric acid products | Boric acid products |
| | D08AE | Phenol and derivatives | Hexachlorophene Policresulen Phenol Triclosan Chloroxylenol Biphenylol |
| | D08AF | Nitrofurane derivatives | Nitrofur |
| | D08AG | Iodine products | Iodine/octylphenoxyglycol ether Povidone iodine Iodine Diiodohydroxypropane |
| | D08AH | Quinolone derivatives | Dequalinium Chlorquinaldol Oxyquinoline Clioquinol |
| | D08AJ | Quaternary ammonium compounds | Benzalkonium Cetrimonium Cetylpyridinium Cetrimide Benzoxonium chloride Didecylmethylammonium chloride |

| | | | | | |
|----|--|---------|--------------------|--|---------|
| | | | | Benzathonium chloride Deca combinations | |
| | | D08AK | Mercurial products | Mercuric amidochloride Phenylmercuric borate Mercuric chloride Mercurochrome Mercury, metallic Thiomersal Mercuric iodide | |
| | | D08AL | Silver compounds | Silver nitrate Silver | |
| | | D08AX | Others | Hydrogen peroxide Eosin Propanol Tosychloramide sodium Isopropanol Potassium permanganate Sodium hypochlorite Ethanol Propanol, combinations | |
| | | | | | |
| | Ant infectives for systemic use | | | | |
| 26 | | J01CA04 | Penicillin's | Amoxicillin | Tablets |

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|----|--|-------|--|---|------------------------|
| | Antibacterial for systemic use | | | | Suspension Capsules |
| | | J01DB | First generation Cephalosporins | Cephalexin Cefadroxil Cefradine | |
| | | J02AB | Imidazole derivatives | Ketoconazole | |
| | | J02AC | Triazole derivatives | Fluconazole | |
| | | J01E | Sulphonamides and trimethoprim | Trimethoprim Sulfamethoxazole | |
| | Respiratory system | | | | |
| 27 | Drugs for obstructive airway diseases | R03AC | Selective beta-2-adrenoceptor agonists | Salbutamol | Inhaler |
| 28 | Decongestants and other nasal preparations for topical use | R01AA | Plain sympathomimetics | Cyclopentamine Ephedrine Phenylephrine Oxymetazoline Tetryzoline Xylometazoline Naphazoline Tramazoline Metizoline Tuaminoheptane Fenoxazoline Tymazoline Epinephrine | Inhaler Aerosol |

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|----|--|-------|---|---|---|
| | | | | Indanazoline | |
| | | R01AB | Sympathomimetic combinations excl corticosteroids | Phenylephrine Naphazoline Tetryzoline Ephedrine Xylometazoline Oxymetazoline Tuaminoheptane | Inhaler Aerosol |
| 29 | Decongestants and other nasal preparations for topical use | R01AC | Antiallergic agents excl corticosteroids | Cromoglicic acid Levocarbastine Azelastine Antazoline Spaglumic acid Thonzylamine Nedocromil Olopatidine | Inhaler Aerosol |
| 30 | Nasal decongestants for systemic use | R01BA | Sympathomimetics for oral use | Phenylpropanolamine Pseudoephedrine Phenylephrine Combinations | Tablets Capsules Suspension |
| 31 | Throat preparations | R02AA | Antiseptics | Ambazone Dequalinium Dichlorobenzylalcohol Chlorhexidine Cetylpyridinium | Sprays Lozenges Caplets Tablets Suspensions Syrups |

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|----|---------------------------------------|-------------------|--|--|-------------------------------|
| | | | | Benzethonium Myristyl-benzalkonium Chlorquinaldol Hexylresorcinol Acriflavinium chloride Oxyquinoline Povidone iodine Bezylnonium Cetrimonium Hexamidine Phenol Octenidine Various | |
| 32 | Drugs for obstructive airway diseases | R03AC | Selective beta-2 adrenoceptor agonists | Salbutamol | Inhaler |
| 33 | Cough and cold preparations | R05CA | Expectorants | All cough remedies excluding, opium alkaloids and derivatives R05DA | Syrups Tablets Capsules |
| | | R05CB | Mucolytics | | |
| | | R05DB, R05DA09 | Cough suppressants | | |
| 34 | Antihistamines | R06AA | Aminoalkyl ethers | Diphenhydramine, Bromazine Clemastine | Tablets Creams Syrups |

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|--|-------|----------------------------------|--|---------------------------------------|
| | | | Chlorphenoxamine Doxylamine Trimethobenzamide Diphenylpyraline Carbinoxamine | Capsules Oral Powder suspension |
| | R06AB | Substituted alkylamines | Brompheniramine Dexchlorpheniramine Dimetindene Chlorphenamine Pheniramine Talastine Dexbropfeniramine | |
| | R06AC | Substituted ethylene diamines | Mepyramine Histapyrrodine Chloropyramine Tripeleennamine Methapyrilene Thonzylamine | |
| | R06AD | Phenothiazines | Alimemazine Promethazine Thiethylperazine Methdilazine Thiazinam Oxomemazineisothipendyl | |
| | R06AE | Piperazines | Buclizine | |

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|--|--|-------|--------|---|--|
| | | | | Cyclizine Meclizine Cetirizine Oxatomide Levocetirizine Meclizine Chlorcyclizine | |
| | | R06AK | Others | Cyproheptadine, Triprolidine, Terfenadine, Astemizlole, Acrivastine, Ebastine, Ketotifen, Fexofenadine, Desloratidines, Azelastine, Rupatidine, Bilastine, Quifenadine, Antazoline, Loratidine, Bamipine, Pyrobutamine, Mebhydrolin, | |

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|----|---|-------|-------------------------|---|--|
| | | | | Tritoqualine | |
| | Musculo-skeletal system | | | | |
| 35 | Musculoskeletal Anti-inflammatory and antirheumatic products, nonsteroids | M01AG | Fenamates | Mefenamic acid, | Syrup suspension |
| | | M01AB | Acetic acid derivatives | Etodolac, Indomethacin, Diclofenac, Ketorolac, Aceclofenac, Acetametacin, Tolmetin, Sulindac, Lonazolac, Zomepirac Alclofenac Bumadizone Etodolac Lonazolac Fentiazac Difenpiramide Oxametacin Proglumetacin Bufexamac Indomethac Combinations | Tablets Capsules Cream Ointments Gel Excluding injections |

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|--|--|-------|----------------------------|--|--|
| | | | | Diclofenac Combinations | |
| | | M01AH | Coxibs | Etoricoxib, Celecoxib | |
| | | M01AE | Propionic acid derivatives | Ibuprofen, Naproxen, Ketoprofen, Fenbufen Fenoprofen, Suorofen Pirprofen Flurbiprofen, Indoprofen Tiaprofenic Acid Oxaprozin Ibuproxam Flunoxaprofen Alminoprofen Dexketoprofen, Naproxinod | |
| | | M01AC | Oxicams | Piroxicam, Tenoxicam, Lornoxicam, Meloxicam, Droxicam, Tenoxicam | |

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|--|--|-------|--|---|-----------------------------|
| | | M01AX | Others | Glucosamine Sulfate Chondroitin Sulfate Glucosaminoglycan Polysulfate | |
| | | M02AA | Anti-inflammatory preparations, non-steroids for topical use | Phenylbutazone Mofebutazone Clofezone Oxyphenbutazone Benzydamine Etofenamate Piroxicam Felbinac Bufexamac Ketoprofen Bendazac Naproxen Ibuprofen Fentiazac Diclofenac Feprazone Niflumic Acid Meclofenamic Acid Flurbiprofen Tolmetin Suxibuzone Indomethacin | Creams Ointments Gels |

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|--|--|-------|--|--|-----------------------------------|
| | | | | Nifenazone Aceclofenac Nimesulide Dexketoprofen | |
| | | M02AB | Capsaicin and similar agents | Capsaicin Zucapsaicin | Creams Ointments Gels |
| 36 | Muscle relaxants, centrally acting | M03BB | Oxazole, thiazine and triazine derivatives | Chlorzoxazone, Chlormezanone Combinations excl psycholeptics | Tablets Capsules |
| | | M03BX | Others | Baclofen tizanidine thiocolchicoside | |
| Antiparasitic products, insecticides and repellents | | | | | |
| 37 | Anthelmintics | P02CA | Antinematodal benzimidazoles | Mebendazole albendazole | Oral suspensions Tablets |
| 38 | Agents against amoebiasis and other protozoa | P01AB | Nitroimidazoles | Metronidazole Tinidazole Ornidazole Secnidazole Nimorazole | Tablets Suspension Capsules |
| | | P01AC | Dichloroacetamides | Diloxonide | |

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|--|-----------------------------------|----------|-----------------------------------|---|---|
| | | P01AX | Others | Nitazoxanide | |
| 39 | Antimalarials | P01BF | Artemisinin and derivatives | Artemether and lumefantrine tablets | Tablets Suspensions |
| | | P01BD | Diaminopyrimidines | Pyrimethamine | |
| 40 | Scabicides | P03AX | Others | Benzyl benzoate | Powders Suspension Lotions Creams ointments |
| | | QP53AX04 | Others | Crotamiton | |
| Nervous system | | | | | |
| 41 | Other nervous system drugs N07 | N07BA01 | Drugs used in nicotine dependence | Nicotine | Chewing gum Sublingual/buccal Tablets |
| 42 | Analgesics | N02BA | | Acetylsalicylic acid | Tablets |
| 43 | Other analgesics and antipyretics | N02BE | Anilides | Paracetamol | Suppositories Suspensions Syrups |
| | | | | Phenacetin Bucetin Paracetamol combinations | |
| Genitourinary system and sex hormones | | | | | |

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|-----------------------|--|-------|--|--|----------------------------------|
| 44 | Hormonal contraceptives for systemic use | G03AA | Progestogens and oestrogens combinations | Levonorgestrel and ethinylestradiol | Tablets |
| | | G03AD | Emergency contraceptives | Levonorgestrel | |
| Sensory organs | | | | | |
| 45 | Decongestants and antiallergens | S01GA | Sympathomimetics used as decongestants | Naphazoline Tetryzoline Xylometazoline Oxymetazoline Phenylephrine Oxedrine Combinations | Eye drops Creams Ointments |

Pharmacy only complementary and alternative medicines

| 1 | Common name | Botanical name | Indication |
|---|--|--------------------------|----------------------------|
| 2 | Common Teak Tree | Tectona grandis | GI disorders |
| 3 | Aniseed Oil | <i>Pimpinella anisum</i> | Carminative |
| 4 | St. Benedict's thistle (also blessed thistle, holy thistle or spotted thistle) | Cnicus Benedictus L. | Gastrointestinal disorders |
| 5 | Baheda | Terminalia Bellirica | Astringent Laxative |

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|----|----------------------------------|---|---|
| 6 | Wild Strawberry Leaf | Fragaria vesca L.; Fragaria moschata Weston; Fragaria viridis Weston; Fragaria x ananassa (Weston) Duchesne ex Rozier | Urinary tract and genital disorders, Gastrointestinal disorders |
| 7 | Chinese Foxglove Root | Rehmannia Glutinosa | Constipation |
| 8 | Coptis Rhizome | Coptis Chinensis | Antidiabetic Antimicrobial |
| 9 | Bearberry Leaf | Arctostaphylos uva-ursi (L.) Spreng. | Urinary tract and genital disorders |
| 10 | Blackcurrant Leaf | Ribes Nigrum L. | Pain and inflammation, Urinary tract and genital disorders |
| 11 | Dill Oil | <i>Anethum Graveolens</i> | Carminative, flavour, in infants gripe water |
| 12 | Sea Bamboo | Ecklonia Maxima | Antioxidant |
| 13 | Gingko | <i>Gingo Biloba</i> | memory loss, dementia |
| 14 | Kantakari, | Solanum Virginianum | Anti-inflammatory |
| 15 | Kunth | Dioscorea Dumetorum | Anti-inflammatory |
| 16 | Olive leaf | Olea Europaea L. | Urinary tract and genital disorders |
| 17 | Pygeum Africanum Bark | Prunus Africana (Hook f.) Kalkm. | Urinary tract and genital disorders |
| 18 | Purple Coneflower Root | Echinacea Purpurea (L.) Moench. | Skin disorders and minor wounds, Cough and cold |
| 19 | Willow Bark | Salix [various species including S. Purpurea L.; S. Daphnoides Vill.; S. fragilis L.] | Pain and inflammation, Cough and cold |
| 20 | Diuretic Herbal Tea Combinations | Combination: Maximum 4 out of 13 possible plants | Urinary tract and genital disorders |

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|----|-----------------------------|---|---|
| 21 | Dried juice of Aloes leaves | Aloe Barbadensis Mill. and Aloe (various species) | Constipation |
| 22 | Sage Leaf | Salvia Officinalis L. | Mouth and throat disorders, Skin disorders and minor wounds, Gastrointestinal disorders |
| 23 | Rose Flower | Rosa Centifolia L.; Rosa Gallica L.; Rosa Damascena Mill. | Mouth and throat disorders, Skin disorders and minor wounds |
| 24 | Soya-Bean Oil | Refined | Skin disorders and minor wounds |
| 25 | Restharrow Root | Ononis Spinosa L. | Urinary tract and genital disorders |
| 26 | Boldo Leaf | Peumus Boldus Molina | Gastrointestinal disorders |
| 27 | Milk Thistle | <i>Silybum Marianum</i> | Liver conditions |
| 28 | Milk Thistle | Silybum Marianum | cholagogue tea (promote flow of bile) Antihepatotoxic and anticancer properties |
| 29 | Peppermint Oil | Mentha x Piperita | Antiseptic and astringent action |
| 30 | Pippali | <i>Piper Longum</i> | Antioxidant, digestive stimulant |
| 31 | Yellow Fruit Nightshade | Solanum spp | Anti-inflammatory |
| 32 | Radix, licorice Extract | Glycyrrhiza Uralensis | Antioxidant |
| 33 | Red Stinkwood | <i>Prunus Africana</i> | Bark used for liver problems and constipation and treating prostate gland hypertrophy and benign prostate hyperplasia |
| 34 | Skullcap Root | Scutellaria Baicalensis | Used for anxiety and nervous tension |
| 35 | Tulsi | <i>Ocimum Santum</i> | Expectorant, febrifuge, immunomodulatory |
| 36 | European Goldenrod | Solidago Virgaurea L. | Urinary tract and genital disorders |
| 37 | Vaska | Adhatoda Vasika | Respiratory disorders, fevers |

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| 38 | Marshmallow Root | Althaea Officinalis L. | Mouth and throat disorders, Cough and cold, Gastrointestinal disorders |
| 39 | Iron Wort | Sideritis scardica Griseb.; Sideritis clandestina (Bory & Chaub.) Hayek; Sideritis raeseri Boiss. & | Cough and cold, Gastrointestinal disorders |
| 40 | Black Cohosh | Cimicifuga Racemosa (L.) Nutt. | Urinary tract and genital disorders |
| 41 | Monkfruit | <i>Fructus Momordicae</i> | Respiratory disorders, longevity |
| 42 | Iceland Moss | <i>Lichen Islandicus</i> | Demulcent |
| 43 | Malabar-nut leaf | <i>Adhatoda Vasika</i> | Respiratory disorders |
| 44 | Milkworts | <i>Polygala Nyikensis</i> | Antifungal activity |
| 45 | Madagascar Periwinkle/ Pink Periwinkle | <i>Catharanthus Roseus</i> | Anticancer |
| 46 | Liquorice | <i>Glycyrrhiza Glabra</i> | Cough and cold, Gastrointestinal disorders |
| 47 | Pumpkin Seeds | <i>Curcubita Maxima</i> | Intestinal infections and kidney problems |
| 48 | Yohimbine | Mentha Sylvestris | Impotence |
| 49 | St. John's Wort | Hypericum Perforatum L | Antidepressant (BHP,19960 |
| 50 | Lovage Root | Levisticum Officinale W.D.J.Koch | Urinary tract and genital disorders |
| 51 | Juniper Cone Berry | Juniperus Communis L. | Urinary tract and genital disorders |
| 52 | Maté Leaf | Lex Paraguariensis A.St.-Hil. | Fatigue and weakness, Urinary tract and genital disorders |

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| 53 | Lemon Verbena leaf | Aloysia Citriodora Paláu (syn. Aloysia triphylla (L'Hér.) Kuntze; Verbena triphylla ... | Sleep disorders and temporary insomnia, Mental stress and mood disorders, Gastrointestinal disorders |
| 54 | Couch Grass Rhizome | Agropyron Repens (L.) P. Beauv. | Urinary tract and genital disorders |
| 55 | Dandelion Root | Taraxacum Officinale F.H. Wigg. | Loss of appetite, Urinary tract and genital disorders, Gastrointestinal disorders |
| 56 | Ash Leaf | Fraxinus Excelsior L., Fraxinus Angustifolia Vahl | Pain and inflammation, Urinary tract and genital disorders |
| 57 | Horse-chestnut Bark | Aesculus Hippocastanum L. | Urinary tract and genital disorders |
| 58 | Java Tea | Orthosiphon Aristatus (Blume) Miq. var. aristatus | Urinary tract and genital disorders |
| 59 | Bitter Fennel | Foeniculum Vulgare Miller subsp. vulgare var. vulgare | Urinary tract and genital disorders, Urinary tract and genital disorders, Cough and cold |
| 60 | Bitter Fennel Fruit Oil | Foeniculum Vulgare Miller subsp. vulgare var. vulgare | Cough and cold |

Pharmacy Only Medical Cosmetics

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| 1 | Salicylic Acid (Or Related Substances) | Salicylate Sodium Salicylate Willow Extract |
| 2 | Alpha Hydroxyacids | Glycolic Acid Lactic Acid Citric Acid |

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| | | Mandelic Acid Malic Acid Tartaric Acid. |
| 3 | Beta Hydroxyacids | 2-Hydroxy-5-Octanoyl Benzoic Acid Beta-Lipohydroxyacid (B-LHA) Tropic Acid. |
| 4 | Depigmenting Agents; | Hydroquinone Monobenzylether Of Hydroquinone 4-Methoxyphenol 4-Isopropylcatechol 4-Hydroxyanisol And N -Acetyl-4-S-Cyteaminyphenol |
| 5 | Hormones | Estrogens Progesterones Botulinum A Exotoxin |
| 6 | Growth Factors | Epidermal Growth Factor Transforming Growth Factor |
| 7 | Retinoids | Tretinoin Isotretinoin Etretinate Arotinoid Retinol |

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| | | Retinal Retinoic Acid |
| 8 | Others | Resveratrol and Polydatins Anthenol Panthothenic Acid And Its Derivatives Minoxidil And Its Derivative 2 4-Diamino-Pyrimidine-3-Oxide 5 5-Dimethyl-1-Pyrroline-N -Oxide 5-Diethoxyphosphoryl-5-Methyl-1- Pyrroline-N-Oxide 1-Hydroxy-2,2,6,6-Tetramethyl-4- Oxo-Piperidine Octopirox Copper peptide Hydroquinone Tosylamide formaldehde Benzophenone Meradimate Ecamsule Octocrylene Benzoyl peroxide Hydrogen peroxide Trolamine salicylate |

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| | | Ketoconazole Furfuryladenine Glycolic Acid Resorcinol Finasteride Cysteine And N-Acetyl Cysteine 4-Tocopherols And 4-Tocotrienols Niacinamide Dimethylaminoethanol (DMAE) Hydroquinone Arbutin Ellagic Acid Beta-Alanyl-L-Histidine Kojic Acid Acetic acid Ginkgo Biloba Extract Allantoin Avobenzone UVA Per-Mulberry Compound Dioxybenzone II Trethocanic Acid Adapalene |
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| | | Tazarotene Glutathione Zinc Pyrithione Vitamin A and its derivatives (retinoids) Sulisobenzone Cinoxate Octinoxate Octisalate Homosalate Methyl anthranilate Octyl methoxycinnamate Padimate O Phenylbenzimidazole sulfonic acid/ensulizole Resorcinol Sulphur Vitamin E Finasteride Ethyl acetate Permanganate Oxybenzone Ubiquinone Ecamsule |
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Annex V: Prescription Only Medicines

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|---|---|-----------------|--|--|-----------------------------------|
| | Alimentary tract and metabolism | | | | |
| 1 | Stomatological preparations | A010AB | Anti-infectives and antiseptics for local oral treatment | Amphotericin B Polynoxylin Domiphen Oxyquinoline Neomycin Miconazole Natamycin Hexetidine Tetracycline Benzoxonium Chloride Tibezonium iodide Mepartricin Metronidazole Clotrimazole Sodium perborate Chlortetracycline Doxycycline Minocycline | Tablets Capsules Injectable |
| | | A01AC | Corticosteroids for local oral treatment | Triamcinolone Dexamethasone Hydrocortisone Prednisolone combinations | Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|---|---|-----------------|--|--|--|
| | | A01AD | Other agents for local oral treatment | Epinephrine Benzydamine Acetylsalicylic acid Adrenalone Amlexanox Becaplermin | Cream Ointment Solution Tablets Capsules |
| 2 | Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) | A02BB | Prostaglandins | Misoprostol Enprostil | Injection Tablets Capsules |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----------|---|-----------------|--|---|------------------------------|
| 3 | | A02BD | Combinations for eradication of Helicobacter Pylori | <p>Omeprazole Amoxicillin and Metronidazole Lansoprazole Tetracycline and Metronidazole Lansoprazole Amoxicillin and Metronidazole Pantoprazole Amoxicillin and Clarithromycin Omeprazole Amoxicillin and clarithromycin Esomeprazole Amoxicillin and clarithromycin Lansoprazole Amoxicillin and clarithromycin Bismuth Subcitrate Tetracycline and Metronidazole Lansoprazole Clarithromycin and Tinidazole Lansoprazole Amoxicillin and Levofloxacin Pantoprazole Amoxicillin Clarithromycin and Metronidazole Rabeprazole Amoxicillin and Clarithromycin Rabeprazole Amoxicillin and Metronidazole Vonoprazan Amoxicillin and Clarithromycin Vonoprazan Amoxicillin and Metronidazole</p> | <p>Tablets Capsules</p> |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|---|---|-----------------|---|---|------------------------------------|
| 4 | Drugs for functional gastrointestinal disorders | A03AA | Synthetic anticholinergics esters with tertiary amino group | Oxyphencyclimine Camylofin Mebeverine Trimebutine Rociverine Dicycloverine Dihexyverine Difemerine Piperidolate | Tablets Capsules Injectables |
| | | A03AB | Synthetic anticholinergics quaternary ammonium compounds | Benzilone Glycopyrronium bromide Oxyphenonium Penthienate Propantheline Otilonium bromide Methantheline Tridihexethyl Isopropamide Hexocyclium Poldine Mepenzolate Bevonium Pipenzolate Diphemanil (2-benzhydryloxyethyl)diethylmethylammonium iodide Tiemonium iodide Prifinium bromide Timepidium bromide Fenpiverinium Oxyphenonium combinations | Tablets Capsules Injectables |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|------------------------------------|
| | | A03AC | Synthetic antispasmodics amides with tertiary amines | Dimethylaminopropionylphenothiazine Nicofetamide Tiropramide | Tablets Capsules Injectables |
| | | A03AD | Papaverine and derivatives | Papaverine Drotaverine Moxaverine | Tablets Capsules Injectables |
| | | A03AE | Serotonin receptor antagonists | Alosetron Cilansetron | Tablets Capsules Injectables |
| | | A03AX | Other drugs for functional gastrointestinal disorders | Fenpiprane Diisopromine Chlorbenzoxamine Pinaverium Fenoverine Idanpramine Proxazole Alverine Trepibutone Isometheptene Caroverine Phloroglucinol Silicones Valethamate Menthae piperitae aetheroleum Trimethyldiphenylpropylamine | Tablets Capsules Injectables |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|---|---|-----------------|--|--|------------------------------------|
| 5 | Belladonna and derivatives plain | A03BA | Belladonna alkaloids tertiary amines | Atropine Hyoscyamine Belladonna total alkaloids | Tablets Capsules Injectables |
| | | A03BB | Belladonna alkaloids semisynthetic quaternary ammonium compounds | Methylatropine Methylscopolamine Fentionium Cimetropium bromide Homatropine methylbromide | Tablets Capsules Injectables |
| 6 | Antispasmodics in combination with psycholeptics | A03CA | Synthetic anticholinergic agents in combination with psycholeptics | Isopropamide and psycholeptics Clidinium and psycholeptics Oxyphencyclimine and psycholeptics Otilonium bromide and psycholeptics Glycopyrronium bromide and psycholeptics Bevonium and psycholeptics Ambutonium and psycholeptics Diphemanil and psycholeptics Pipenzolate and psycholeptics Emepronium and psycholeptics Propantheline and psycholeptics | Tablets Capsules Injectables |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|---|---|-----------------|---|--|------------------------------------|
| | | A03CB | Belladonna and derivatives in combination with psycholeptics | Methylscopolamine and psycholeptics Belladonna total alkaloids and psycholeptics Atropine and psycholeptics Homatropine methylbromide and psycholeptics Hyoscyamine and psycholeptics | Tablets Capsules Injectables |
| 7 | Antispasmodics in combination with analgesics | A03DA | Synthetic anticholinergic agents in combination with analgesics | Tropenzilone and analgesics Pitofenone and analgesics Bevonium and analgesics Ciclonium and analgesics Camylofin and analgesics Trospium and analgesics Tiemonium iodide and analgesic | Tablets Capsules Injectables |
| 8 | Antispasmodics and anticholinergics in combination with other drugs | A03EA | Antispasmodics psycholeptics and analgesics in combination | Antispasmodics Psycholeptics and analgesics in combination | Tablets Capsules Injectables |
| | | A03ED | Antispasmodics in combination with other drugs | Antispasmodics in combination with other drugs | Tablets Capsules Injectables |
| 9 | Propulsives | A03FA | Propulsives | Cisapride Bromopride Alizapride Clebopride Itopride Cinitapride Mosapride | Tablets Capsules Injectables |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|------------------------------------|
| 10 | Antiemetics and antinauseants | A04AA | Serotonin (5HT3) antagonists | Ondansetron Granisetron Tropisetron Dolasetron Palonosetron Palonosetron combinations | Tablets Capsules Injectables |
| | | A04AD | Other antiemetics | Scopolamine Cerium oxalate Chlorobutanol Metopimazine Dronabinol Nabilone Aprepitant Casopitant Rolapitant Scopolamine combinations Chlorobutanol combinations | Tablets Capsules Injectables |
| 11 | Bile therapy | A05AA | Bile acids and derivatives | Chenodeoxycholic acid Ursodeoxycholic acid Cholic acid Obeticholic acid | Tablets Capsules Injectables |
| | | A05AB | Preparations for biliary tract therapy | Nicotinyl methylamide | |
| | | A05AX | Other drugs for bile therapy | Piprozolin Hymecromone Cyclobutyrol | Tablets Capsules Injectables |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | A05BA | Liver therapy | Arginine glutamate Silymarin Citolone Epomediol Ornithine oxoglurate Tidiacic arginine Glycyrrhizic acid Metadoxine | Tablets Capsules Injectables |
| | | A05BC | Drugs for bile therapy and lipotropics in combination | Drugs for bile therapy and lipotropics in combination | Tablets Capsules Injectables |
| 12 | Drugs for constipation | A06AH | Peripheral opioid receptor antagonists | Methylnaltrexone bromide Alvimopan Naloxegol Naloxone Naldemedine | Tablets Capsules Syrup Suspension |
| | | A06AX | Other drugs for constipation | Glycerol Carbon dioxide producing drugs Lubiprostone Linaclotide Prucalopride Tegaserod Plecanatide Tenapanor | Tablets Capsules Syrup Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|---|
| 13 | Intestinal anti-infectives | A07AA | Antibiotics | Neomycin Nystatin Natamycin Streptomycin Polymyxin B Paromomycin Amphotericin B Kanamycin Vancomycin Colistin Rifaximin Fidaxomicin Rifamycin Neomycin combinations Streptomycin combinations | Tablets Capsules Syrup Suspension Injection |
| | | A07AB | Sulfonamides | Phthalylsulfathiazole Sulfaguanidine Succinylsulfathiazole | Tablets Capsules Syrup Suspension Injection |
| | | A07AC | Imidazole derivatives | Miconazole | Tablets Capsules Syrup Suspension Injection |
| | | A07AX | Other intestinal anti-infectives | Broxyquinoline Acetarsol Nifuroxazide Nifurzide | Tablets Capsules Syrup Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|---|
| 14 | Antipropulsives | A07DA | Antipropulsives | Diphenoxylate Opium Difenoxin Eluxadoline Morphine combinations Loperamide combinations | Tablets Capsules Syrup Suspension Injection |
| 15 | Intestinal anti-inflammatory agents | A07EA | Corticosteroids acting locally | Prednisolone Hydrocortisone Prednisone Betamethasone Tixocortol Budesonide Beclometasone | Tablets Capsules Syrup Suspension Injection |
| | | A07EB | Antiallergic agents excluding corticosteroids | Cromoglicic acid | Tablets Capsules Syrup Suspension Injection |
| | | A07EC | Aminosalicylic acid and similar agents | Sulfasalazine Mesalazine Olsalazine Balsalazide | Tablets Capsules Syrup Suspension Injection |
| 16 | Other antidiarrheals | A07XA | Other antidiarrheals | Albumin tannate Ceratonina Calcium compounds Racecadotril Crofelemer Albumin tannate combinations | Tablets Capsules Syrup Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|---|
| 17 | Antiobesity preparations excluding diet products | A08AA | Centrally acting antiobesity products | Phentermine Fenfluramine Amfepramone Dexfenfluramine Mazindol Etilamfetamine Cathine Clobenzorex Mefenorex Sibutramine Lorcaserin Ephedrine combinations Bupropion and naltrexone | Tablets Capsules Syrup Suspension Injection |
| | | A08AB | Peripherally acting antiobesity products | Orlistat | Tablets Capsules Syrup Suspension Injection |
| | | A08AX | Other antiobesity drugs | Rimonabant | Tablets Capsules Syrup Suspension Injection |
| 18 | Digestives including enzymes | A09AA | Enzyme preparations | Diastase Multienzymes (lipase protease etc.) Pepsin Tilactase | Tablets Capsules Syrup Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|---|--|---|
| | | A09AB | Acid preparations | Glutamic acid hydrochloride Betaine hydrochloride Hydrochloric acid Citric acid | Tablets Capsules Syrup Suspension Injection |
| | | A09AC | Enzyme and acid preparations combinations | Pepsin and acid preparations Multienzymes and acid preparations | Tablets Capsules Syrup Suspension Injection |
| 19 | Insulins and analogues | A10AB | Insulins and analogues for injection fast-acting | Insulin (human) Insulin (beef) Insulin (pork) Insulin lispro Insulin aspart Insulin glulisine combinations | Injection |
| | | A10AC | Insulins and analogues for injection intermediate-acting | Insulin (human) Insulin (beef) Insulin (pork) Insulin lispro combinations | Injection |
| | | A10AD | Insulins and analogues for injection intermediate- or long-acting combined with fast-acting | Insulin (human) Insulin (beef) Insulin (pork) Insulin lispro Insulin aspart Insulin degludec and insulin aspart Combinations | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|-----------------------------------|
| | | A10AE | Insulins and analogues for injection long-acting | Insulin (human) Insulin (beef) Insulin (pork) Insulin glargine Insulin detemir Insulin degludec Insulin glargine and lixisenatide Insulin degludec and liraglutide | Injection |
| | | A10AF | Insulins and analogues for inhalation | Insulin (human) | Injection |
| 20 | Blood glucose lowering drugs excluding insulins | A10BA | Biguanides | Phenformin Metformin Buformin | Tablets Capsules Suspension |
| | | A10BB | Sulfonylureas | Glibenclamide Chlorpropamide Tolbutamide Glibornuride Tolazamide Carbutamide Glipizide Gliquidone Gliclazide Metahexamide Glisoxepide Glimepiride Acetohexamide | Tablets Capsules Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|-----------------------------------|
| | | A10BC | Sulfonamides (heterocyclic) | Glymidine | Tablets Capsules Suspension |
| | | A10BD | Combinations of oral blood glucose lowering drugs | Phenformin and sulfonylureas Metformin and sulfonylureas Metformin and rosiglitazone Glimepiride and rosiglitazone Metformin and pioglitazone Glimepiride and pioglitazone Metformin and sitagliptin Metformin and vildagliptin Pioglitazone and alogliptin Metformin and saxagliptin Metformin and linagliptin Pioglitazone and sitagliptin Metformin and alogliptin Metformin and repaglinide Metformin and dapagliflozin Metformin and canagliflozin Metformin and acarbose Metformin and gemigliptin Linagliptin and empagliflozin Metformin and empagliflozin Saxagliptin and dapagliflozin Metformin and evogliptin Metformin and ertugliflozin Sitagliptin and ertugliflozin Metformin, saxagliptin and dapagliflozin Metformin and lobeglitazone | Tablets Capsules Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|-----------------------------------|
| | | A10BF | Alpha glucosidase inhibitors | Acarbose Miglitol Voglibose | Tablets Capsules Suspension |
| | | A10BG | Thiazolidinediones | Troglitazone Rosiglitazone Pioglitazone Lobeglitazone | Tablets Capsules Suspension |
| | | A10BH | Dipeptidyl peptidase 4 (DPP-4) inhibitors | Sitagliptin Vildagliptin Saxagliptin Alogliptin Linagliptin Gemigliptin Evogliptin Teneligliptin Sitagliptin and simvastatin Gemigliptin and rosuvastatin | Tablets Capsules Suspension |
| | | A10BI | Glucagon-like peptide-1 (GLP-1) analogues | Exenatide Liraglutide Lixisenatide Albiglutide Dulaglutide Semaglutide Beinaglutide | Tablets Capsules Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|-----------------------------------|
| | | A10BJ | Sodium-glucose co-transporter 2 (SGLT2) inhibitors | Dapagliflozin Canagliflozin Empagliflozin Ertugliflozin Ipragliflozin Sotagliflozin Luseogliflozin | Tablets Capsules Suspension |
| | | A10BX | Other blood glucose lowering drugs excl. insulins | Guar gum Repaglinide Nateglinide Pramlintide Benfluorex Mitiglinide | Tablets Capsules Suspension |
| 21 | Other drugs used in diabetes | A10XA | Aldose reductase inhibitors | Tolrestat | Tablets Capsules Suspension |
| 22 | Vitamin A and D including combinations of the two | A11CA | Vitamin A plain | Retinol (Vit A) Betacarotene | Injection |
| | | A11CB | Vitamin A and D in combination | Vitamin A and D in combination | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|-----------------------|
| | | A11CC | Vitamin D and analogues | Ergocalciferol Dihydrotachysterol Alfacalcidol Calcitriol Colecalciferol Calcifediol combinations Colecalciferol combinations | Capsules Injection |
| 23 | Vitamin B1 plain and in combination with vitamin B6 and B12 | A11DA | Vitamin B1 plain | Thiamine (vit B1) Sulbutiamine Benfotiamine | Injection |
| | | A11DB | Vitamin B1 in combination with vitamin B6 and/or vitamin B12 | Vitamin B1 in combination with vitamin B6 and/or vitamin B12 | Injection |
| 24 | Vitamin B-complex including combinations | A11EA | Vitamin B-complex plain | Vitamin B-complex plain | Injection |
| | | A11EB | Vitamin B-complex with vitamin C | Vitamin B-complex with vitamin C | Injection |
| | | A11EC | Vitamin B-complex with minerals | Vitamin B-complex with minerals | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|------------------------------------|
| | | A11ED | Vitamin B-complex with anabolic steroids | Vitamin B-complex with anabolic steroids | Injection |
| | | A11EX | Vitamin B-complex other combinations | Vitamin B-complex other combinations | Injection |
| 25 | Ascorbic acid (vitamin C) including combinations | A11GA | Ascorbic acid (vitamin C) plain | Ascorbic acid (Vit C) | Injection |
| | | A11GB | Ascorbic acid (vitamin C) combinations | Ascorbic acid (Vit C) and calcium | Injection |
| 26 | Other plain vitamin preparations | A11HA | Other plain vitamin preparations | Nicotinamide Pyridoxine (Vit B6) Tocopherol (Vit E) Riboflavin (Vit B2) Biotin Pyridoxal Phosphate Inositol Tocofersolan Dexpanthenol Calcium Pantothenate Pantethine | Injection Capsules Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|---------------------|
| 27 | Other vitamin products combinations | A11JA | Combinations of vitamins | Combinations of vitamins | Injection |
| | | A11JB | Vitamins with minerals | Vitamins with minerals | Injection |
| | | A11JC | Vitamins other combinations | Vitamins other combinations | Injection |
| 28 | Calcium | A12AA | Calcium | Calcium phosphate Calcium gluconate Calcium gluconate Calcium carbonate Calcium lactate Calcium lactate gluconate Calcium chloride Calcium glycerylphosphate Calcium citrate lysine complex Calcium glucoheptonate Calcium pangamate Calcium citrate Calcium (different salts in combination) Calcium laevulate | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|---------------------|
| | | A12AX | Calcium combinations with vitamin D and/or other drugs | Calcium combinations with vitamin D and/or other drugs | Injection |
| 29 | Potassium | A12BA | Potassium | Potassium chloride Potassium citrate Potassium hydrogentartrate Potassium hydrogencarbonate Potassium gluconate Potassium (different salts in combination) Potassium chloride combinations | Injection |
| 30 | Other mineral supplements | | | | |
| | | A12CB | Zinc | Zinc sulfate Zinc gluconate Zinc protein complex | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|---------------------|
| | | A12CC | Magnesium | Magnesium chloride Magnesium sulfate Magnesium gluconate Magnesium citrate Magnesium aspartate Magnesium lactate Magnesium levulinate Magnesium pidolate Magnesium orotate Magnesium oxide Magnesium (different salts in combination) | Injection |
| | | A12CD | Fluoride | Sodium fluoride Sodium monofluorophosphate Fluoride combinations | Injection |
| | | A12CE | Selenium | Sodium selenate Sodium selenite | Injection |
| | | A12CX | Other mineral products | Other mineral products | Injection |
| 31 | Tonics | A13A | Tonics | Tonics | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| 32 | Anabolic steroids | A14AA | Androstan derivatives | Androstanolone Stanozolol Metandienone Metenolone Oxymetholone Quinbolone Prasterone Oxandrolone Norethandrolone | Tablets Capsules Injection Suspension |
| | | A14AB | Estren derivatives | Nandrolone Ethylestrenol Oxabolone cipionate | Tablets Capsules Injection Suspension |
| 33 | Other anabolic agents | A14B | Other anabolic agents | Other anabolic agents | Tablets Capsules Injection Suspension |
| 34 | Appetite stimulants | A15 | Appetite stimulants | Appetite stimulants | Tablets Capsules Injection Suspension |
| 35 | Other alimentary tract and metabolism products | A16AA | Amino acids and derivatives | Levocarnitine Ademetionine Glutamine Mercaptamine Carglumic acid Betaine Mentreleptin | Tablets Capsules Injection Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | A16AB | Enzymes | Alglucerase Imiglucerase Agalsidase alfa Agalsidase beta Laronidase Sacrosidase Alglucosidase alfa Galsulfase Idursulfase Velaglucerase alfa Taliglucerase alfa Elosulfase alfa Asfotase alfa Sebelipase alfa Velmanase alfa Idursulfase beta Cerliponase alfa Vestronidase alfa Pegvaliase | Tablets Capsules Injection Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--|
| | | A16AX | Various alimentary tract and metabolism products | Thiocctic acid Anethole trithione Sodium phenylbutyrate Nitisinone Zinc acetate Miglustat Sapropterin Teduglutide Glycerol phenylbutyrate Eliglustat Sodium benzoate Trientine Uridine triacetate Migalastat Telotristat Givosiran Triheptanoin Lumasiran Sodium benzoate and sodium phenylacetate | Tablets Capsules Injection Suspension |
| | Blood and blood forming organs | | | | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 36 | Antithrombotic agents | B01AA | Vitamin K antagonists | Dicoumarol Phenindione Warfarin Phenprocoumon Acenocoumarol Ethyl biscoumacetate Clorindione Diphenadione Tiocloamarol Fluindione | Tablets Capsules Injection Suspension |
| | | B01AB | Heparin group | Heparin Antithrombin III Dalteparin Enoxaparin Nadroparin Parnaparin Reviparin Danaparoid Tinzaparin Sulodexide Bemiparin Heparin combinations | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--|
| | | B01AC | Platelet aggregation inhibitors excluding heparin | Ditazole Cloricromen Picotamide Clopidogrel Ticlopidine Acetylsalicylic acid Dipyridamole Carbasalate calcium Epoprostenol Indobufen Iloprost Abciximab Aloxiprin Eptifibatide Tirofiban Triflusal Beraprost Treprostinil Prasugrel Cilostazol Ticagrelor Cangrelor Vorapaxar Selexipag Combinations of Acetylsalicylic acid with proton pump inhibitors | Tablets Capsules Injection Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | B01AD | Enzymes | Streptokinase Alteplase Anistreplase Urokinase Fibrinolysin Brinase Retepase Saruplase Ancrod Drotrecogin alfa (activated) Tenecteplase Protein C | Tablets Capsules Injection Suspension |
| | | B01AE | Direct thrombin inhibitors | Desirudin Lepirudin Argatroban Melagatran Ximelagatran Bivalirudin Dabigatran etexilate | Tablets Capsules Injection Suspension |
| | | B01AF | Direct factor Xa inhibitors | Rivaroxaban Apixaban Edoxaban Betrixaban | Tablets Capsules Injection Suspension |
| 37 | Antifibrinolytics | B02AA | Amino acids | Aminocaproic acid Tranexamic acid Aminomethylbenzoic acid | Tablets Capsules Injection Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | B02AB | Proteinase inhibitors | Aprotinin Alfa ₁ antitrypsin Camostat Ulinastatin | Tablets Capsules Injection Suspension |
| 38 | Vitamin K and other hemostatics | B02BA | Vitamin K | Phytomenadione Menadione | Tablets Capsules Injection Suspension |
| | | B02BB | Fibrinogen | Human fibrinogen | Injection |
| | | B02BC | Local hemostatics | Absorbable gelatin sponge Oxidized cellulose Tetragalacturonic acid hydroxymethylester Adrenalone Thrombin Collagen Calcium alginate Epinephrine | Injection Suspension Solution |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | B02BD | Blood coagulation factors | Coagulation factor IX, II, VII and X in combination Coagulation factor VIII Factor VIII inhibitor bypassing activity Coagulation factor IX Coagulation factor VII von Willebrand factor and coagulation factor VIII in combination Coagulation factor XIII Coagulation factor VIIa von Willebrand factor Catridecacog Coagulation factor X Susoctocog alfa Thrombin | Injection |
| | | B02BX | Other systemic hemostatics | Etamsylate Carbazochrome Batroxobin Romiplostim Eltrombopag Emicizumab Lusutrombopag Avatrombopag Fostamatinib | Tablets Capsules Injection Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|-----------------------------------|
| 39 | Iron preparations | B03AA | Iron bivalent oral preparations | Ferrous glycine sulfate Ferrous fumarate Ferrous gluconate Ferrous carbonate Ferrous chloride Ferrous succinate Ferrous sulfate Ferrous tartrate Ferrous aspartate Ferrous ascorbate Ferrous iodine Ferrous sodium citrate | Tablets Capsules Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--|
| | | B03AB | Iron trivalent oral preparations | Ferric sodium citrate Saccharated iron oxide Sodium ferredetate Ferric hydroxide Ferric oxide polymaltose complexes Chondroitin sulfate-iron complex Ferric acetyl transferrin Ferric proteinsuccinylate ferric maltol | Tablets Capsules Suspension |
| | | B03AC | Iron parenteral preparations | Iron sucrose (iron(III)-hydroxide sucrose complex) | Injection |
| | | B03AD | Iron in combination with folic acid | Ferrous amino acid complex Ferrous fumarate Ferrous sulfate Ferric oxide polymaltose complexes Ferrous gluconate | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | B03AE | Iron in other combinations | Iron vitamin B12 and folic acid Iron multivitamins and folic acid Iron and multivitamins Iron multivitamins and minerals | Tablets Capsules Suspension Injection |
| 40 | Vitamin B ₁₂ and folic acid | B03BA | Vitamin B ₁₂ (cyanocobalamin and analogues) | Cyanocobalamin Cyanocobalamin tannin complex Hydroxocobalamin Cobamamide Mecobalamin Cyanocobalamin combinations Hydroxocobalamin combinations | Injection |
| | | B03BB | Folic acid and derivatives | Folic acid Folic acid combinations | Injection |
| 41 | Other antianemic preparations | B03XA | Other antianemic preparations | Erythropoietin Darbepoetin alfa Methoxy polyethylene glycol-epoetin beta Peginesatide Roxadustat Luspatercept | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|---------------------|
| 42 | Blood and related products | B05AA | Blood substitutes and plasma protein fractions | Albumin Other plasma protein fractions Fluorocarbon blood substitutes Dextran Gelatin agents Hydroxyethylstarch Hemoglobin crosfumaril Hemoglobin raffimer Hemoglobin glutamer (bovine) | Injection |
| | | B05AX | Other blood products | Erythrocytes Thrombocytes Blood plasma Stem cells from umbilical cord blood | Injection |
| 43 | I.V. solutions | B05BA | Solutions for parenteral nutrition | Amino acids Fat emulsions Carbohydrates Protein hydrolysates | Injection |
| | | B05BB | Solutions affecting the electrolyte balance | Electrolytes Electrolytes with carbohydrates Trometamol Electrolytes in combination with other medicines | Injection |
| | | B05BC | Solutions producing osmotic diuresis | Mannitol Carbamide | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|---------------------|
| 44 | Peritoneal dialytics | B05DA | Isotonic solutions | Isotonic solutions | Solution |
| | | B05DB | Hypertonic solutions | Hypertonic solutions | Solution |
| 45 | I.V. solution additives | B05XA | Electrolyte solutions | Potassium chloride Sodium bicarbonate Sodium chloride Ammonium chloride Magnesium sulfate incl. Combination of Potassium phosphate with other potassium salts Calcium chloride Sodium acetate Sodium phosphate Magnesium phosphate Magnesium chloride Zinc chloride Hydrochloric acid Sodium glycerophosphate Potassium lactate Cardioplegia solutions Potassium acetate Zinc sulfate Combinations of electrolytes Electrolytes in combination with other medicines | Injectable |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | B05XB | Amino acids | Arginine hydrochloride Alanyl glutamine Lysine | Injectable |
| | | B05XC | Vitamins | All vitamins | Injectable |
| | | B05XX | Other I.V. solution additives | Trometamol | Tablets Capsules Suspension Injection |
| 46 | Hemodialytic and hemofiltrates | B05ZA | Hemodialytics concentrates | Hemodialytics concentrates | Injection |
| | | B05ZB | Hemofiltrates | Hemofiltrates | Injection |
| 47 | Other hematological agents | B06AA | Enzymes | Fibrinolysin and desoxyribonuclease Hyaluronidase Chymotrypsin Trypsin Desoxyribonuclease Streptokinase combinations | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|------------------------------|---|-----------------|--|--|--|
| | | B06AB | Heme products | Hemin | Injection |
| | | B06AC | Drugs used in hereditary angioedema | Plasma derived C1-inhibitor Icatibant Ecallantide Conestat alfa Lanadelumab | Tablets Capsules Suspension Injection |
| | | B06AX | Other hematological agents | Crizanlizumab Betibeglogene autotemcel | Tablets Capsules Suspension Injection |
| Cardiovascular system | | | | | |
| 48 | Cardiac glycosides | C01AA | Digitalis glycosides | Acetyldigitoxin Acetyldigoxin Digitoxin Digoxin Lanatoside C Deslanoside Metildigoxin Gitoformate Acetyldigoxin combinations | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C01AB | Scilla glycosides | Proscillaridin proscillaridin combinations | Tablets Capsules Suspension Injection |
| | | C01AC | Strophanthus glycosides | g-strophanthin Cymarin | Tablets Capsules Suspension Injection |
| | | C01AX | Other cardiac glycosides | Peruvoside | Tablets Capsules Suspension Injection |
| 49 | Antiarrhythmics class I and III | C01BA | Antiarrhythmics Class Ia | Quinidine Procainamide Disopyramide Sparteine Ajmaline Prajmaline Lorajmine Hydroquinidine Quinidine Combinations of quinidine with and without psycholeptics | Tablets Capsules Suspension Injection |
| | | C01BB | Antiarrhythmics Class Ib | Lidocaine Mexiletine Tocainide Aprindine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--|
| | | C01BC | Antiarrhythmics Class Ic | Propafenone Flecainide Lorcainide Encainide Ethacizine | Tablets Capsules Suspension Injection |
| | | C01BD | Antiarrhythmics Class III | Amiodarone Bretylium tosilate Bunaftine Dofetilide Ibutilide Tedisamil Dronedarone | Tablets Capsules Suspension Injection |
| | | C01BG | Other antiarrhythmics Class I and III | Moracizine Cibenzoline Vernakalant | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 50 | Cardiac stimulants excluding cardiac glycosides | C01CA | Adrenergic and dopaminergic agents | Etilefrine Isoprenaline Norepinephrine Dopamine Norfenefrine Phenylephrine Dobutamine Oxedrine Metaraminol Methoxamine Mephentermine Dimetofrine Prenalterol Dopexamine Gepefrine Ibopamine Midodrine Octopamine Fenoldopam Cafedrine Arbutamine Theodrenaline Epinephrine Amezinium metilsulfate Ephedrine Droxidopa Etilefrine combinations | Tablets Capsules Suspension Injection |
| | | C01CE | Phosphodiesterase inhibitors | Amrinone Milrinone Enoximone Bucladesine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | C01CX | Other cardiac stimulants | Angiotensinamide Xamoterol Levosimendan Angiotensin II | Tablets Capsules Suspension Injection |
| 51 | Vasodilators used in cardiac diseases | C01DA | Organic nitrates | Glyceryl trinitrate Methylpropylpropanediol dinitrate Pentaerithryl tetranitrate Propatylnitrate Isosorbide dinitrate Trolnitrate Eritrityl tetranitrate Isosorbide mononitrate Organic nitrates in combination Tenitramine Glyceryl trinitrate combinations Methylpropylpropanediol dinitrate combinations Pentaerithryl tetranitrate combinations Propatylnitrate combinations Isosorbide dinitrate combinations Trolnitrate combinations Eritrityl tetranitrate combinations Organic nitrates in combination with psycholeptics | Tablets Capsules Suspension Injection |
| | | C01DB | Quinolone vasodilators | Flosequinan | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C01DX | Other vasodilators used in cardiac diseases | Itramin tosilate Prenylamine Oxyfedrine Benziodarone Carbocromen Hexobendine Etafenone Heptaminol Imolamine Dilazep Trapidil Molsidomine Efloxate Cinepazet Cloridarol Nicorandil Linsidomine Nesiritide Serelaxin Vericiguat Itramin tosilate combinations Prenylamine combinations Oxyfedrine combination Benziodarone combinations | Tablets Capsules Suspension Injection |
| 52 | Other cardiac preparations | C01EA | Prostaglandins | Alprostadil | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | C01EB C01EX | Other cardiac preparations | Camphora Indometacin Crataegus glycosides Creatinolfosphate Fosfocreatine Fructose 1 6-diphosphate Ubidecarenone Adenosine Tiracizine Acadesine Trimetazidine Ibuprofen Ivabradine Ranolazine Regadenoson Meldonium Tiazotic acid | Tablets Capsules Suspension Injection |
| 53 | Antiadrenergic agents centrally acting | C02AA | Rauwolfia alkaloids | Rescinnamine Reserpine Combinations of rauwolfia alkaloids Rauwolfia alkaloids (whole root) Deserpidine Methoserpidine Bietaserpine Reserpine combinations Rauwolfia alkaloids combinations Bietaserpine combinations | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C02AB | Methyldopa | Methyldopa (levorotatory) Methyldopa (racemic) | Tablets Capsules Suspension Injection |
| | | C02AC | Imidazoline receptor agonists | Clonidine Guanfacine Tolonidine Moxonidine Rilmenidine | Tablets Capsules Suspension Injection |
| 54 | Antiadrenergic agents ganglion-blocking | C02BA | Sulfonium derivatives | Trimetaphan | Tablets Capsules Suspension Injection |
| | | C02BB | Secondary and tertiary amines | Mecamylamine | Tablets Capsules Suspension Injection |
| | | C02BC | Bisquaternary ammonium compounds | Bisquaternary ammonium compounds | Tablets Capsules Suspension Injection |
| 55 | Antiadrenergic agents peripherally acting | C02CA | Alpha-adrenoreceptor antagonists | Prazosin Indoramin Trimazosin Doxazosin Urapidil | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | C02CC | Guanidine derivatives | Betanidine Guanethidine Guanoxan Debrisoquine Guanoclor Guanazodine Guanoxabenz | Tablets Capsules Suspension Injection |
| 56 | Arteriolar smooth muscle agents acting on | C02DA | Thiazide derivatives | Diazoxide | Tablets Capsules Suspension Injection |
| | | C02DB | Hydrazinophthalazine derivatives | Dihydralazine Hydralazine Endralazine Cadralazine | Tablets Capsules Suspension Injection |
| | | C02DC | Pyrimidine derivatives | Minoxidil | Tablets Capsules Suspension Injection |
| | | C02DD | Nitroferricyanide derivatives | Nitroprusside | Tablets Capsules Suspension Injection |
| | | C02DG | Guanidine derivatives | Pinacidil | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 57 | Other antihypertensives | C02KA | Alkaloids excluding rauwolfia | Veratrum | Tablets Capsules Suspension Injection |
| | | C02KB | Tyrosine hydroxylase inhibitors | Metirosine | Tablets Capsules Suspension Injection |
| | | C02KC | MAO inhibitors | Pargyline | Tablets Capsules Suspension Injection |
| | | C02KD | Serotonin antagonists | Ketanserin | Tablets Capsules Suspension Injection |
| | | C02KX | Antihypertensives for pulmonary arterial hypertension | Bosentan Ambrisentan Sitaxentan Macitentan Riociguat Ambrisentan and tadalafil | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|---|---|--|
| 58 | Antihypertensives and diuretics in combination | C02LA | Rauwolfia alkaloids and diuretics in combination | Reserpine and diuretics Rescinnamine and diuretics Deserpidine and diuretics Methoserpidine and diuretics Bietaserpine and diuretics Rauwolfia alkaloids whole root and diuretics Syroserpine and diuretics Combination of rauwolfia alkaloids and diuretics including other combinations Reserpine, diuretics and combinations with other drugs Rescinnamine, diuretics and combinations with other drugs Reserpine, diuretics and combinations with psycholeptics | Tablets Capsules Suspension Injection |
| | | C02LB | Methyldopa and diuretics in combination | Methyldopa (levorotatory) and diuretics | Tablets Capsules Suspension Injection |
| | | C02LC | Imidazoline receptor agonists in combination with diuretics | Clonidine and diuretics Moxonidine and diuretics Clonidine diuretics and combinations with other drugs | Tablets Capsules Suspension Injection |
| | | C02LE | Alpha-adrenoreceptor antagonists and diuretics | Prazosin and diuretics | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|---|---|--|
| | | C02LF | Guanidine derivatives and diuretics | Guanethidine and diuretics | Tablets Capsules Suspension Injection |
| | | C02LG | Hydrazinophthalazine derivatives and diuretics | Dihydralazine and diuretics Hydralazine and diuretics Picodralazine and diuretics Dihydralazine, diuretics and combinations with other drugs Picodralazine, diuretics and combinations with psycholeptics | Tablets Capsules Suspension Injection |
| | | C02LK | Alkaloids excluding rauwolfia in combination with diuretics | Veratrum and diuretics | Tablets Capsules Suspension Injection |
| | | C02LL | MAO inhibitors and diuretics | Pargyline and diuretics | Tablets Capsules Suspension Injection |
| | | C02LN | Serotonin antagonists and diuretics | Serotonin antagonists and diuretics | Tablets Capsules Suspension Injection |
| | | C02LX | Other antihypertensives and diuretics | Pinacidil and diuretics | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|---|---|--|
| 59 | Low-ceiling diuretics thiazides | C03AA | Thiazides plain | Bendroflumethiazide Hydroflumethiazide Hydrochlorothiazide Chlorothiazide Polythiazide Trichlormethiazide Cyclopenthiazide Methyclothiazide Cyclothiazide Mebutizide | Tablets Capsules Suspension Injection |
| | | C03AB | Thiazides and potassium in combination | Bendroflumethiazide and potassium Hydroflumethiazide and potassium Hydrochlorothiazide and potassium Chlorothiazide and potassium Polythiazide and potassium Trichlormethiazide and potassium Cyclopenthiazide and potassium Methyclothiazide and potassium Cyclothiazide and potassium | Tablets Capsules Suspension Injection |
| | | C03AH | Thiazides combinations with psycholeptics and/or analgesics | Chlorothiazide combinations Hydroflumethiazide combinations | Tablets Capsules Suspension Injection |
| | | C03AX | Thiazides combinations with other drugs | Hydrochlorothiazide combinations | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 60 | Low-ceiling diuretics excl. thiazides | C03BA | Sulfonamides plain | Quinethazone Clopamide Chlortalidone Mefruside Clofenamide Metolazone Meticrane Xipamide Indapamide Clorexolone Fenquizone Clorexolone combinations with psycholeptics | Tablets Capsules Suspension Injection |
| | | C03BB | Sulfonamides and potassium in combination | Quinethazone and potassium Clopamide and potassium Chlortalidone and potassium Mefruside and potassium Clofenamide and potassium | Tablets Capsules Suspension Injection |
| | | C03BC | Mercurial diuretics | Mersalyl | Tablets Capsules Suspension Injection |
| | | C03BD | Xanthine derivatives | Theobromine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C03BB | Sulfonamides combinations with other drugs | Sulfonamides in combination with other medicines | Tablets Capsules Suspension Injection |
| | | C03BX | Other low-ceiling diuretics | Cicletanine | Tablets Capsules Suspension Injection |
| 61 | High-ceiling diuretics | C03CA | Sulfonamides plain | Furosemide Bumetanide Piretanide Torasemide | Tablets Capsules Suspension Injection |
| | | C03CB | Sulfonamides and potassium in combination | Furosemide and potassium Bumetanide and potassium | Tablets Capsules Suspension Injection |
| | | C03CC | Aryloxyacetic acid derivatives | Etacrynic acid Tienilic acid | Tablets Capsules Suspension Injection |
| | | C03CD | Pyrazolone derivatives | Muzolimine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | C03CX | Other high-ceiling diuretics | Etozolin | Tablets Capsules Suspension Injection |
| | Peripheral vasodilators | C03DA | Aldosterone antagonists | Spironolactone Potassium canrenoate Canrenone Eplerenone | Tablets Capsules Suspension Injection |
| | | C03DB | Other potassium-sparing agents | Amiloride Triamterene | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| 62 | Peripheral vasodilators | C03EA | Low-ceiling diuretics and potassium-sparing agents | Hydrochlorothiazide and potassium-sparing agents Trichlormethiazide and potassium-sparing agents Epitizide and potassium-sparing agents Altizide and potassium-sparing agents Mebutizide and potassium-sparing agents Chlortalidone and potassium-sparing agents Cyclopenthiazide and potassium-sparing agents Metolazone and potassium-sparing agents Bendroflumethiazide and potassium-sparing agents Butizide and potassium-sparing agents | Tablets Capsules Suspension Injection |
| 63 | Peripheral vasodilators | C03EB | High-ceiling diuretics and potassium-sparing agents | Furosemide and potassium-sparing agents Bumetanide and potassium-sparing agents | Tablets Capsules Suspension Injection |
| 64 | Other diuretics | C03XA | Vasopressin antagonists | Tolvaptan Conivaptan | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 65 | Peripheral vasodilators | C04AA | 2-amino-1-phenylethanol derivatives | Isoxsuprine Buphenine Bamethan | Tablets Capsules Suspension Injection |
| | | C04QAB | Imidazoline derivatives | Phentolamine Tolazoline | |
| | | C04AC | Nicotinic acid and derivatives | Nicotinic acid Nicotinyl alcohol (pyridylcarbinol) Inositol nicotinate Ciclonicate | Tablets Capsules Suspension Injection |
| | | C04AD | Purine derivatives | Pentifylline Xantinol nicotinate Pentoxifylline Etofylline nicotinate | Tablets Capsules Suspension Injection |
| | | C04AE | Ergot alkaloids | Ergoloid mesylates Nicergoline Dihydroergocristine Ergoloid mesylates combinations Dihydroergocristine combinations | Tablets Capsules Suspension Injection |
| | | C04AF | Enzymes | Kallidinogenase | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | C04AX | Other peripheral vasodilators | Cyclandelate Phenoxybenzamine Vincamine Moxisylyte Bencyclane Vinburnine Suloctidil Buflomedil Naftidrofuryl Butalamine Visnadine Cetiedil Cinepazide Ifenprodil Azapetine Fasudil | Tablets Capsules Suspension Injection |
| 66 | Agents for treatment of hemorrhoids and anal fissures for topical use | C05AA | Corticosteroids | Hydrocortisone Prednisolone Betamethasone Fluorometholone Fluocortolone Dexamethasone Fluocinolone acetonide Fluocinonide Triamcinolone | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|---|--|--|
| | | C05AD | Local anesthetics | Lidocaine Tetracaine Benzocaine Cinchocaine Procaine Oxetacaine Pramocaine | Injection Solution |
| | | C05AE | Muscle relaxants | Glyceryl trinitrate isosorbide dinitrate Diltiazem | Tablets Capsules Suspension Injection |
| | | C05AX | Other agents for treatment of hemorrhoids and anal fissures for topical use | Aluminium preparations Bismuth preparations combinations Zinc preparations Tribenoside | Tablets Capsules Suspension |
| 67 | Antivaricose therapy | C05BA | Heparins or heparinoids for topical use | Organo-heparinoid Sodium apolate Heparin Pentosan polysulfate sodium Heparinoid combinations Heparin combinations | Injection |
| | | C05BB | Sclerosing agents for local injection | Organo-heparinoid Sodium apolate Heparin Pentosan polysulfate sodium Heparinoid combinations Heparin combinations | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C05BX | Other sclerosing agents | Monoethanolamine oleate Polidocanol Sodium tetradecyl sulfate Phenol Glucose combinations | Tablets Capsules Suspension Injection |
| 68 | Capillary stabilizing agents | C05CA | Bioflavonoids | Rutoside Monoxerutin Diosmin Troxerutin Hidrosmine Rutoside combinations Diosmin combinations Troxerutin combinations | Tablets Capsules Suspension Injection |
| | | C05CX | Other capillary stabilizing agents | Tribenoside Naftazone Hippocastani semen | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 69 | Beta blocking agents | C07AA | Beta blocking agents non-selective | Alprenolol Oxprenolol Pindolol Propranolol Timolol Sotalol Nadolol Mepindolol Carteolol Tertatolol Bopindolol Bupranolol Penbutolol Cloranolol | Tablets Capsules Suspension Injection |
| | | C07AB | Beta blocking agents selective | Practolol Metoprolol Atenolol Acebutolol Betaxolol Bevantolol Bisoprolol Celiprolol Esmolol Epanolol S-atenolol Nebivolol Talinolol Landiolol | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C07AG | Alpha and beta blocking agents | Labetalol Carvedilol | Tablets Capsules Suspension Injection |
| 70 | Beta blocking agents and thiazides | C07BA | Beta blocking agents non-selective and thiazides | Oxprenolol and thiazides Propranolol and thiazides Timolol and thiazides Sotalol and thiazides Nadolol and thiazides Metipranolol with thiazides and other medicines | Tablets Capsules Suspension Injection |
| | | C07BB | Beta blocking agents selective and thiazides | Metoprolol and thiazides Atenolol and thiazides Acebutolol and thiazides Bevantolol and thiazides Bisoprolol and thiazides Nebivolol and thiazides Metoprolol with thiazides and other medicines | Tablets Capsules Suspension Injection |
| | | C07BG | Alpha and beta blocking agents and thiazides | Labetalol and thiazides | Tablets Capsules Suspension Injection |
| 71 | Beta blocking agents and other diuretics | C07CA | Beta blocking agents non-selective and other diuretics | Oxprenolol and other diuretics Pindolol and other diuretics Bopindolol and other diuretics Penbutolol and other diuretics | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C07CB | Beta blocking agents selective and other diuretics | Metoprolol and other diuretics Atenolol and other diuretics Atenolol with diuretics and combinations | Tablets Capsules Suspension Injection |
| | | C07CG | Alpha and beta blocking agents and other diuretics | Labetalol and other diuretics | Tablets Capsules Suspension Injection |
| 72 | Beta blocking agents thiazides and other diuretics | C07DA | Beta blocking agents non-selective thiazides and other diuretics | Timolol Thiazides and other diuretics | Tablets Capsules Suspension Injection |
| | | C07DB | Beta blocking agents selective thiazides and other diuretics | Atenolol Thiazides and other diuretics | Tablets Capsules Suspension Injection |
| 73 | Beta blocking agents and other antihypertensives | | Beta blocking agents and calcium channel blockers | Metoprolol and felodipine Atenolol and nifedipine Bisoprolol and amlodipine Nebivolol and amlodipine Metoprolol and amlodipine | Tablets Capsules Suspension Injection |
| | | | Beta blocking agents other combinations | Propranolol and other combinations Sotalol and acetylsalicylic acid Metoprolol and acetylsalicylic acid Bisoprolol and acetylsalicylic acid Metoprolol and ivabradine Carvedilol and ivabradine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|---|--|--|
| 74 | Selective calcium channel blockers with mainly vascular effects | C08CA | Dihydropyridine derivatives | Amlodipine Felodipine Isradipine Nicardipine Nifedipine Nimodipine Nisoldipine Nitrendipine Lacidipine Nilvadipine Manidipine Barnidipine Lercanidipine Cilnidipine Benidipine Clevidipine Amlodipine and celecoxib Nifedipine combinations | Tablets Capsules Suspension Injection |
| | | C08CX | Other selective calcium channel blockers with mainly vascular effects | Mibefradil | Tablets Capsules Suspension Injection |
| 75 | Selective calcium channel blockers with direct cardiac effects | C08DA | Phenylalkylamine derivatives | Verapamil Gallopamil Verapamil combinations | Tablets Capsules Suspension Injection |
| | | C08DB | Benzothiazepine derivatives | Diltiazem | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 76 | Non-selective calcium channel blockers | C08EA | Phenylalkylamine derivatives | Fendiline Bepridil | Tablets Capsules Suspension Injection |
| | | C08EX | Other non-selective calcium channel blockers | Lidoflazine Perhexiline | Tablets Capsules Suspension Injection |
| 77 | Calcium channel blockers and diuretics | C08GA | Calcium channel blockers and diuretics | Nifedipine and diuretics Amlodipine and diuretics | Tablets Capsules Suspension Injection |
| 78 | ACE inhibitors plain | C09AA | ACE inhibitors plain | Captopril Enalapril Lisinopril Perindopril Ramipril Quinapril Benazepril Cilazapril Fosinopril Trandolapril Spirapril Delapril Moexipril Temocapril Zofenopril Imidapril | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 79 | ACE inhibitors combinations | C09BA | ACE inhibitors and diuretics | Captopril and diuretics Enalapril and diuretics Lisinopril and diuretics Perindopril and diuretics Ramipril and diuretics Quinapril and diuretics Benazepril and diuretics Cilazapril and diuretics Fosinopril and diuretics Delapril and diuretics Moexipril and diuretics Zofenopril and diuretics | Tablets Capsules Suspension Injection |
| | | C09BB | ACE inhibitors and calcium channel blockers | Enalapril and lercanidipine Lisinopril and amlodipine Perindopril and amlodipine Ramipril and felodipine Enalapril and nitrendipine Ramipril and amlodipine Trandolapril and verapamil Delapril and manidipine | Tablets Capsules Suspension Injection |
| | | C09BX | ACE inhibitors other combinations | Perindopril amlodipine and indapamide Perindopril and bisoprolol Ramipril, amlodipine and hydrochlorothiazide Perindopril, bisoprolol and amlodipine Ramipril and bisoprolol | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 80 | Angiotensin II receptor blockers (ARBs) plain | C09CA | Angiotensin II receptor blockers (ARBs) plain | Losartan Eprosartan Valsartan Irbesartan Tasosartan Candesartan Telmisartan Olmesartan medoxomil Azilsartan medoxomil Fimasartan | Tablets Capsules Suspension Injection |
| 81 | Angiotensin II receptor blockers (ARBs) combinations | C09DA | Angiotensin II receptor blockers (ARBs) and diuretics | Losartan and diuretics Eprosartan and diuretics Valsartan and diuretics Irbesartan and diuretics Candesartan and diuretics Telmisartan and diuretics Olmesartan medoxomil and diuretics Azilsartan medoxomil and diuretics Fimasartan and diuretics | Tablets Capsules Suspension Injection |
| | | C09DB | Angiotensin II receptor blockers (ARBs) and calcium channel blockers | Valsartan and amlodipine Olmesartan medoxomil and amlodipine Telmisartan and amlodipine Irbesartan and amlodipine Losartan and amlodipine Candesartan and amlodipine Valsartan and lercanidipine Fimasartan and amlodipine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|---|---|--|
| | | C09DX | Angiotensin II receptor blockers (ARBs) other combinations | Valsartan, amlodipine and hydrochlorothiazide Valsartan and aliskiren Olmesartan, medoxomil, amlodipine and hydrochlorothiazide Valsartan and sacubitril Valsartan and nebivolol Candesartan, amlodipine and hydrochlorothiazide Irbesartan, amlodipine and hydrochlorothiazide | Tablets Capsules Suspension Injection |
| 82 | Other agents acting on the renin-angiotensin system | C09XA | Renin-inhibitors | Remikiren Aliskiren Aliskiren and hydrochlorothiazide Aliskiren and amlodipine Aliskiren, amlodipine and hydrochlorothiazide | Tablets Capsules Suspension Injection |
| 83 | Lipid modifying agents plain | C10AA | HMG CoA reductase inhibitors | Simvastatin Lovastatin Pravastatin Fluvastatin Atorvastatin Cerivastatin Rosuvastatin Pitavastatin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | C10AB | Fibrates | Clofibrate Bezafibrate Aluminium clofibrate Gemfibrozil Fenofibrate Simfibrate Ronifibrate Ciprofibrate Etofibrate Clofibrade Choline fenofibrate | Tablets Capsules Suspension Injection |
| | | C10AC | Bile acid sequestrants | Colestyramine Colestipol Colextran Colesevelam | Tablets Capsules Suspension Injection |
| | | C10AD | Nicotinic acid and derivatives | Niceritrol Nicotinic acid Nicoferanose Aluminium nicotinate Nicotinyl alcohol (pyridylcarbinol) Acipimox Nicotinic acid and combinations | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| | | C10AX | Other lipid modifying agents | Dextrothyroxine Probucol Tiadenol Meglutol Omega-3-triglycerides incl. Other esters and acids Magnesium pyridoxal 5-phosphate glutamate Policosanol Ezetimibe Alipogene tiparvovec Mipomersen Lomitapide Evolocumab Alirocumab Bempedoic acid Inclisiran | Tablets Capsules Suspension Injection |
| 84 | Lipid modifying agents combinations | C10BA | Combinations of various lipid modifying agents | Lovastatin and nicotinic acid Simvastatin and ezetimibe Pravastatin and fenofibrate Simvastatin and fenofibrate Atorvastatin and ezetimibe Rosuvastatin and ezetimibe Rosuvastatin and omega-3 fatty acids Atorvastatin and omega-3 fatty acids Rosuvastatin and fenofibrate Bempedoic acid and ezetimibe | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | C10BX | Lipid modifying agents in combination with other drugs | Simvastatin and acetylsalicylic acid Pravastatin and acetylsalicylic acid Atorvastatin and amlodipine Simvastatin, acetylsalicylic acid and ramipril Rosuvastatin and acetylsalicylic acid Atorvastatin, acetylsalicylic acid and ramipril Rosuvastatin, amlodipine and lisinopril Atorvastatin and acetylsalicylic acid Rosuvastatin and amlodipine Rosuvastatin and valsartan Atorvastatin, amlodipine and perindopril Atorvastatin, acetylsalicylic acid and perindopril Rosuvastatin, perindopril and indapamide Rosuvastatin, amlodipine and perindopril Atorvastatin and perindopril Rosuvastatin and fimasartan Rosuvastatin and ramipril Atorvastatin, amlodipine and ramipril | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--------------------------|
| | Dermatologicals | | | | |
| 85 | Antipruritics incl antihistamines, anesthetics etc | D04AB | Anesthetics for topical use | Lidocaine Cinchocaine Oxybuprocaine Benzocaine Quinisocaine Tetracaine pramocaine | lotion, cream, ointment |
| 86 | Antipsoriatics for systemic use | D05BA | Psoralens for systemic use | Trioxysalen Methoxsalen Bergapten | Tablets Capsules s |
| | | D05BB | Retinoids for treatment of psoriasis | Etretinate acitretin | |
| | | D05BX | Other antipsoriatics for systemic use | Fumaric acid derivatives | |
| 87 | Chemotherapeutics for topical use | D06BB | Antivirals | Idoxuridine Tromantadine Podophyllotoxin Inosine Lysozyme Ibacinabine Edoxudine Imiquimod Docosanol Sinecatechins | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|---|
| 88 | Corticosteroids, dermatological preparations | D07AD | Group 4 corticosteroids, very potent | Clobetasol Halcinonide | lotion, cream, ointment |
| | | D07CD | Very potent corticosteroids combinations with antibiotics | Clobetasol with antibiotics | lotion, cream, ointment |
| 89 | Antiacne preparations | D10BA D10BX | Antiacne preparations for systemic use | Isotretinoin Ichtasol | Tablets Capsules |
| 90 | Other dermatological preparations | D11AE | Androgens for topical use | Metandienone | lotion, cream, ointment |
| | | D11AF | Wart and anticorn preparations | Wart and anticorn preparations | lotion, cream, ointment |
| | | D11AH | Agents for dermatitis excl corticosteroids | Tacrolimus Pimecrolimus Cromoglicic acid Alitretinoin | lotion, cream, ointment tablets capsules |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---|
| | | D11AX | Other dermatologicals | Minoxidil Gamolenic acid Calcium gluconate Lithium succinate Magnesium sulfate Mequinol Tiratricol Oxaceprol Finasteride Hydroquinone Pyrithione zinc Diclofenac Brimonidine Ivermectin Collagen combinations | lotion, cream, ointment tablets capsules |
| | Anti-infectives for systemic use | | | | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| 91 | Tetracyclines | J01AA | Tetracyclines | Demeclocycline Doxycycline Chlortetracycline Lymecycline Metacycline Oxytetracycline Tetracycline Minocycline Rolitetracycline Penimepicycline Clomocycline Tigecycline Eravacycline Sarecycline Omadacycline Combinations of tetracyclines Oxytetracycline combinations | Tablets Capsules Suspension Injection |
| 92 | Amphenicols | J01BA | Amphenicols | Chloramphenicol Thiamphenicol Thiamphenicol combinations | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 93 | Beta-lactam antibacterials penicillins | J01CA | Penicillins with extended spectrum | Ampicillin Pivampicillin Carbenicillin Amoxicillin Carindacillin Bacampicillin Epicillin Pivmecillinam Azlocillin Mezlocillin Mecillinam Piperacillin Ticarcillin Metampicillin Talampicillin Sulbenicillin Temocillin Hetacillin Aspoxicillin combinations Ampicillin combinations | Tablets Capsules Suspension Injection |
| | | J01CE | Beta-lactamase sensitive penicillins | Benzylpenicillin Phenoxymethylpenicillin Benzathine benzylpenicillin Procaine benzylpenicillin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|---|--|--|
| | | J01CF | Beta-lactamase resistant penicillins | Dicloxacillin Cloxacillin Meticillin Oxacillin Flucloxacillin Nafcillin | Tablets Capsules Suspension Injection |
| | | J01CG | Beta-lactamase inhibitors | Sulbactam Tazobactam | Tablets Capsules Suspension Injection |
| | | J01CR | Combinations of penicillins incl. beta-lactamase inhibitors | Ampicillin and beta-lactamase inhibitor Amoxicillin and beta-lactamase inhibitor Ticarcillin and beta-lactamase inhibitor Sultamicillin Piperacillin and beta-lactamase inhibitor Combinations of penicillins | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 94 | Other beta-lactam antibacterials | JO1DB | First-generation cephalosporins | Cefalexin Cefaloridine Cefalotin Cefazolin Cefadroxil Cefazedone Cefatrizine Cefapirin Cefradine Cefacetrile Cefroxadine Ceftezole | Tablets Capsules Suspension Injection |
| | | JO1DC | Second-generation cephalosporins | Cefoxitin Cefuroxime Cefamandole Cefaclor Cefotetan Cefonicid Cefotiam Loracarbef Cefmetazole Cefprozil Ceforanide Cefminox Cefbuperazone Flomoxef | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | J01DD | Third-generation cephalosporins | Cefotaxime Ceftazidime Cefsulodin Ceftriaxone Cefmenoxime Latamoxef Ceftizoxime Cefixime Cefodizime Cefetamet Cefpiramide Cefoperazone Cefpodoxime Ceftibuten Cefdinir Cefditoren Cefcapene Cefteram Cefotaxime and beta-lactamase inhibitor Ceftazidime and beta-lactamase inhibitor Ceftriaxone combinations Cefoperazone and beta-lactamase inhibitor Ceftriaxone and beta-lactamase inhibitor Cefpodoxime and beta-lactamase inhibitor | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| | | J01DE | Fourth-generation cephalosporins | Cefepime Cefpirome Cefozopran | Tablets Capsules Suspension Injection |
| | | J01DF | Monobactams | Aztreonam Carumonam | Tablets Capsules Suspension Injection |
| | | J01DH | Carbapenems | Meropenem Ertapenem Doripenem Biapenem Tebipenem pivoxil Imipenem and cilastatin Meropenem and vaborbactam Panipenem and betamipron Imipenem Cilastatin and relebactam | Tablets Capsules Suspension Injection |
| | | J01DI | Other cephalosporins and penems | Ceftobiprole medocaril Ceftaroline fosamil Faropenem Cefiderocol Ceftolozane and beta-lactamase inhibitor | Tablets Capsules Suspension Injection |
| 95 | Sulfonamides and trimethoprim | J01EA | Trimethoprim and derivatives | Trimethoprim Brodinoprim Iclaprim | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|---|---|--|
| | | J01EB | Short-acting sulphonamides | Sulfaisodimidine Sulfamethizole Sulfadimidine Sulfapyridine Sulfafurazole Sulfanilamide Sulfathiazole Sulfathiourea combinations | Tablets Capsules Suspension Injection |
| | | J01EC | Intermediate-acting sulfonamides | Sulfamethoxazole Sulfadiazine Sulfamoxole Combinations | Tablets Capsules Suspension Injection |
| | | J01ED | Long-acting sulfonamides | Sulfadimethoxine Sulfalene Sulfametomidine Sulfametoxydiazine Sulfamethoxyypyridazine Sulfaperin Sulfamerazine Sulfaphenazole Sulfamazone combinations | Tablets Capsules Suspension Injection |
| | | J01EE | Combinations of sulfonamides and trimethoprim incl. derivatives | Sulfamethoxazole and trimethoprim Sulfadiazine and trimethoprim Sulfametrole and trimethoprim Sulfamoxole and trimethoprim Sulfadimidine and trimethoprim Sulfadiazine and tetroxoprim Sulfamerazine and trimethoprim | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|---|--|
| 96 | Macrolides lincosamides and streptogramins | J01FA | Macrolides | Erythromycin Spiramycin Midecamycin Oleandomycin Roxithromycin Josamycin Troleandomycin Clarithromycin Azithromycin Miocamycin Rokitamycin Dirithromycin Flurithromycin Telithromycin Solithromycin | Tablets Capsules Suspension Injection |
| | | J01FF | Lincosamides | Clindamycin Lincomycin | Tablets Capsules Suspension Injection |
| | | J01FG | Streptogramins | Pristinamycin Quinupristin/dalfopristin | Tablets Capsules Suspension Injection |
| 97 | Aminoglycoside antibacterials | J01GA | Streptomycins | Streptomycin Streptoduocin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---|
| | | JO1GB | Other aminoglycosides | Tobramycin Gentamicin Kanamycin Neomycin Amikacin Netilmicin Sisomicin Dibekacin Ribostamycin Isepamicin Arbekacin Bekanamycin Plazomicin | Tablets Capsules Suspension Injection Inhalation powder |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|----|---|-----------------|--|--|--|
| 98 | Quinolone antibacterials | J01MA | Fluoroquinolones | Ofloxacin Ciprofloxacin Pefloxacin Enoxacin Temafoxacin Norfloxacin Lomefloxacin Fleroxacin Sparfloxacin Rufloxacin Grepafloxacin Levofloxacin Trovafoxacin Moxifloxacin Gemifloxacin Gatifloxacin Prulifloxacin Pazufloxacin Garenoxacin Sitafloxacin Tosufloxacin Delafloxacin Levonadifloxacin Lascufloxacin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--|
| | | J01MB | Other quinolones | Rosoxacin Nalidixic acid Piromidic acid Pipemidic acid Oxolinic acid Cinoxacin Flumequine Nemonoxacin | Tablets Capsules Suspension Injection |
| 99 | Combinations of antibacterials | J01RA | Combinations of antibacterials | Penicillins combinations with other antibacterials Sulfonamides combinations with other antibacterials (excl. Trimethoprim) Cefuroxime and metronidazole Spiramycin and metronidazole Levofloxacin and ornidazole Cefepime and amikacin Azithromycin, fluconazole and secnidazole Tetracycline and oleandomycin Ofloxacin and ornidazole Ciprofloxacin and metronidazole Ciprofloxacin and tinidazole Ciprofloxacin and ornidazole Norfloxacin and tinidazole | Tablets Capsules Suspension Injection |
| 100 | Other antibacterials | J01XA | Glycopeptide antibacterials | Vancomycin Teicoplanin Telavancin Dalbavancin Oritavancin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--|
| | | J01XB | Polymyxins | Colistin Polymixin B | Tablets Capsules Suspension Injection |
| | | J01XC | Steroid antibacterials | Fusidic acid | Tablets Capsules Suspension Injection |
| | | J01XD | Imidazole derivatives | Metronidazole Tinidazole Ornidazole | Injection |
| | | J01XE | Nitrofurantoin derivatives | Nitrofurantoin Nifurtoinol Furazidin Nitrofurantoin combinations | Tablets Capsules Suspension Injection |
| | | J01XX | Other antibacterials | Fosfomicin Xibornol Clofoctol Spectinomycin Methenamine Mandelic acid Nitroxoline Linezolid Daptomycin Bacitracin Tedizolid Lefamulin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--|
| 101 | Antimycotics for systemic use | J02AA | Antibiotics | Amphotericin B Hachimycin | Tablets Capsules Suspension Injection |
| | | J02AB | Imidazole derivatives | Miconazole Ketoconazole | Tablets Capsules Suspension Injection |
| | | J02AC | Triazole derivatives | Fluconazole Itraconazole Voriconazole Posaconazole Isavuconazole | Tablets Capsules Suspension Injection |
| | | J02AX | <u>Other antimycotics for systemic use</u> | Flucytosine Caspofungin Micafungin Anidulafungin | Tablets Capsules Suspension Injection |
| 102 | Drugs for treatment of tuberculosis | J04AA | Aminosalicylic acid and derivatives | 4-aminosalicylic acid Sodium aminosalicylate Calcium aminosalicylate | Tablets Capsules Suspension Injection |
| | | J04AB | Antibiotics | Cycloserine Rifampicin Rifamycin Rifabutin Rifapentine Enviomycin Capreomycin | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | J04AC | Hydrazides | Isoniazid Isoniazid combinations | Tablets Capsules Suspension Injection |
| | | J04AD | Thiocarbamide derivatives | Protionamide Tiocarlide Ethionamide | Tablets Capsules Suspension Injection |
| | | J04AK | Other drugs for treatment of tuberculosis | Pyrazinamide Ethambutol Terizidone Morinamide Bedaquiline Delamanid Thioacetazone Pretomanid | Tablets Capsules Suspension Injection |
| | | J04AM | Combinations of drugs for treatment of tuberculosis | Streptomycin and isoniazid Rifampicin and isoniazid Ethambutol and isoniazid Thioacetazone and isoniazid Rifampicin, pyrazinamide and isoniazid Rifampicin, pyrazinamide ethambutol and isoniazid Rifampicin ,ethambutol and isoniazid Isoniazid, sulfamethoxazole trimethoprim and pyridoxine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--|
| 103 | Drugs for treatment of lepra | J04BA | Drugs for treatment of lepra | Clofazimine Dapsone Aldesulfone sodium | Tablets Capsules Suspension Injection |
| 104 | Direct acting antivirals | J05AA | Thiosemicarbazones | Metisazone | Tablets Capsules Suspension Injection |
| | | J05AB | Nucleosides and nucleotides excl. reverse transcriptase inhibitors | Aciclovir Idoxuridine Vidarabine Ganciclovir Famciclovir Valaciclovir Cidofovir Penciclovir Valganciclovir Brivudine | Tablets Capsules Suspension Injection |
| | | J05AC | Cyclic amines | Rimantadine Tromantadine | Tablets Capsules Suspension Injection |
| | | J05AD | Phosphonic acid derivatives | Foscarnet Fosfonet | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | J05AE | Protease inhibitors | Saquinavir Indinavir Ritonavir Nelfinavir Amprenavir Fosamprenavir Atazanavir Tipranavir Darunavir | Tablets Capsules Suspension Injection |
| | | J05AF | Nucleoside and nucleotide reverse transcriptase inhibitors | Zidovudine Didanosine Zalcitabine Stavudine Lamivudine Abacavir Tenofovir disoproxil Adefovir dipivoxil Emtricitabine Entecavir Telbivudine Clevudine Tenofovir alafenamide | Tablets Capsules Suspension Injection |
| | | J05AG | Non-nucleoside reverse transcriptase inhibitors | Nevirapine Delavirdine Efavirenz Etravirine Rilpivirine Doravirine | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | J05AH | Neuraminidase inhibitors | Zanamivir Oseltamivir Peramivir Laninamivir | Tablets Capsules Suspension Injection |
| | | J05AI | Integrase inhibitors | Raltegravir Elvitegravir Dolutegravir Cabotegravir | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | | Antivirals for treatment of HCV infections | Ribavirin Telaprevir Boceprevir Faldaprevir Simeprevir Asunaprevir Daclatasvir Sofosbuvir Dasabuvir Elbasvir Grazoprevir Sofosbuvir and ledipasvir Dasabuvir Ombitasvir Paritaprevir and ritonavir Ombitasvir, paritaprevir and ritonavir Elbasvir and grazoprevir Sofosbuvir and velpatasvir Sofosbuvir, velpatasvir and voxilaprevir Glecaprevir and pibrentasvir Daclatasvir, asunaprevir and beclabuvir | Tablets Capsules Suspension Injection |

| | | | | | |
|--|--|-------|---|--|---|
| | | J05AR | Antivirals for treatment of HIV infections combinations | <p>Zidovudine and lamivudine Lamivudine and abacavir Tenofovir disoproxil and emtricitabine Zidovudine, lamivudine and abacavir Zidovudine, lamivudine and nevirapine Emtricitabine, tenofovir disoproxil and efavirenz Stavudine, lamivudine and nevirapine Emtricitabine, tenofovir disoproxil and rilpivirine Emtricitabine, tenofovir disoproxil elvitegravir and cobicistat Lopinavir and ritonavir Lamivudine, tenofovir disoproxil and efavirenz Lamivudine and tenofovir disoproxil Lamivudine, abacavir and dolutegravir Darunavir and cobicistat Atazanavir and cobicistat Lamivudine and raltegravir Emtricitabine and tenofovir alafenamide Emtricitabine, tenofovir alafenamide elvitegravir and cobicistat Emtricitabine, tenofovir alafenamide and rilpivirine Emtricitabine, tenofovir alafenamide and bictegravir Dolutegravir and rilpivirine Emtricitabine, tenofovir alafenamide darunavir and cobicistat Atazanavir and ritonavir Lamivudine</p> | <p>Tablets Capsules Suspension Injection</p> |
|--|--|-------|---|--|---|

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--|
| | | | | tenofovir disoproxil and doravirine Lamivudine and dolutegravir Darunavir and ritonavir Lamivudine tenofovir disoproxil and dolutegravir | |
| | | J05AX | Other antivirals | Moroxydine Lysozyme Inosine pranobex Pleconaril Enfuvirtide Maraviroc Maribavir Umifenovir Enisamium iodide Letermovir Tilorone Pentanedioic acid imidazolyl Ethanamide Ibalizumab Tecovirimat Baloxavir marboxil Amenamevir Favipiravir Bulevirtide Fostemsavir | Tablets Capsules Suspension Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---------------------|
| 105 | Immune sera | J06AA | Immune sera | Diphtheria antitoxin Tetanus antitoxin Snake venom antiserum Botulinum antitoxin Gas-gangrene sera Rabies serum | Injection |
| 106 | Immunoglobulins | J06BA | Immunoglobulins normal human | Immunoglobulins normal human for extravascular adm. Immunoglobulins normal human for intravascular adm. | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---------------------|
| | | J06BB | Specific immunoglobulins | Anti-D (rh) immunoglobulin Tetanus immunoglobulin Varicella/zoster immunoglobulin Hepatitis B immunoglobulin Rabies immunoglobulin Rubella immunoglobulin Vaccinia immunoglobulin Staphylococcus immunoglobulin Cytomegalovirus immunoglobulin Diphtheria immunoglobulin Hepatitis A immunoglobulin Encephalitis tick borne immunoglobulin Pertussis immunoglobulin Measles immunoglobulin Mumps immunoglobulin Palivizumab Motavizumab Raxibacumab Anthrax immunoglobulin Bezlotoxumab Obiltoxaximab combinations | Injection |
| | | J06BC | Other immunoglobulins | Nebacumab | Injection |
| 107 | Bacterial vaccines | J07AC | Anthrax vaccines | Anthrax antigen | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | J07AD | Brucellosis vaccines | Brucella antigen | Injection |
| | | J07AE | Cholera vaccines | Cholera inactivated whole cell Cholera live attenuated Cholera combinations with typhoid vaccine inactivated whole cell | Injection |
| | | J07AF | Diphtheria vaccines | Diphtheria toxoid | Injection |
| | | J07AG | Haemophilus influenzae B vaccines | Haemophilus influenzae B purified antigen conjugated Haemophilus influenzae B combinations with toxoids Haemophilus influenzae B combinations with pertussis and toxoids Haemophilus influenzae B combinations with meningococcus C conjugated | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | J07AK | Plague vaccines | Plague inactivated whole cell | Injection |
| | | J07AL | Pneumococcal vaccines | Pneumococcus purified polysaccharides antigen Pneumococcus purified polysaccharides antigen conjugated Pneumococcus purified polysaccharides antigen and haemophilus influenza conjugated | Injection |
| | | J07AM | Tetanus vaccines | Tetanus toxoid Tetanus toxoid combinations with diphtheria toxoid Tetanus toxoid combinations with tetanus immunoglobulin | Injection |
| | | J07AN | Tuberculosis vaccines | Tuberculosis live attenuated | Injection |
| | | J07AP | Typhoid vaccines | Typhoid oral live attenuated Typhoid inactivated whole cell Typhoidm purified polysaccharide antigen Typhoid combinations with paratyphi types | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---------------------|
| | | J07AR | Typhus (exanthematicus) vaccines | Typhus exanthematicus inactivated whole cell | Injection |
| | | J07B | Viral vaccines | Encephalitis vaccines Influenza vaccines Hepatitis vaccines Measles vaccines Mumps vaccines Poliomyelitis vaccines Rabies vaccines Rotavirus diarrhea vaccines Rubella vaccines Varicella zoster vaccines Yellow fever vaccines Papillomavirus vaccines Small pox vaccines | Injection |
| | | J07C | Bacterial and viral vaccines | Bacterial and viral vaccines combined | Injection |
| | Genito urinary antiinfectives and antiseptics | | | | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---------------------|
| 108 | Antinfectives and antiseptic excl combinations with corticosteroids | G01AA | Antibiotics | Nystatin Natamycin Amphotericin b Candicidin Chloramphenicol Hachimycin Oxytetracyclin Carfecilin Mepartricin Clindamycin Pentamycin Nystatin combinations | Pessaries |
| | | G01AB | Arsenic compounds | Acetarsol | |
| | | G01AC | Quinolone derivatives | Diiodohydroxyquinolone Clioquinol Chlorquinaldol Dequalinium Broxyquinoline Oxyquinoline | |
| | | G01AD | Organic acids | Lactic acid Acetic acid Ascorbic acid | |
| | | G01AE | Sulfonamides | Sulfatolamide combinations | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---------------------|
| | | G01AF | Imidazole derivatives | Metronidazole Clotrimazole Miconazole Econazole Ornidazole Isoconazole Tioconazole Ketoxconazole Fenticonazole Azanidazole Propenidazole Butoconazole Omoconazole Oxiconazole Flutrimazole Sertaconazole combinations | |
| | | G01AG | Triazole derivatives | Terconazole | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|--|---|--|--|---|
| | | G01AX | Others | Clodantoin Inosine Policresulen Nifuratel Furazolidone Methylrosaniline Povidone iodine Ciclopirox Protiofate lactobacillus fermentum Copper sunate Hexetidine Octenidine combinations | |
| 109 | Antiinfectives/anti septics in combination with steroids | G01BA G01BC G01BD G01BE G01BF | Combinations with steroids | Antibiotics & corticosteroids Quinolone derivatives & corticosteroids Antiseptics & corticosteroids Sulfonamides & corticosteroids Imidazole derivatives and corticosteroidssteroids | Pessaries |
| 110 | Uterotonics | G02AB | Ergot alkaloids | Methylergometrine Ergot alkaloids Ergometrine | Tablets capsules injection pessaries intrauterine |
| | | G02AC | Ergot alkaloids & oxytocin cominations | Methylergometrine and ocytocin | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| | | G02AD | prostaglandins | Dinoprost Dinoprostone Gemeprost Carboprost Sulprotone Misoprostol | |
| | | G02AX | Other uterotonics | | |
| 111 | Contraceptives for topical use | G02BA | Intrauterine contraceptives | Plastic IUD Plastic IUD with copper Plastic IUD with progestogen | |
| | | G02BB | Intravaginal contraceptives | Vaginal ring with progestogen and estrogen | |
| 112 | Other gynecologicals | G02CA | Sympathomimetics labor suppressants | Ritodrine Buphenine Fenoterol | Tablets capsules injection pessaries |
| | | G02CB | Prolactine inhibitors | Bromocriptine lisuride Cabergoline Quinagolide Metrergoline Terguride | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|--|-----------------|--|---|--|
| | | G02CC | Antinflammatories for vaginal administration | Ibuprofen Naproxen Benzydamine Flunaxaprofen | |
| | | G02CX | Others | Atosiban Flibanserin Agnicastifruetus Cimicifugae rhizoma | |
| 113 | Sex hormones and modulators of genital system hormonal contraceptives for systemic use | G03AA | Progestogens & estrogens fixed combinations | Etynodiol & ethinylestradiol quinagestanol & ethinylestradiol lynestrol & ethinylestradiol Megestrol & ethinylestradiol Norethisterone Norgestrel levonogestrel Medovyprogesterone with ethinylestradiol etc | Injection Tablets Implant Patch Vaginal ring Rectal forms |
| | | G03AB | Progestogens & estrogens sequential preparations | Megestrol lynestrol levonogestrel Norethisterone Desogestrel Gestoden Chlormadinone dienogest(all with ethinylestradiol) | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | G03AC | progestogens | Norethisterone lynestrenol levonogestrel Quingestanol Megestrol Medroxyprogesterone Norgestrienone Etonogestrel Desogestrel Drospirenone | |
| | | G03AD | Emergency contraceptives | Ulipristal | |
| | | G03BA | 3-oxoandrogen derivatives | Fluoxymesterone Methyltestosterone Testosterone | |
| | | G03BB | 5-androstanone derivatives | Mesterolone Androstanolone | |
| | | G03CA | Natural & semisynthetic estrogens plain | Ethinylestradiol Estradiol Estriol Chlorotrianisene Estrone Promestriene Conjugated estrogens Estradiol combinations | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | G03CB | Synthetic estrogens plain | Dienostrol Diethylstilbestrol Methallenstril Moxestrol | |
| | | G03CC | Estrogen combinations with other drugs | Dienestrol Methallenenstril Estrone Diethylstilbestrol Estriol Conjugated estrogens & bazedoxifene | |
| | | G03CX | Other estrogens | Tibolone | |
| | | G03DA | Pregnen derivatives | Gestonorone Medroxyprogesterone Progesterone | |
| | | G03DB | Pregnadien derivatives | Dydrogesterone Megestrol Medrogestone Nomegestrol Demegestone Chlormadinone Promegestone Dienogest | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---------------------|
| | | G03DC | Etren derivatives | Allylestrenol Norethisterone lynestrenol Ethisterone Etyndiol Methylestrenolone | |
| | | G03EA | Androgens and estrogens | Methytestosterone & estrogen Testosterone & estrogen Prasterone & estrogen | |
| | | G03EB G03EK | Androgens progestogen & estrogen in combination also with other drugs | Androgens Progestogen & estrogen in combination also with other drugs | |
| | | G03FA | Progestogens & estrogens fixed preparations | Norethisterone Hydroxyprogesterone Ethisterone Progesterone Methylnortesterone Etyndiol lynestrenol Megestrol Noretynodrel levonogestrel Medocyprogesterone Norgestimate Dydrogesterone Dienogest Trimegestone drospirenone (all with estrogen) | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---------------------|
| | | G03FB | Progestogens & estrogens sequential preparations | Norgestrel lynestrenol Chlormadinone Megestrol Norethisterone Medoxyprogesterone Medrogestone Dydrogesterone levonogestrel Desogestrel Trimegestone Nomegestrol (all with estrogen) | |
| | | G03GA | Gonadotrophins | Chorionic gonadotrophin Human menopausal gonadotrophin Serum Gonadotrophinurofollitropin Follitropin alfa Follitropin beta lutropin alfa Choriogonadotrophin alfa Corifollitropin alfa combinations | |
| | | G03GB | Ovulation stiumulants synthetic | Cyclofenil Clomifene Epimestrol | |
| | | G03HA G03HB | Antiandrogens | Cyproterone Cyproterone & estrogen. | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--|
| | | G03XA | Antiandrogens others | Danazol Getrinone | |
| | | G03XB | Progesterone receptor modulators | Mifepristone Ulipristal Mifepristone combinations | |
| | | G03XC | Selective estrogen receptor modulators | Raloxifene Bazedoxifene lasofoxifene Ormeloxifene Ospemifene | |
| 114 | Urologicals | G04BD | Drugs for incontinence | Emepronium Flavoxate Meladrazine Oxybutynin Terodiline Propiverine toterodine Solifenacin Trospium Darifenacin Fesoterodine Mirabegron | Tablet Capsules Transdermal Urethral Powder Jelly |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | G04BE | Drugs used in erectile dysfunction | Alprostadil Papaverine Sildenafil Yohimbine Moxisylyte Apomorphine Tadalafil Vardenafil Avanafil Udenafil combinations | |
| | | G04BX | Other urologicals | Magnesium hydroxide Acetohydroxamic acid Phenazopyridine Succinimide Collagen Phenylsalicylate Dimethylsulfoxide Dapoxetine Pentosan polysulfate sodium | |
| | | G04CA | Alpha adrenocepto antagonists | Alfuzosin Tamsulosin Terazosin Silodosin Alfuzosin & finasteride Tamsulosin & dutasteride Tamsulocin & solifenacin | |
| | | G04CB | Testosterone 5 alfa reductase inhibitors | Finasteride Dutasteride | |
| | | G04CX | Others | Prunus africanae cortex Sabalis serrulatae fructus Mepartricin | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|--|-----------------|--|--|---|
| | Systemic hormonal preparations excl sex hormones and insulins | | | | |
| 115 | Anterior pituitary lobe hormones and analogues | H01AA | ACTH | Corticotropin Tetracosactide | Tablet Capsule Injection Nasal |
| | | H01AB | Thyrotropin | Thyrotropin alfa | |
| | | H01AC | Somatotropin and agonists | Somatropin Somatrem Mecasermin Sermorelin Mercasermin rinfabate Tesamorelin | |
| | | H01AX | Others | Pegvisomant | |
| 116 | Posterior pituitary hormones | H01BA | Vasopressin and analogues | Vasopressin Desmopressin lypressin Terlipressin Ornipressin Argipressin | Tablets Capsules Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|---------------------|
| | | H01BB | Oxytocin and analogues | Demoxytocin Oxytocin Carbetocin | |
| 117 | Hypothalamic hormones | H01CA | Gonadotropin releasing hormone | Gonadorelin Nafarelin | Injection Nasal |
| | | H01CB | Somatostatin and analogues | Somatostatin Octreotide lanreotide Vapreotide Pasireotide | |
| | | H01CC | Antigonadotropin releasing hormone | Ganirelix Cetrorelix | |
| | | | | | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 118 | Corticosteroids for systemic use | H02AB | Glucocorticoids | Betamethasone Dexamethasone Fluocortolone Methylprednisolone Paramethasone Prednisolne Prednisone Triamcinolone Hydrocortisone Cortisone Prtednylidene Rimexolone Deflazacort Cloprednol Meprodnisolone Cortivazol | Tablet Capsule Injection |
| | | H02CA | Anticorticosteroids | Trilostane | Tablet Capsule |
| | | H02AA | Mineralocorticoids | Aldosterone Fludrocortisone Desoxycortone. | Tablet Capsule Injection |
| | | H02BX | Corticosteroids combinations | Methylprednisolone combinations | Tablet Capsule Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|----------------------------------|
| 119 | Thyroid preparations | H03AA | Thyroid hormones | Levothyroxine sodium liothyronine sodium combinations Tiratricol Thyroid gland preparations | Tablets capsules Injection |
| | | H03BA | Antithyroid thiouracils | Methylthiouracil Propylthiouracil Benzylthiouracil | Tablets capsules |
| | | H03BB | Sulfur containing imidazole derivatives | Carbimazole Thiamazole Thiamazole combinations | Tablets capsules |
| | | H03BC | Antithyroids perchlorates | Potassium perchlorate | Tablets capsules |
| | | H03BX | Other antithyroids | Diodotyrosine Dibromotyrosine | Tablets capsules |
| | | H03CA | Iodine therapy | Iodine therapy | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-------------------------------|---|-----------------|--|---|--|
| 110 | Pancreatic hormones | H04AA | Glycogenolytic hormones | Glucagon | Injection |
| 111 | Calcium homeostasis | H05AA | Parathyroid hormones and analogues | Parathyroid gland extract Teriparatide Parathyroid hormone | Injection Nasal preparations Tablets Capsules |
| | | H05BA | Calcitonin preparations | Calcitonin(salmon synthetic) (pork natural) (human synthetic) Elcatonin. | |
| | | H05BX | Other antiparathyroid agents | Cinacalcet Paricalcitol Doxecalciferol | |
| Musculoskeletal system | | | | | |
| 112 | Antinflammatory and rheumatic products nonsteroids | M01AA | Butylpyrazolidines | Phenylbutazone Mofebutazone Oxyphenabutazone Clofezone Kebuzone | Injection Tablets Capsules Suppositories |
| | | M01AB | Acetic acid derivatives | Indomethacin injection Sulindac injection Tolmetin Diclofenac injection Ketorolac injection | Injection Tablets Capsules Suppositories |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---|
| | | M01AH | Coxibs | Parecoxib injection Rofecoxib Valdecoxib Lumiracoxib | Injection Tablets Capsules |
| | | M01AX | Others | Nabumetone Niflumic acid Azaprazone Benzydamine Glucosaminoglycan polysulfate injection Proquazone Orgotein Nimesulide Feprazone Diacerein Morniflumate Tenidap Oxaceprol Feprazone combinations | Injection Tablets Capsules Suppositories |
| | | M01AC | Oxicams | Piroxicam Tenoxicam Droxicam Lornoxicam Meloxicam | Injection Tablets Capsules Suppositories |
| | | M01AE | Propionic acid derivatives | Rectal ibuprofen Naproxen Ketoprofen Dexketoprofen | Injection Suppositories |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| | | M01AG | Fenamates | Tolfenac Acid Meclofenamic Acid, Flufenamic Acid | Injection Tablets Capsules Suppositories |
| | | M01BA M01BX | Antiinflammatory agents in combination | Phenylbutazone and corticosteroids Dipyrrocetyl and corticosteroids Acetylsalicylic acid and corticosteroids | Injection Tablets Capsules Suppositories |
| | | M01CA | Quinolones | Oxycinchophen | Tablets Capsules |
| | | M01CB | Gold preparations | Sodium aurothiomalate Sodium aurothiosulfate Auranofin Aurothioglucose Aurotioprol | Injection Tablets Capsules |
| | | M01CC | Penicillamine and similar agents | Penicillamine Bucillamine | Tablets Capsules |
| | | M02AX M02AC | Others Preparations with salicylic acid derivatives | Tolazoline Dimethyl sulfoxide Idrocilamide Tolperisone | Cream, Ointments, Gel |
| 113 | Muscle relaxants | M03AA | Curare alkaloids | Alcuronium Tubocurarine Dimethyltubocurarine | Injection |
| | | M03AB | Choline derivatives | Suxamethonium | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|----------------------------------|
| | | M03AC | Other quaternary ammonium compounds | Pancuronium Gallamine Vecuronium Atracurium Hexafluronium Pipcuronium bromide Doxacurium chloride Fazadinium bromide Rocuronium bromide Mivacurium chloride Cisatracurium | Injection |
| | | M03AX | Others | Botulinium toxin | Injection |
| | | M03BA | Carbamic acid esters | Phenbromate Carisoprodol Methocarbamol Styramate Febarbamate combinations | Injection Tablets Capsules |
| | | M03BB | Oxazol, thiazine and triazine derivatives | Chlormezanone with psycholeptics Chlorzoxazone with psycholeptics | Tablets Capsules |
| | | M03BC | Esthers close to antihistamines | Orphenadrine citrate Orphenadrine combinations | Injection Tablets Capsules |
| | | M03BX | Others centrally acting | Baclofen Pridinol Tolperisone Mephenesin Tizanidine Tetrazepam Cyclobenzaprine Eperisone Fenyramidol | Injection Tablets Capsules |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|----------------------------------|
| | | M03CA | Dantrolene and derivatives | Dantrolene | Tablets Capsules |
| 114 | Antigout preparations | M04AA | Preparations inhibiting uric acid production | Allopurinol Tisopurine Febuxostat Allopurinol | Injection Tablets Capsules |
| | | M04AB | Preparations increasing uric acid excretion | Probenecid Sulfinpyrazone Benzbromarone Isobromindione Lesinurad | Tablets Capsules |
| | | M04AC | Preparations with no effect on uric acid metabolism | Colchicine Cinchophen | Injection Tablets Capsules |
| | | M04AX | Other antigout preparations | Urate oxidase Pegloticase | Injection Tablets Capsules |
| 115 | Drugs for treatment of bone diseases | M05BA | Bisphosphonates | Etidronic acid Clodronic acid Pamidronic acid Alendronic acid Tiludronic acid Ibandronic acid Risedronic acid Zoledronic acid | Injection Tablets Capsules |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|----------------------------------|
| | | M05BB | Bisphosphonates, combinations | Etidronic acid and calcium, sequential Risedronic acid and calcium, sequential Alendronic acid and colecalciferol Risedronic acid, calcium and colecalciferol, sequential Alendronic acid, calcium and colecalciferol, sequential Risedronic acid and colecalciferol Zoledronic acid, calcium and colecalciferol, sequential | Injection Tablets Capsules |
| | | M05BC | Bone morphogenetic proteins | Dibotermin alfa Eptotermin alfa | Injection Tablets Capsules |
| | | M05BX | Others | Ipriflavone Aluminium chlorohydrate Strontium renelate Denosumab Strontium renelate and colecalciferol | Injection Tablets Capsules |
| 116 | Other drugs for the disorders of the musculoskeletal system | M09AA | Quinine and derivatives | Hydroquinone Quinine combinations with psycholeptics | |
| | | M09AB | Enzymes | Chymopapain Colleganase clostridiumhistolyticum Bromelains Trypsin combinations | |
| | | M09AX | Others | Hyaluronic acid Chondrocytes, autologous Ataluren Drisapersen | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--|
| | Antineoplastic and immunomodulating agents | | | | |
| 117 | Alkylating agents | L01AA | Nitrogen mustard analogs | Meclorethamine Cyclophosphamide Ifosfamide Chlorambucil Melphalan Mafosfamide | Tablet Capsule Injection |
| | | L01AB | Alkyl sulfonates | Busulfan Treosulfan | Tablet Capsule Injection |
| | | L01AC | Ethylene imines | Thiotepa Triaziquone Carboquone | Tablet Capsule Injection Tablet Capsule Injection |
| | | L01AD | Nitrosoureas | Bendamustine Hydrochloride Carmustine Uramustine Semustine Streptozocin Ranimustine Nimustine Fotemustine Fotemustineestramuhstine Phosphate Lomustine | Tablet Capsule Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | L01AG | Epoxides | Etoglucid | Tablet Capsule Injection |
| | | L01AX | Other Alkylating agents | Mitobronitol Pipobroman Temozolomide Dacarbazine | Tablet Capsule Injection |
| 118 | Antimetabolites | L01BA | Folic acid analogs | Methotrexate Ralitrexed Pametrexed Praltrexate | Tablet Capsule Injection |
| | | L01BC | Pyrimidine analogs | Cytarabine Fluorouracil Tegafur Carmofur Gemcitabine Capecitabine Azacitidine Decitabine | Tablet Capsule Injection |
| | | L01BB | Purine analogs | G Mercaptopurine Tioguanine Cladribine Fludarabine Clofarabine Nelarabine | Tablet Capsule Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 119 | Plant alkaloids and other natural products | L01CA | Vinca alkaloids | Vincristine Vinblastine Vinorelbine Vindesine Vinflunine Vintafolide | Tablet Capsule Injection |
| | | L01CD | Taxanes | Paclitaxel Docetaxel Cabazitaxel | Tablet Capsule Injection |
| | | L01CB | Podophyllotoxin derivatives | Etoposide Teniposide | Tablet Capsule Injection |
| | | L01CX | Other plant alkaloids and natural products | Trabectedin | Tablet Capsule Injection |
| | | L01CC | Colchicine derivatives | Demecolcine | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| 120 | Cytotoxic antibiotics and related substances | L01DB | Anthracyclines and related substances | Doxorubicin Daunorubicin Epirubicin Aclarubicin Zorubicin Idarubicin Mitoxantrone Pirarubicin Valrubicin Amrubicin Pixantrone. | Tablet Capsule Injection |
| | | L01DA | Actinomycins | Dactinomycin | Tablet Capsule Injection |
| | | L01DC | other cytotoxic antibiotics | Bleomycin Plicamycin Mitomycin Ixabepilone | Tablet Capsule Injection |
| 121 | Other antineoplastic agents | L01XA | Platinum compounds | Cisplatin Carboplatin Oxaliplatin Satraplatin Polyplattillen | Tablet Capsule Injection |
| | | L01XB | Methylhydrazines | Procarbazine | Tablet Capsule Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--------------------------------|
| | | L01XC | Monoclonol antibodies | Edrocolomab Rituximab Trastuzumab Gemtuzumab Cetuximab Bevacizumab Panitumumab Catumaxomab Ofatumumab Ipilimumab Brentuximab Pertuzumab | Tablet Capsule Injection |
| | | L01XD | Sensitizers used in photodynamic/radiation therapy | Porfimer Sodium Methylaminolevulinate Aminolevulinate Temorporfin Efaproxiral | Tablet Capsule Injection |
| | | L01XE | Protein kinase inhibitors | Imatinib Gefitinib Erlotinib Sunitinib Sorafenib Dasatinib Lapatinib Nilotinib | Tablet Capsule Injection |

| | | | | | |
|--|--|-------|-----------------------------|---|--------------------------------|
| | | L01XX | Other antineoplastic agents | Amsacrine Asparaginase Altretamine Hydroxycarbamide Lonidamine Pentostatin Miltefosine Masoprocol Etramustine Tretinoin Mitoguazone Topotecan Tiazofurine Irinotecan Alitretinoin Mitotane Pegasparase Bexarotene Arsenic Trioxide Denileukin Bortezomib Celecoxib Anagrelide Oblimerse Vorinostat Romidepsin Omacetaxine Eribulin Panobinostat Vismodegib Aflibercept Carfilizomab Olaparib Idelalisib Sonidegib Belinostat Ixazomib | Tablet Capsule Injection |
|--|--|-------|-----------------------------|---|--------------------------------|

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--|
| 122 | Hormones and related agents | L02AA | Estrogens | Diethylstilbestrol Polyestradiol Phosphate Ethinylestradiol Fosfestrol | Tablet Capsule Injection Implant Patch |
| | | L02AB | Progestogens | Megestrol Medoxyprogesterone Gestonorone | |
| | | L02AE | Gonadotrophin releasing hormone analogues | Buserelin Leuprolin Goserelin Triptorelin Histrelin | |
| | | L02BA | Antioestrogens | Tamoxifen Toremifene Fulvestrant | |
| | | L02BB | Antiandrogens | Flutamide Nilutamide Bicalutamide Enzalutamide | |
| | | L02BG | Aromatase inhibitors | Aminoglutethimide Formestane Anastrozole Letrozole Vorozole Exemestane | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | L02BX | Other hormone antagonists | Abarelix Degarelix Abiraterone | |
| | | L03AA | Colony stimulating factors | Filgrastim Molgramostim Sargramostim Lenograstim Ancestim Pefilgrastim Lipegfilgrastim Balugrastim | |
| | | L03AB | Interferons | Interferons Alfa Natural Beta Natural Gamma Alfa-2a, 2b, N1 Beta 1a, 1b Alfacon 1 Etc | |
| | | L03AC | Interleukins | Aldesleukin Oprelvekin | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | L03AX | Other immunostimulants | Lentinan Roquinimex BCG Vaccine Pegademase Pidotimod Poly I:C Poly ICLC Thymopentin Immunocyanin Tasonermin Melanoma Vaccine Gelatremaer Acetate Histamine Dihydrochloride Mifamurtide Plexixafor Sipuleucel-T Cridanimod Dasiprotimut-T | |
| | | L04AA | Selective immunosuppressants | Leflunomide Sirolimus Alefacept Everolimus Efalizumab Gusperimus Belimumab Mycophenolic acid | |
| | | L04AB | TNF-Alpha inhibitors | Etanercept Infliximab Afelimomab Adalimumab Golimumab Certolizumab | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---------------------|
| | | L04AC | Interleukin inhibitors | Daclizumab Basiliximab Anakinra Rilonacept Ustekinumab Mepolizumab Tocilizumab | |
| | | L04AD | Calcineurin inhibitors | Ciclosporin Tacrolimus Voclosporin | |
| | | L04AX | Other immuno-suppressants | Azathioprine Thalidomide Methotrexate Lenalidomide Pirfenidone Pomalidomide | |
| 123 | General Anesthetics | N01AA | Ethers | Diethyl Ether Vinyl Ether | |
| | | N01AB | Halogenated hydrocarbons | Halothane Chloroform Enflurane Trichloroethylene Isoflurane Desflurane Sevoflurane | Inhalation gas |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | N01AF | Barbiturates | Methohexital Hexobarbital Thiopental | Injection |
| | | N01AG | Barbiturates in combination with other drugs | Narcobarbital | Injection |
| | | N01AH | Opioid anesthetics | Fentanyl Alfentanil Sufentanil Phenoperidine Anileridine Remifentanil Fentanyl combinations | Injection |
| | | N01AX | Other general anesthetics | Ketamine Propanidid Alfaxalone Etomidate Propofol Sodium Oxybate Nitrous Oxide Esketamine Xenon Nitrous Oxide Combinations | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--|
| 124 | Local anaesthetics | N01BA | Esters of aminobenzoic acid | Metabutethamine Procaine Tetracaine Chloroprocaine Benzocaine Procaine combinations Tetracaine combinations | Injection Solution Cream Ointment |
| | | N01BB | Amides | Bupivacaine Lidocaine Mepivacaine Prilocaine Butanilicaine Cinchocaine Etidocaine Articaine Ropivacaine Levobupivacaine combinations Bupivacaine combinations Lidocaine combinations Mepivacaine combinations Prilocaine combinations Etidocaine combinations Articaine combinations Bupivacaine and meloxicam | Injection Solution Cream Ointment |
| | | N01BC N01BX | Other local anaesthetics | Ethyl Chloride Dyclonine Phenol Capsaicin Cocaine | Injection Solution Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-------|---|---------------------------------|--|--|--------------------------------|
| 125 | Opioid analgesics | N02AA | Natural opium alkaloids | Morphine Opium Hydromorphone Nicomorphine Oxycodone Dihydrocodeine Papaveretum Oxymophone Morphine Combinations Hydromorphone And Naloxone Oxycodone And Naltrexone Dihydrocodeine combinations Codeine combinations | Injection Tablet Capsule |
| N02AB | | Phenylpiperidine derivatives | Fentanyl Ketomidone Pethidine Pethidine combinations | Injection Tablet Capsule | |
| N02AC | | Diphenylpropylamine derivatives | Dextromoramide Piritramide Dextropropoxyphene Bezitramide Methadone Methadone combinations Dextropropoxyphene combinations | Injection Tablet Capsule | |
| N02AD | | Benzomorphan derivatives | Pentazocine Phenazocine | Injection Tablet Capsule | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N02AE | Oripavine derivatives | Buprenorphine | Injection Tablet Capsule |
| | | N02AF | Morphinan derivatives | Butorphanol Nalbuphine | Injection Tablet Capsule |
| | | N02AG | Opioids in combination with antispasmodics | Combinations of antispasmodics with morphine Pethidine Ketobemidone Hydromorphone | Injection Tablet Capsule |
| | | N02AE | Opioids in combination with non-opioid analgesics | Dihydrocodeine and paracetamol Dihydrocodeine and acetylsalicylic acid Codeine and paracetamol Codeine and acetylsalicylic acid Codeine and Ibuprofen Tramadol and paracetamol Oxycodone and paracetamol Oxycodone and Ibuprofen | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| | | N02AX | Other opioids | Tilidine Tramadol Dezocine Meptazinol Tapentadol | Injection Tablet Capsule |
| 126 | Other Analgesics and antipyretics | N02BG | Other analgesics and antipyretics | Rimazolium Glafenine Floctafenine Viminol Nefopam Flupirtine Ziconotide Methoxyflurane Cannabinoids Mirogabalin | Injection Tablet Capsule |
| | | N02BA | Salicylic Acid Derivatives | Acetylsalicylic Acid Aloxipirin Salsalate Morpholine Salicylate Diflunisal Guacetisal Dipyrrocetyl Etc | Injection Tablet Capsule |
| | | N02BB | pyrazolones | Phenazone Metamizole Sodium Aminophenazone Propylphenazone combinations. | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | N02BE | Anilides | Paracetamol Phenacetin Bucetin Propacetamol | Injection |
| 127 | Antimigraine preparations | N02CA | Ergot alkaloids | Dihydroergotamine Ergotamine Methylsergide Lisuride combinations | Injection Tablet Capsule |
| | | N02CB | Corticosteroid derivatives | Flumedroxone | Injection Tablet Capsule |
| | | N02CC | Selective serotonin (5HT ₁) agonists | Sumatriptan Naratriptan Zolmitriptan Rizatripta Almotriptan Eletriptan Flovatriptan | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | N02CD | Calcitonin gene related peptide | Erenumab Galcanezumab Fremanezumab | Injection Tablet Capsule |
| | | N02CX | Other antimigraine preparations | Clonidine Pizotifen Iprazochrome Dimetotiazine Oxetorone | Injection Tablet Capsule |
| 128 | Antiepileptics | N03AA | Barbiturates and derivatives | Methylphenobarbital Phenobarbital Primidone Barbexaclone Metharbital | Injection Tablet Capsule |
| | | N03AB | Hydantoin derivatives | Ethotoin Amino(Diphenylhydantoin) Valeric Acid Mephenytoin Fosphenytoin Phenytoin combinations of Phenytoin | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N03AC | Oxazolidone derivatives | Paramethadione Trimethadione Ethadione | Injection Tablet Capsule |
| | | N03AD | Succinimide derivatives | Ethosuximide Phensuximide Mesuximide Ethosuximide Combinations | Injection Tablet Capsule |
| | | N03AE | Benzodiazepine derivatives | Clonazepam | Injection Tablet Capsule |
| | | N03AF | Carboxamide derivatives | Carbamazepine Oxcarbazepine Rufinamide Eslicarbazepine | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N03AG | Fatty acid derivatives | Valproic Acid Valpromide Aminobutyric Acid Vigabatrin Progabide Tiagabine | Injection Tablet Capsule |
| | | N03AX | Other antiepileptics | Sultiame Phenacemide Lamotrigine Felbamate Topiramate Gabapentin Pheneturide Levetiracetam Zonisamide Pregabalin Stiripentol Lacosamide Carisbamate Retigabine Perampanel Brivaracetam Cannabidiol Cenobamate Fenfluramine Beclamine | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| 129 | Anti-Parkinson Drugs: Anticholinergic Agents Anti-Parkinson Drugs: Dopaminergic Agents | N04AA | Tertiary amines | Trihexyphenidyl Biperiden Metixene Procyclidine Profenamine Dexetimide Phenglutaramide Mezaticol Bornaprine Tropatepine | Injection Tablet Capsule |
| | | N04AB | Ethers chemically close to antihistamines | Etanautine Orphenadrine chloride | Injection Tablet Capsule |
| | | N04AC | Ethers of tropine or tropine derivative | Benzatropine Etybenzatropine | Injection Tablet Capsule |
| | | N04BA | Dopa and dopa derivatives | Levodopa Melevodopa Etilevodopa Combinations with decarboxylase inhibitors and other dopaminergic agents | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N04BB | Adamantine derivatives | Amantadine | Injection Tablet Capsule |
| | | N04BC | Dopamine agonists | Bromocriptine Cabergoline Pergolide Dihydroergocryptine Mesylate Ropinirole Pramipexole Apomorphine Piribedil Rotigotin | Injection Tablet Capsule |
| | | N04BD | Monoamine oxidase B inhibitors | Selegiline Rasagiline Safinamide | Injection Tablet Capsule |
| | | N04BX | Other dopaminergic agents | Topicapone Entacapone Bupidine Opicapone | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | | Other antiparkinson drugs | Istradefylline | Injection Tablet Capsule |
| 130 | Antipsychotics | N05AA | Phenothiazines with aliphatic side chain | Chlorpromazine Levomepromazine Promazine Acepromazine Triflupromazine Cyamemazine Chlorproethazine | Injection Tablet Capsule |
| | | N05AB | Phenothiazines with piperazine structure | Dixyrazine Fluphenazine Perphenazine Prochlorperazine Thiopropazate Trifluoperazine Thioproperazine Perazine | Injection Tablet Capsule |
| | | N05AC | Phenothiazines with piperidine structure | Periclazine Thioridazine Mesoridazine Pipotiazine | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N05AD | Butyrophenone derivatives | Haloperidol Trifluoperidol Melperone Moperone Pipamperone Bromoperidol Benperidol Benperidol Droperidol Fluanisone | Injection Tablet Capsule |
| | | N05AE | Indole derivatives | Oxypertine Molindone Sertindole Ziprasidone Lurasidone | Injection Tablet Capsule |
| | | N05AF | Thioxanthene derivatives | Flupentixol Clopenthixol Chlorprothixene Tiotixene Zuclopenthixol | Injection Tablet Capsule |
| | | N05AG | Diphenylbutylpiperidine derivatives | Fluspirilene Pimozide Penfluridol | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N05AH | Diazepines oxazepines thiazepines and oxepines | Ioxapine Clozapine Olanzapine Quetiapine Asenapine Clotiapine | Injection Tablet Capsule |
| | | N05AL | Benzamides | Sulpiride Sultopride Tiapride Remoxipride Amisulpride Veralipride Levosulpiride | Injection Tablet Capsule |
| | | N05AN | Lithium | Lithium | Injection Tablet Capsule |
| | | N05AX | Other antipsychotics | Prothypendil Risperidone Mosapramine Zotepine Aripiprazole Paliperidone loperidone Cariprazine Brexipiprazole Pimavanserin | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 131 | Anxiolytics | N05BA | Benzodiazepine derivatives | Diazepam Chlordiazepoxide Medazepam Potassium Chlorazepate Lorazepam Adinazolam Bromazepam Clobazam Ketoazolam Prazepam Alprazolam Lalazepam Pinazepam Camazepam Nordazepam Fludiazepam Ethyl Loflazepate Etizolam Clotiazepam Cloxazolam Tofisopam Bentazepam Lorazepam combinations | Injection Tablet Capsule |
| | | N05BB | Diphenyl methane derivatives | Hydroxyzine Captodiame Hydroxyzine combinations | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N05BC | Carbamates | Meprobamate Emylcamate Meprobamate Cominations | Injection Tablet Capsule |
| | | N05BD | Dibenzo-bicyclo-octadiene derivatives | Benzoctamine | Injection Tablet Capsule |
| | | N05BE | Azaspirodecanedione derivatives | Buspirone | Injection Tablet Capsule |
| | | N05BX | Other anxiolytics | Mephenoxalone Gedocamil Etifoxine Fabomotizole Lavandulae Aetheroleum | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 132 | Hypnotics and sedatives | N05CA | Barbiturates plain | Pentobarbital Amobarbital Butobarbital Barbital Aprobarbital Talbutal Vinylbital Vinbarbital Cyclobarbital Heptobarbital Reposal Methohexital Hexobarbital Thiopental Etallobarbital Allobarbital Proxibarbital | Injection Tablet Capsule |
| | | N05CB | Barbiturates combinations | Tetrabarmate | Injection Tablet Capsule |
| | | N05CC | Aldehydes and derivatives | Chloral Hydrate Chloralodol Acetylglycinamide chloral hydrate Dichloralphenazone Paraldehyde | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N05CD | Benzodiazepine derivatives | Midazolam Flurazepam Nitrazepam Flunitrazepam Estazolam Triazolam Lormetazepam Temazepam Brotizolam Quazepam Loprazolam Doxefazepam Cinalozepam Remimazolam Nimetazepam | Injection Tablet Capsule |
| | | N05CE | Piperidinedione derivatives | Glutethimide Methylprylon Pyrithyldione | Injection Tablet Capsule |
| | | N05CF | Benzodiazepine related drugs | Zopiclone Zolpidem Zaleplon Eszopiclone | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N05CH | Melatonin receptor agonists | Melatonin Ramelteon Tasimelteon | Injection Tablet Capsule |
| | | N05CM | Other hypnotics and sedatives | Methaqualone Clomethiazole Bromisoval Carbrmal Scopolamine Propiomazine Triclofos Ethchlorvynol <i>Valerianae Radix</i> Hexapropymate Bromides Apronal Vanoctamide Methylpentynol Niaprazine Dexmedetomidine Suvorexant | Injection Tablet Capsule |
| | | N05CX | Hypnotics and sedatives in combination excl. barbiturates | Combinations with meprobamate or methaqualone or methylpentynol or chlomethiazole or emeprium or dipiperonylaminoethanol | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| 133 | Antidepressants | N06AA | Nonselective monoamine re-uptake inhibitors | Despiramine Imipramine Imipramine Oxide Clomipramine Opipramol Trimipramine Lofepamine Dibanzepin Amitriptyline Doxepin Prindole Melitracen Butriptyline Dosulepin Amoxapine Dimetacrine Amineptine Maprotiline Quinupramine | Injection Tablet Capsule |
| | | N06AB | Selective serotonin reuptake inhibitors | Zimeldine Fluoxetine Citalopram Paroxetine Sertraline Alaprociate Fluvoxamine Etoferidone Escitalopram | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N06AF | Monoamine oxidase inhibitors nonselective | Isocarboxazid Nialamide Phenelzine Tranlycypromine Iproniazide Iproclozide | Injection Tablet Capsule |
| | | N06AG | Monoamine oxidase A inhibitors | Moclobemide Toloxatone | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N06AX | Other antidepressants | Oxatriptan Tryptophan Mianserin Nomifensine Trazodone Nefazodone Minaprine Bifemelane Vilxazine Oxaflozane Mirtazapine Bupropion Medifoxamine Tianeptine Pivagabine Venlafaxine Milnacipran Reboxetine Gepirone Duloxetine Agomelatine Desvenlafaxine Vilazodone <i>Hyperici Herba</i> Vortioxetine Esketamine | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| 134 | Psychostimulants agents used for ADHD and nootropics | N06BA | Centrally acting sympathomimetics | Amfetamine 15mg Dexamfetamine 15mg Metamfetamine 15 Mg Methylphenidate Pemoline Fencamfamin Modafinil Fenozolone Atomoxetine Fenetylline Dexmethylphenidate Lisdexamfetamine Armodafinil Solriamfetol | Injection Tablet Capsule |
| | | N06BC | Xanthine derivatives | Caffeine Propentofylline | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | N06BX | Other psychostimulants and nootropics | Meclofenoxate Pyritinol Piracetam Deanol Fipexide Citicoline Oxiracetam Pirisudanol Linopirdine Nizofenone Aniracetam Acetylcarnitine Idebenone Prolintane Pipradrol Pramiracetam Adrafinil Vinpocetine Tetramethylglycoluril Phenibut | Injection Tablet Capsule |
| | | N06CA | Antidepressants in combination with psycholeptics | Combination of psycholeptics with amitriptyline Melitracen or fluoxetine | Injection Tablet Capsule |
| | | N06CB | Psychostimulants in combination with psycholeptics | Psychostimulants in combination with psycholeptics | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 135 | Anti-dementia drugs | N06DA | Anti-cholinesterases | Tacrine Donepezil Rivastigmine Galantamine Ipidacrine Donepezil and Memantine Donepezil Memantine and <i>Ginkgo Folium</i> | Injection Tablet Capsule |
| | | N06DX | Other anti-dementia drugs | Memantine <i>Ginkgo Folium</i> combinations | Injection Tablet Capsule |
| 136 | Parasympathomimetics | N07AA | Anticholinesterases | Neostigmine Pyridostigmine Distigmine Ambenonium Neostigmine combinations | Injection Tablet Capsule |
| | | N07AB | Choline esters | Carbachol Bethanechol | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| | | N07AX | Other Parasympathomimetics | Polocarpine Choline Alfoscerate Cevimeline | Injection Tablet Capsule |
| 137 | Drugs used in addictive disorders | N07BA | Drugs used in nicotine dependence | Nicotine Varenicline Cytisine | Injection Tablet Capsule |
| | | N07BB | Drugs used in alcohol dependence | Disulfiram Calcium Carbamide Acamprosate Naltrexone Nalmefene | Injection Tablet Capsule |
| | | N07BC | Drugs used in opioid dependence | Buprenorphine Methadone Levacetylmethadol Lofexidine Levomethadone Diamorphine Combinations of buprenorphine | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| 138 | Antivertigo preparations Other nervous system drugs | N07CA | Antivertigo preparations | Betahistine Cinnarizine Flunarizine Acetylleucine Cinnarizine combinations | Injection Tablet Capsule |
| | | N07XA | Gangliosides and ganglioside derivatives | | |
| | | N07XX | Other nervous system drugs | Tirilazad Riluzole Xaliproden Sodium Oxybate Amifampiride Tetrabenazine Fampridine Tafamidis Iaquinimod Pitolisant Patisiran Valbenazine Edaravone Inotersen Dextromethorphan combinations | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|---|--|---|--------------------------------|
| | | Antiparasitic Products Insecticides and Repellents | | | |
| 139 | Agents against amebiasis and other protozoal diseases | P01AA | Hydroxyquinoline derivatives | Broxyquinoline Clioquinol Chlorquinaldol Tilbroquinol All combined preparations containing clioquinol | Injection Tablet Capsule |
| | | P01AB | Nitroimidazole derivatives | Metronidazole Nimorazole Secnidazole | Injection |
| | | P01AC | Dichloroacetamide derivatives | Diloxanide Clefamide Etofamide Teclozan | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|---|--|--------------------------------|
| | | P01AR | Arsenic compounds | Arsthinol Difetarstone Glycobiarsol Glycobiarsol combinatons | Injection Tablet Capsule |
| | | P01AX | Other agents against amebiasis and other protozoal diseases | Chinofon Emetine Phanquinone Mepacrine Atovaquone Trimetrexate Tenonitrozole Dehydroemetine Fumagillin Nitazoxanide Emetine combinations | Injection Tablet Capsule |
| 140 | Antimalarials | P01BA | Aminoquinolines | Chloroquine Hydroxychloroquine Primaquine Amodiaquine Tafenoquine | Injection Tablet Capsule |
| | | P01BB | Biguanides | Proguanil Cycloguanil embonate Proguanil combinations | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | P01BD | Diaminopyrimidines | Pyrimethamine Pyrimethamine Combinations | Injection Tablet Capsule |
| | | P01BC | Methanolquinolines | Quinine Mefloquine | Injection Tablet Capsule |
| | | P01BE | Artemisinin and derivatives plain | Artemisinin Artemether Artesunate Artemotil Artenimol | Injection Tablet Capsule |
| | | P01BF | Artemisinin and derivatives ombinations | Artemether and lumefantrine Artesunate and mefloquine Artesunate and amodiaquine Artesunate Sulfalene and pyrimethamine Artenimol and piperaquine Artesunate and pyronaridine | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | P01BX | Other antimalarials | Halofantrine Arterolane and piperazine | Injection Tablet Capsule |
| 141 | Agents against leishmaniasis and trypanosomiasis | P01CA | Nitroimidazole derivatives | Benznidazole Fexinidazole | Injection Tablet Capsule |
| | | P01CB | Antimony compounds | Meglumine antimonate Sodium stibogluconate | Injection Tablet Capsule |
| | | P01CC | Nitrofurantoin derivatives | Nifurtimox Nitrofurantoin | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| | | P01CD | Arsenic compounds | Melarsoprol Acetarsol | Injection Tablet Capsule |
| | | P01CX | Other agents against leishmaniasis and trypanosomiasis | Pentamidine Isethionate Suramin Sodium Eflornithine Miltefosine | Injection Tablet Capsule |
| 142 | Antitrepatodals | P02BA | Quinoline derivatives and related compounds | Praziquantel Oxamniquine | Injection Tablet Capsule |
| | | PO2BB | Organophosphorous compounds | Metrifonate | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| | | P02BX | Other antitrepatodal agents | Bithionol Niridazole Stibophen Triclabendazole | Injection Tablet Capsule |
| 143 | Antinematodal agents | P02CA | Benzimidazole derivatives | Tiabendazole Ciclobendazole Flubendazole Fenbendazole Mebendazole combinations | Injection Tablet Capsule |
| | | P02CB | Piperazine and derivatives | Piperazine Diethylcarbazine | Injection Tablet Capsule |
| | | P02CC | Tetrahydropyrimidine derivatives | Pyrantel Oxantel | Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--------------------------------------|--------------------------------|
| | | P02CE | Imidazothiazole derivatives | Levamisol | Injection Tablet Capsule |
| | | P02CF | Avermectines | Ivermectin | Injection Tablet Capsule |
| | | P02CX | Other antinematodals | Pyrvinium Bephenium Moxidectin | Injection Tablet Capsule |
| 144 | Anticestodals | P02DA | Salicylic acid derivatives | Niclosamide | Injection Tablet Capsule |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| | | P02DX | Other anticestodals | Desaspidin Dichlorophen | Injection Tablet Capsule |
| 145 | Ectoparasiticides incl scabicides | P03AC | Pyrethrines incl. synthetic compounds | Pyrethrum Products Including synthetic pyrethrinoids and combinations with e.g Piperonyl Butoxide. Pyrethrum Biallethrin Phenothrin Permethrin combinations | Ointment Cream |
| | | P03AA | Sulfur containing compounds | Dixanthogen Potassium Polysulfide Mesulfen Disulfiram Thiram Disulfiram Combinations | Ointment Cream |
| | | P03AB | Chlorine containing compounds | Clofenotane Lindane Clofenotane combinations | Ointment Cream |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|---------------------------|--|-----------------|--|---|----------------------------|
| | | P03AX | Other ectoparasiticides incl. scabicides | Benzyl Benzoate Copper Oleinate Malathion Quassia Dimeticone Benzyl Alcohol | Ointment Cream |
| 146 | Insecticides and repellents | P03BA P03BX | Pyrethrines others. | Cyfluthrin Cypermethrin Decamethrin Tetramethrin Etohexadiol Diethyltoluamide Dimethylphthalate | Ointment Cream Spray |
| Respiratory system | | | | | |
| 147 | Drugs for obstructive airway diseases: Adrenergics inhalants | R03AA | Alpha and beta-adrenoceptor agonists | Epinephrine | Inhaler Aerosol |
| | | R03AB | Non-selective beta-adrenoceptor agonists | Isoprenaline Orciprenaline | Inhaler Aerosol |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---------------------|
| | | R03AC | Selective beta-2-adrenoceptor agonists | Terbutaline Fenoterol Rimiterol Hexoprenaline Isoetarine Pirbuterol Tretoquinol Carbuterol Tulobuterol Salmeterol Indacaterol Formoterol Clenbuterol Reproterol Procaterol Bitolterol Olodaterol | Inhaler Aerosol |
| | | R03AH | Combination of adrenergics | | Inhaler Aerosol |
| | | R03AK | Adrenergics in combination with corticosteroids or other drugs excl. anticholinergics | Salmeterol And Fluticasone Formeterol And Budesonide Formeterol And Mometasone | Inhaler Aerosol |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|---|--|---------------------|
| | | R03AL | Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids | Salbutamol and Ipratropium | Inhaler Aerosol |
| 148 | Other drugs for obstructive airway diseases inhalants | R03BA | Glucocorticoids | Beclomethasone Budesonide Flunisolide Betamethasone Fluticasone Triamcinolone Mometasone Ciclesonide Fluticasone Furoate | Inhaler Aerosol |
| | | R03BB | Anticholinergics | Ipratropium Bromide Oxipropium Bromide Stramoni Preparations Tiotropium Bromide Aclidinium Bromide Glycopyrronium Bromide Umeclidinium Bromide Revefenacin Tiotropium Bromide combinations | Inhaler Aerosol |
| | | R03BC R03BX | Other drugs for obstructive airway diseases inhalants | Fenspiride Cromoglicic Acid Nedocromil | Inhaler Aerosol |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| 149 | Adrenergics for systemic use | R03CA | Alpha- and beta-adrenoreceptor agonists | Oral Ephedrine 50mg | Tablet Capsule Injection |
| | | R03CB | Non-selective beta-adrenoreceptor agonists | Oral Isoprenaline Oral Methoxyphenamine Orciprenaline Isoprenaline Combinations Orciprenaline Combinations | Tablet Capsule Injection |
| | | R03CC | Selective beta-2-adrenoreceptor agonists | Salbutamol Terbutaline Fenoterol Hexoprenaline Isoetarine Pirbuterol Procaterol Tretoquinol Carbuterol Tulobuterol Bambuterol Clenbuterol Reproterol Terbutaline combinations Clenbuterol And Ambroxol | Tablet Capsule Injection Inhaler |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|---|--|---|
| | | R03CK | Adrenergics and other drugs for obstructive airway diseases | Combinations of adrenergics and other drugs for obstructive airway diseases e.g. Bronchial Asthma and COPD | Tablet Capsule Injection |
| 150 | Other systemic drugs for obstructive airway diseases | R03DA | Xanthines | Diprophylline Choline Theophyllinate Proxyphylline Theophylline Aminophylline Etamiphylline Theobromine Bamifylline Acefylline Piperazine Bufylline Doxophylline Mepyramine theophyllinacetate combinations | Tablet Capsule Injection Syrup Suspension |
| | | R03DB | Xanthines and adrenergics | Combinations of xanthines and adrenergics | Tablet Capsule Injection Syrup Suspension |
| | | R03DC | Leukotriene receptor antagonists | Zarfilukast Pranlukast Montelukast Ibudilast Combinations with antihistamines | Tablet Capsule Injection Syrup Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| | | R03DX | Other systemic drugs for obstructive airway diseases | Amlexanox Eprozinol Fenspride Omalizumab Seratrodast Roflumilast Reslizumab Mepolizumab Beralizumab | Tablet Capsule Injection Syrup Suspension |
| 151 | Decongestants and other nasal preparations | R01AD | Corticosteroids | Beclometasone Prednisolone Dexamethasone Flunisolide Budesonide Tixocortal Fluticasone Mometasone Triamcinolone Fluticasone Furoate Ciclosenide combinations | Inhaler Aerosol |
| 152 | Decongestants and other nasal preparations | R01AX | Other nasal preparations | Calcium Hexamine Thiocyanate Retinol Ipratropium Bromide Ritiometan Mupirocin Hexamidine Framycetin Hyaluronic Acid Others | Inhaler Aerosol |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| 153 | Throat preparations | R02AB | Antibiotics | Neomycin Tyrothricin Fusafungine Bacitracin Gramicidine | Sprays Lozenges Caplets Tablets Suspensions Syrups |
| | | R02AX | Other throat preparations | Flurbiprofen Ibuprofen | |
| | | R02AD | Anesthetics, local | Benzocaine Lidocaine Cocaine Dyclonine | |
| 154 | Cough suppressants | R05DA | Opium alkaloids and derivatives | Ethylmorphine Hydrocodone Codeine Opium alkaloids with morphine Normethadone Noscapine Pholcodine Dextromethorphan Thebacon Dimemorfan Acetyldihydrocodeine combinations | Tablet Capsule Syrup Suspension |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| 155 | Other respiratory system drugs | R07AA | Lung surfactants | Colfosceril Palmitate Natural Phospholipids combinations | Tablet Capsule Injection Syrup Suspension |
| | | R07AB | Respiratory stimulants | Doxapram Nkethamide Pentetrazol Etamivan Bemegrade Prethcamide Almitrine Dimeflin Mepixanox combinations | Tablet Capsule Injection Syrup Suspension |
| | | R07AX | Other respiratory system products | Nitric oxide Ivacaftor Ivacaftor and lumacaftor Ivacaftor and tezacaftor Tezacaftor and Elaxacaftor | Tablet Capsule Injection Syrup Suspension |
| | Sensory Organs | | | | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 156 | Ophthalmological anti-infectives | S01AA | Antibiotics | Chloramphenicol Chlortetracycline Neomycin Oxytetracycline Tyrothricin Framycetin Tetracycline Natamycin Gentamicin Tobramycin Fusidic Acid Benzylpenicillin Dihydrostreptomycin Rifamycin Erythromycin Polymyxin B Ampicillin Amikacin Micronomicin Netilmicin Kanamycin Azidamfenicol Azithromycin Cefuroxime Vancomycin Combinations of antibiotics or With other drugs | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | S01AB | Sulfonamides | Sulfamethizole Sulfafurazole Sulfadiazole Sulfacetamide Sulfafenazol | Eye Drops Cream Ointment |
| | | S01AD | Antivirals | Idoxuridine Trifluridine Acyclovir Interferon Vidarabine Famciclovir Fomivirsen Ganciclovir | Eye Drops Cream Ointment |
| | | S01AE | Fluroquinolones | Ofloxacin Norfloxacin Ciprofloxacin Lomefloxacin Levofloxacin Gatifloxacin Moxifloxacin Besifloxacin | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|---|--|--------------------------------|
| | | S01AX | Other antieffectives | Mercury Compounds Silver Compounds Zinc Compounds Nitrofurals Bibrocathol Resorcinol Sodium Borate Hexamide Chlorhexidine Sodium Propionate Dibrompropamide Propamide Picloxydine Povidone-Iodine | Eye Drops Cream Ointment |
| 157 | Ophthalmological anti-inflammatory agents and antieffectives in combination | S01CA | Corticosteroids and ant infectives in combinations | Corticosteroids and ant infectives in combinations | Eye Drops Cream Ointment |
| | | S01CB | Corticosteroids/ ant infectives/ mydriatics in combinations | Corticosteroids/ ant infectives/ mydriatics in combinations | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | S01BA | Plain corticosteroids | Dexamethasone Hydrocortisone Cortisone Prednisolone Triamcinolone Betamethasone Fluorometholone Medrysone Clobetasone Aclometasone Desonide Formocortal Rimexolone Loteprednol Fluocinolone acetonide | Eye Drops Cream Ointment |
| | | S01BB | Corticosteroids and mydiatrics in combination | Hydrocortisone and Mydriatics Prednisolone and Mydiatrics Fluorometholone And Mydiatrics Betamethasone and Mydriatics | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|--------------------------------|
| | | S01BC | Anti-inflammatory agents, non-steroids | Indomethacin Oxyphenbutazone Diclofenac Flurbiprofen Ketorolac Piroxicam Bendazac Salicylic Acid Pranoprofen Nepafenac Bromfenac | Eye Drops Cream Ointment |
| | | S01C | Combinations | Ant inflammatory, Anti-infectives And Steroids Combinations | Eye Drops Cream Ointment |
| | | S01CC | Anti-inflammatory agents non-steroids and anti-infectives | Combinations Of anti-infective With Diclofenac or Indomethacin | Eye Drops Cream Ointment |
| 158 | Antiglaucoma preparations and miotics | S01EA | Sympathomimetics in glaucoma therapy | Epinephrine Dipivefrine Apraclonidine Clonidine Brimonidine Epinephrine Combinations | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|--------------------------------|
| | | S01EB | Parasympathomimetics | Pilocarpine Carbochol Ecothiopate Demecarium Physostigmine Neostigmine Aceclidine Acetylcholine Paraoxon Pilocarpine Combinations Aceclidine Combinations | Eye Drops Cream Ointment |
| | | S01EC | Carbonic anhydrase inhibitors | Acetazolamide Diclofenamide Dorzolamide Brinzolamide Methazolamide Brinzolamide Combinations | Eye Drops Cream Ointment |
| | | S01ED | Beta blocking agents | Timolol Betaxolol Levobunolol Metipranolol Carteolol Befunolol Timolol Combinations Betaxolol Combinations Metipranolol Combinations Carteolol Combinations | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | S01EE | Prostaglandin analogues | Latanoprost Unoprostone Bimatoprost Travoprost Tafluprost Latanoprostene Bunod Latanoprost And Netarsudil | Eye Drops Cream Ointment |
| | | S01EX | Other antiglaucoma preparations | Guanethidine Dapiprazole Netarsudil Omidenepag | Eye Drops Cream Ointment |
| 159 | Mydriatics and cycloplegics | S01FA | anticholinergics | Atropine Scopolamine Methylscopolamine Cyclopentolate Homatropine Tropicamide Cyclopentolate Combinations Tropicamide Combinations | Eye Drops Cream Ointment |
| | | S01FB | Sympathomimetics excl. antiglaucoma preparations | Phenylephrine Ephedrine Ibopamide Phenylephrine And Ketorolac | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| | | S01GX | Other antiallergics | Cromogilicic Acid Levocabastine Nedocromil Ketotifen Lodoxamide Olopatidine Epinastine Emedastine Alcaftadine Etc | |
| 160 | Ophthalmologic al local anesthetics | S01HA | Local anesthetics | Cocaine Oxybuprocaine Tetracaine Proxymetacaine Procaine Cinchocaine Lidocaine combinations | Eye Drops Cream Ointment |
| 161 | Ophthalmologic al diagnostic agents | S01JA | Coloring agents | Fluorescein Rose Bengal Sodium Fluorescein Combinations | Eye Drops Cream Ointment |
| | | S01JX | Other ophthalmological diagnostic agents | Other Ophthalmological Diagnostic Agents | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|--|---|
| 162 | Ophthalmological surgical aids | S01KA | Viscoelastic substances | Hyaluronic Acid Hypromellose Hyaluronic Acid Combinations | Eye Drops Cream Ointment |
| | | S01KX | Other surgical aids | Chymotrypsin | Eye Drops Cream Ointment |
| 163 | Ocular vascular disorder agents | S01LA | Antineovascularisation agents | Verteporfin Anecortave Pegaptanib Ranibzumab Aflibercept Brolucizumab Abicipar Pegol | Eye Drops Cream Ointment Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|--------------------------------|
| 164 | Other Ophthalmologicals | S01XA | Other ophthalmologicals | Guaiazulen Retinol Hypertonic Sodium Chloride Potassium Iodide Sodium Edetate Ethylmorphine Alum Acetylcysteine Iodoheparinate Inosine Nandrolone Dexpanthenol Alteplase Heparin Ascorbic Acid Ciclosporin Autologous Limbal Stem Cells Artificial Tears And Other Indifferent Preparations Mercaptamine Ocriplasmin Sirolimus Cenegermin Lifitegrast Riboflavin Voretigene Neparvovec | Eye Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|----------------------------|
| 165 | Otologicals | S02AA | anti-infective | Chloramphenicol Nitrofurazone Boric Acid Aluminum Acetotartrate Clioquinol Hydrogen Peroxide Neomycin Tetracycline Chlorhexidine Acetic Acid Polymyxin B Rifamycin Miconazole Gentamicin Ciprofloxacin combinations | Drops Cream Ointment |
| | | S02BA | Corticosteroids | Hydrocortisone Prednisolone Dexamethasone Betamethasone Fluocinolone Acetonide | Drops Cream Ointment |
| | | S02CA | corticosteroids and antiinfectives in combination | Prednisolone and Antinfectives Flumetasone and Antinfectives Hydrocortisone and Antinfectives Triamcinolone and Antinfectives Fluocinolone and Antinfectives Dexamethasone and Antinfectives Fludrocortisone and Antinfectives | Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|---|--|----------------------------|
| 166 | Ophthalmological and otological preparations | S03AA | antiinfectives | Preparations which can be used in both Eye and Ear: Neomycin Tetracycline Polymyxin B Chlorhexidine Hexamidine Gentamicin Ciprofloxacin Chloramphenicol Combinations | Drops Cream Ointment |
| | | S03CA | Ophthalmological and ontological preparations: corticosteroids and antinfectives in combination | Preparations which can be used in both Eye and Ear | Drops Cream Ointment |
| | | S03D | Other Ophthalmological and ontological preparations: | Preparations which can be used in both Eye and Ear | Drops Cream Ointment |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|---|
| 167 | All other therapeutic products | V03AB | Antidotes | Nalorphine Edatates Pralidoxime Prednisolone and Promethazine Thiosulfate Sodium Nitrite Dimercaprol Obidoxime Protamine Naloxone Ethanol Methylthioninium Chloride Potassium Permanganate Physostigmine Copper Sulfate Potassium Iodide Amyl Nitrate Acetylcysteine Digitalis Antitoxin Flumazenil Methionine 4- Dimethylaminophenol Cholinesterase Prussian Blue Glutathione Hydroxocobalamin Fomepizole Sugarmmadex Phentolamine Idarucizumab Andexanet Alfa | Tablet Ointment Cream Capsule Solution Powder Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--------------------------------|
| | | V03AC | Iron chelating agents | Deferoxamine Deferiprone Defasirox | Tablet Capsule Injection |
| | | V03AE | Drugs for treatment of hyperkalemia and hyperphosphatemia | Polystyrene Sulfonate Selamer Ianthanum Carbonate Calcium Acetate and Magnesium Carbonate Sucroferric Oxyhydroxide Colestilan Calcium Acetate Ferric Citrate Patiromer Calcium Sodium Zirconium Cyclosilicate | Tablet Capsule Injection |
| | | V03AF | Detoxifying agents for antineoplastic treatment | Mesna Dexrazoxane 1.5g Calcium Folate 60mg Calcium Levofolate 30mg Amifostine 1.7 G Sodium Folate 60mg Rasburicase 14mg Palifermin 4.2 Mg Glucarpidase Sodium Levofolate 30 Mg Arginine And Lysine | Tablet Capsule Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|--------------------------------|
| | | V03AG | Drugs for treatment of hypercalcemia | Sodium Cellulose Phosphate | Tablet Capsule Injection |
| | | V03AH | Drugs for treatment of hypoglycemia | Diazoxide | Tablet Capsule Injection |
| | | V03AK | Tissue adhesives | Cyanoacrylate Based Adhesives (Not containing Fibrinogen or Other Local Hemostatics) | |
| | | V03AN | Medical gases | Oxygen Carbon Dioxide Helium Nitrogen Medical Air | Gas |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|------------|--|-----------------|--|--|--------------------------------|
| | | V03AX | Other therapeutic products | Nalfurafine Cobicistat | Tablet Capsule Injection |
| | | V03AZ | Nerve depressants | Ethanol Used in Ablation Procedures | Solution |
| 168 | Therapeutic radiopharmaceuticals: ant inflammatory agents | V10AA | Yttrium (⁹⁰ Y) compounds | Yttrium (⁹⁰ Y) Citrate Colloid Yttrium (⁹⁰ Y) Ferrihydroxide Colloid Yttrium (⁹⁰ Y) Silicate Colloid | Injection |
| | | V10AX | Other anti-inflammatory therapeutic radiopharmaceuticals | Phosphorous (³² P) Chromicphosphate Colloid Samarium (¹⁵³ Sm)Hydroxyapatite Colloid Dysprosium (¹⁶⁵ Dy) Colloid Erbium (¹⁶⁹ Er) Citrate Colloid Rhenium (¹⁸⁶ Re) Sulfide Colloid Gold (¹⁹⁸ Au) Colloidal | Injection |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|-----|---|-----------------|--|---|---------------------|
| | | V10BX | Various pain palliation radiopharmaceuticals | Strontium (⁸⁹ Sr) Chloride Samarium (¹⁵³ Sm) Lexidronam Rhenium (¹⁸⁶ Re) Etidronic Acid | Injection |
| | | V10XA | Iodine (¹³¹ I) compounds | Sodium Iodide (¹³¹ I) Iobenguane (¹³¹ I) Tositumomab/Iodine (¹³¹ I) Tositumomab | Injection |
| | | V10XX | Various therapeutic radiopharmaceuticals | Sodium Phosphate (³² P) Ibritumomab Tiuxetan (⁹⁰ Y) Radium (²²³ Ra) Dichloride | Injection |
| 169 | Other diagnostic agents | V04CA | Tests for diabetes | Tolbutamine | All forms |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | V04CB | Tests for fat absorption | Vitamin A Concentrates | |
| | | V04CC | Tests for bile duct patency | Sorbitol Magnesium Sulfate Sincalide Ceruletide | |
| | | V04CD | Tests for pituitary function | Metyrapone Sermorelin Cortimorelin Somatostatin Macimorelin | |
| | | V04CE | Tests for liver functional capacity | Galactose Sulfobromophthalein Methacetin (13C) | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|--|---------------------|
| | | V04CF | Tuberculosis diagnostics | Tuberculin | |
| | | V04CG | Tests for gastric secretion | Cation exchange resins Betazole Histamine Phosphate Pentagastrin Methylthioninium Chloride Caffeine and Sodium Benzoate | |
| | | V04CH | Tests for renal function and ureteral injuries | Inulin and other polyfructosans Indigo carmine Phenolsulfonphthalein Alsactide Aminohippuric acid | |
| | | V04CJ | Tests for thyroidea function | Thyrotropin Protirelin | |

| | Chemical or Pharmacological or Therapeutic class | ATC CODE | Chemical or Pharmacological or Therapeutic subclass | Examples | Dosage Forms |
|--|---|-----------------|--|---|---------------------|
| | | V04CK | Tests for pancreatic function | Secretin Pancreozymin (Cholecystokinin) Bentiromide | |
| | | V04CL | Tests for allergic diseases | | |
| | | V04CM | Tests for fertility disturbance | Gonadorelin | |

Prescription only complementary and alternative medicines

| | Common name | Botanical name | Indication |
|----|-------------------------------|---|--|
| 1. | Castor oil (for internal use) | <i>Ricinus communis</i> | Laxative, GI disorders. |
| 2. | Corydalis rhizome | <i>Corydalis yanhusuo</i> | Neuropathic pain, anxiolytic, analgesic. |
| 3. | Dandelion root | <i>Herba taxaci- Taraxacum officinale</i> | Restoration of hepatic and biliary function, dyspepsia, loss of appetite |
| 4. | Dryopteris roots/shield fern | <i>Dryopteris crassirhizoma</i> | Antimicrobial, antiparasitic |

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| 5. | False daisy | <i>Eclipta alba</i> | Emesis, Antiseptic, tonic, and deobstruent in splenomegally |
| 6. | Fracjoin/ veld grape | <i>Cissus quadrangularis</i> | Broken bones and injured ligaments & tendons |
| 7. | Intravenous Milk Thistle | <i>Silybum marianum</i> | Hepatoprotective |
| 8. | Licorice root | <i>Glycyrrhiza uralensis</i> | Adjuvant therapy of gastric and duodenal ulcers and gastritis, coughs and bronchial catarrh |
| 9. | Olibanum | <i>Gummi Boswellii</i> | Anti-inflammatory activity |
| 10. | Pax tubers | <i>Dioscorea bulbifera / Dioscorea dumetorum</i> | Treatment of Diabetes mellitus |
| 11. | African Cherry | <i>Prunus africana</i> | Various uses, Appetite stimulant, fevers |
| 12. | Salvia or Cinnabar root/ red sage | <i>Salvia miltorrhiza</i> | Cardiovascular diseases Cerebrovascular diseases |
| 13. | Wild chrysanthemum flower | <i>Chrysanthemum indicum</i> | Insecticide |
| 14. | Japanese honesuckle | <i>Flos lonicerae japonicae</i> | Antipyretic, ant inflammatory |
| 15. | Chinese wedelia | <i>Sphagneticola calendulacea</i> | Alopecia, use in cephalalgia |
| 16. | Beberis. | <i>Cortex Berberidis</i> | Anti-inflammatory and digestive disorders |
| 17. | Garden heliotrope | <i>Valeriana officinalis</i> | Sleep disorders and anxiety disorders. |
| 18. | Satavari | <i>Asparagus racemosus</i> | GI disorders |
| 19. | Digitalis leaf | <i>Digitalis purpurea</i> | Cardioactive |

Annex VI: Controlled Substances

| | CLASS | EXAMPLES |
|---|---------|---|
| 1 | Class I | Alpha-Methylthiofentanyl Alpha-methyltryptamine alpha-pyrrolidinobutiophenone (a-PBP) alpha-pyrrolidinopentiophenone (aPVP) AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole) AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole) Aminorex Benzethidine Benzylmorphine Betacetylmethadol Beta-hydroxy-3-methylfentanyl Beta-hydroxyfentanyl Beta-hydroxythiofentanyl Betameprodine Betamethadol Betaprodine Bufotenine Butylone Butyryl Fentanyl Cathinone Clonitazene Codeine methylbromide Codeine-n-oxide CP-47497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol]) CP-47497 C8-homolog (5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol]) Cyprenorphine desomorphine dextromoramide diampromide |

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| | diethylthiambutene Allylprodine Alphacetylmethadol except levo-alphacetylmethadol Alpha-Ethyltryptamine Alphameprodine Alphamethadol Alpha-Methylfentanyl Alpha-Methylthiofentanyl Alpha-methyltryptamine alpha-pyrrolidinobutiophenone (a-PBP) alpha-pyrrolidinopentiophenone (aPVP) AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole) AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole) Aminorex Benzethidine Benzylmorphine Betacetylmethadol Beta-hydroxy-3-methylfentanyl Beta-hydroxyfentanyl Beta-hydroxythiofentanyl Betameprodine Betamethadol Betaprodine Bufotenine Butylone Butyryl Fentanyl Cathinone Clonitazene Codeine methylbromide Codeine-n-oxide CP-47497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol]) CP-47497 C8-homolog (5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol]) |
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| | <p> Cyprenorphine desomorphine dextromoramide diampromide diethylthiambutene diethyltryptamine difenoxin dihydromorphine dimenoxadol dimepheptanol dimethylthiambutene dimethyltryptamine dioxaphetyl butyrate dipipanone drotebanol Ethylmethylthiambutene Etonitazene Etorphine (except HCl) Etoxidine Fenethylamine Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)- N-phenylfuran-2-carboxamide) Furethidine Gamma Hydroxybutyric Acid Heroin Hydromorphanol Hydroxypethidine ibogaine JWH-018 (known as AM-678) (1-Pentyl-3-(1-naphthoyl) indole) JWH-073 (1-Butyl-3-(1-naphthoyl) indole) JWH-019 (1-Hexyl-3-(1-naphthoyl) indole) JWH-200 (1-[2-(4-Morpholinyl) ethyl]-3-(1-naphthoyl) indole) JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole) </p> |
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| | <p> JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole) JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole) JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole) JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole) Ketobemidone Levomoramide Levophenacylmorphane Lysergic acid diethylamide MAB-CHMINACA (N-(1-amino-3,3dimethyl- 1-oxobutan-2-yl)- 1-(cyclohexylmethyl)-1H-indazole-3-carboxamide) Marijuana Marijuana Extract MDPV (3,4-Methylenedioxypropylvalerone) Mecloqualone Mephedrone (4-Methyl-N-methylcathinone) Mescaline Methaqualone Methcathinone Methyldesorphine Methyldihydromorphine Morpheridine Morphine methylbromide Morphine methylsulfonate Morphine-n-oxide Myrophine n,n-dimethylamphetamine Naphyrone n-Benzylpiperazine n-Ethyl-1-phenylcyclohexylamine n-Ethyl-3-piperidyl benzilate n-Ethylamphetamine n-Hydroxy-3,4-methylenedioxyamphetamine nicocodeine </p> |
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| | <p>nicomorphine n-Methyl-3-piperidyl benzilate noracymethadol norlevorphanol normethadone normorphine norpipanone Para-Fluorofentanyl Parahexyl PB-22 (Quinolin-8-yl 1-pentyl-1H-dole-3-carboxylate) Pentdrone (a-methylaminovalerophenone) Pentylone Peyote Phenadoxone Phenampromide Phenomorphane Phenoperidine Pholcodine Piritramide Proheptazine Propiridine Propiram Psilocybin Racemoramide SR-18 (known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole) SR-19 (known as RCS-4) (1-Pentyl-3-[(4-methoxy)- benzoyl] indole) Tetrahydrocannabinols Thebacon Thiofentanyl THJ-2201 [1-(5-fluoropentyl)-1H-indazol-3-yl] (naphthalen-1-yl) methanone Tilidine</p> |
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| | | <p>Trimeperidine U-47700 (3,4-dichloro-N-[2-dimethylamino]cyclohexyl]-N-methylbenzamide) UR-144 (1-Pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclo-propyl)methanone</p> |
| 2 | Class II | <p>1-Phenylcyclohexylamine 1-Piperidinocyclohexanecarbonitrile 4-Anilino-N-phenethyl-4-piperidine (ANPP) Alfentanil Alphaprodine Amobarbital Amphetamine Anileridine Benzoyllecgonine Bezitramide Carfentanil Coca Leaves Cocaine Codeine Dextropropoxyphene, bulk (non-dosage forms) Dihydrocodeine Dihydroetorphine Diphenoxylate Diprenorphine Ecgonine Ethylmorphine Etorphine Fentanyl Glutethimide Hydrocodone Hydromorphone Isomethadone Levo-alphaacetylmethadol</p> |

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| | <p> Levomethorphan Levorphanol Lisdexamfetamine Meperidine Meperidine intermediate-A Meperidine intermediate-B Meperidine intermediate-C Metazocine Methadone Methadone intermediate Methamphetamine Methylphenidate MetoponMoramide-intermediate Morphine Nabilone Opium extracts Opium fluid extract Opium poppy Opium tincture Opium, granulated Opium, powdered Opium, raw Oripavine Oxycodone Oxymorphone Pentobarbital Phenazocine Phencyclidine Phenmetrazine Phenylacetone Piminodine Poppy Straw Poppy Straw Concentrate </p> |
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| | | <p>Racemethorphan Racemorphan Remifentanil Secobarbital Sufentanil Tapentadol Thebaine Thiafentanil</p> |
| 3 | Class III | <p>13Beta-ethyl-17beta-hydroxygon-4-en-3-one 17Alpha-methyl-3alpha,17beta-dihydroxy-5alphaandrostane 17Alpha-methyl-3beta,17beta-dihydroxy-5alphaandrostane 17Alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene 17Alpha-methyl-4-hydroxynandrolone (17alpha-methyl- 4-hydroxy-17beta-hydroxyestr-4-en-3-one) 17Alpha-methyl-delta1-dihydrotestosterone (17beta- hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one) 19-Nor-4,9(10)-androstedione 19-Nor-4-androstenedione (estr-4-en-3,17-dione) 4000 III N 19-Nor-5-androstenediol (3beta,17beta-dihydroxyestr-5-ene; 3alpha,17beta-dihydroxyestr-5-ene) 19-Nor-5-androstenedione (estr-5-en-3,17-dione) 1-Androstenediol (3beta,17beta-dihydroxy-5alphaandrost- 1-ene; 3alpha,17beta-dihydroxy-5alphaandrost-1-ene) 1-Androstenedione (5alpha-androst-1-en-3,17-dione) 3Alpha,17beta-dihydroxy-5alpha-androstane 3Beta,17beta-dihydroxy-5alpha-androstane 4-Androstenediol (3beta,17beta-dihydroxy-androst-4-ene) 4-Androstenedione (androst-4-en-3,17-dione) 4-Dihydrotestosterone (17beta-hydroxyandrost-3-one) 4-Hydroxy-19-nortestosterone (4,17beta-dihydroxyestr-4-en-3-one) 4-Hydroxytestosterone (4,17beta-dihydroxyandrost-4-en-3-one)</p> |

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| | | <p>5-Androstenediol (3beta,17beta-dihydroxy-androst-5-ene) 5-Androstenedione (androst-5-en-3,17-dione) Amobarbital & noncontrolled active ingred. Amobarbital suppository dosage form Anabolic steroids Androstanedione (5alpha-androstan-3,17-dione) Aprobarbital Barbituric acid derivative Benzphetamine Bolasterone (7alpha,17alpha-dimethyl-17beta- hydroxyandrost-4-en-3-one) Boldenone (17beta-hydroxyandrost-1,4-diene-3-one) Boldione Buprenorphine Butabarbital (secbutabarbital) Butalbital Butobarbital (butethal) Calusterone (7beta,17alpha-dimethyl- 17betahydroxyandrost-4-en-3-one) Chlorhexadol Chlorphentermine Clortermine Clostebol (4-chloro-17beta-hydroxyandrost-4-en-3-one) Codeine & isoquinoline alkaloid 90 mg/du Codeine combination product 90 mg/du Dehydrochloromethyltestosterone (4-chloro-17betahydroxy- 17alpha-methylandrost-1,4-dien-3-one) Delta1-dihydrotestosterone (17beta-hydroxy- 5alphaandrost-1-en-3-one) Desoxymethyltestosterone Dihydrocodeine combination product 90 mg/du Dronabinol (synthetic) in sesame oil in soft gelatin capsule as approved by FDA Drostanolone (17beta-hydroxy-2alpha-methyl- 5alphaandrost-3-one) Embutramide Ethylestrenol (17alpha-ethyl-17beta-hydroxyestr-4-ene)</p> |
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| | | <p>Ethylmorphine combination product 15 mg/du Fluoxymesterone (9-fluoro-17alpha-methyl-11beta, 17beta-dihydroxyandrost-4-en-3-one) Formebolone (2-formyl-17alpha-methyl-11alpha, 17beta-dihydroxyandrost-1,4-dien-3-one) Furazabol (17alpha-methyl- 17betahydroxyandrostano[2,3-c]-furazan) Gamma Hydroxybutyric Acid preparations Hydrocodone & isoquinoline alkaloid <15 mg/du Hydrocodone combination product <15 mg/du Ketamine Lysergic acid Lysergic acid amide Mestanolone (17alpha-methyl-17beta-hydroxy- 5alphaandrostan-3-one) Mesterolone (1alpha-methyl-17beta-hydroxy-5alphaandrostan-3-one) Methandienone (17alpha-methyl- 17betahydroxyandrost-1, 4-diene-3-one) Methandriol (17alpha-methyl-3beta, 17betadihydroxyandrost-5-ene) Methasterone (2alpha,17alpha-dimethyl-5alpha-androstan- 17beta-ol-3-one) Methenolone (1-methyl-17beta-hydroxy-5alpha-androst- 1-en-3-one) Methyldienolone (17alpha-methyl- 17beta-hydroxyestr-4,9(10)-dien-3-one) Methyltestosterone (17alpha-methyl- 17betahydroxyandrost-4-en-3-one) Methyltrienolone (17alpha-methyl-17beta- hydroxyestr-4,9,11-trien-3-one) Methypylon Mibolerone (7alpha,17alpha-dimethyl- 17betahydroxyestr-4-en-3-one) Morphine combination product/50 mg/100 ml or gm Nalorphine Nandrolone (17beta-hydroxyestr-4-en-3-one) Norbolethone (13beta,17alpha-diethyl- 17betahydroxygon-4-en-3-one) Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one) Norethandrolone (17alpha-ethyl- 17beta-hydroxyestr-4-en-3-one) Normethandrolone (17alpha-methyl- 17betahydroxyestr-4-en-3-one) Opium combination product 25 mg/du Oxandrolone (17alpha-methyl-</p> |
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| | | <p>17beta-hydroxy-2-oxa-5alpha-androstan-3-one) Oxymesterone (17alpha-methyl-4, 17betadihydroxyandrost-4-en-3-one) Oxymetholone (17alpha-methyl-2-hydroxymethylene- 17beta-hydroxy-5alpha-androstan-3-one) Pentobarbital & noncontrolled active ingred. Pentobarbital suppository dosage form Perampanel Phendimetrazine Prostanozol (17beta-hydroxy-5alpha-androstano[3,2-c]pyrazole) Secobarbital & noncontrolled active ingred Secobarbital suppository dosage form Stanozolol (17alpha-methyl-17beta-hydroxy-5alpha-androst- 2-eno[3,2-c]-pyrazole) Stanozolol (17alpha-methyl-17beta-hydroxy- 5alphaandrost-2-eno[3,2-c]-pyrazole) Stenbolone (17beta-hydroxy-2-methyl- 5alpha-androst-1-en-3-one) Stimulant compounds previously excepted Sulfondiethylmethane Sulfonethylmethane Sulfonmethane Talbutal Testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1, 4-dien-17-oic acid lactone) Testosterone (17beta-hydroxyandrost-4-en-3-one) Tetrahydrogestrinone (13beta,17alpha-diethyl- 17betahydroxygon-4,9,11-trien-3-one) Thiamylal Thiopental Tiletamine & Zolazepam Combination Product Trenbolone (17beta-hydroxyestr-4,9,11-trien-3-one) Vinbarbital</p> |
| 4 | Class IV | <p>Alfaxalone Alprazolam Barbital</p> |

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| | Bromazepam Butorphanol Camazepam Carisoprodol Cathine Chloral betaine Chloral hydrate Chlordiazepoxide Clobazam Clonazepam Clorazepate Clotiazepam Cloxazolam Delorazepam Dexfenfluramine Dextropropoxyphene dosage forms Diazepam Dichloralphenazone Diethylpropion Difenoxin 1 mg/25 ug AtSO4/du Eluxadoline Estazolam Ethchlorvynol Ethinamate Ethyl loflazepate Fencamfamin Fenfluramine Fenproporex Fludiazepam Flunitrazepam Flurazepam Fospropofol Halazepam |
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| | Haloxazolam Ketazolam Loprazolam Lorazepam Lorcaserin Lormetazepam Mazindol Mebutamate Medazepam Mefenorex Meprobamate Methohexital Methylphenobarbital (mephobarbital) Midazolam Modafinil Nimetazepam Nitrazepam Nordiazepam Oxazepam Oxazolam Paraldehyde Pemoline Pentazocine Petrichloral Phenobarbital Phentermine Pinazepam Pipradrol Prazepam Quazepam Sibutramine SPA Suvorexant |
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| | | <p>Temazepam Tetrazeepam Tramadol (2-[dimethylamino)methyl]-1-(3-methoxy- phenyl) cyclohexanol) Triazolam Zaleplon Zolpidem Zopiclone</p> |
| 5 | Class V | <p>Brivaracetam Codeine preparations - 200 mg/100 ml or 100 gm Difenoxin preparations - 0.5 mg/25 ug AtSO4/du Dihydrocodeine preparations 10 mg/100 ml or 100 gm Diphenoxylate preparations 2.5 mg/25 ug AtSO4 Ethylmorphine preparations 100 mg/100 ml or 100 gm Ezogabine Lacosamide Opium preparations - 100 mg/100 ml or gm Pregabalin Pyrovalerone</p> |

Annex VII: Chemical and Poisons

| | 7A-Regulated explosives pre-cursors |
|----|--|
| 1 | Hydrogen peroxide over 12% w/w |
| 2 | Nitromethane over 30% w/w |
| 3 | Nitric acid over 3% w/w |
| 4 | Potassium chlorate over 40% w/w |
| 5 | Potassium perchlorate over 40%w/w |
| 6 | Sodium chlorate over 40% w/w |
| 7 | Sodium perchlorate over 40% w/w |
| 8 | Sulphuric acid over 15% w/w |
| | |
| | 7B-Regulated Poisons |
| 1. | Aluminum phosphide |
| 2. | Arsenic and its compounds (other than calcium arsenites, copper acetoarsenite, copper arsenates, copper arsenites, lead arsenates) |
| 3. | Barium salts (other than barium sulphate, barium carbonate and barium silicofluoride) |
| 4. | Bromomethane |
| 5. | Chloropicrin |
| 6. | Fluor acetic acid and its salts Fluoroacetamide |
| 7. | Hydrogen cyanide; metal cyanides, other than ferrocyanides and ferricyanides |
| 8. | Lead acetates |

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| | Magnesium phosphide |
| 9. | Mercury, compounds of, the following: - |
| | 1. Nitrates Of Mercury |
| | 2. Mercuric Cyanide Oxides |
| | 3. Mercuric Thiocyanate |
| | 4. Ammonium Mercuric Chlorides |
| | 5. Potassium Mercuric Iodides |
| | 6. Organic Compounds of Mercury Which Contain a Methyl Group Directly Linked to The Mercury Atom |
| 10. | Oxalic acid: 10% w/w |
| 11. | Phenols (phenol; phenolic isomers of the following cresols, xylenols, monoethylphenols) except in substances containing less than 60% weight in weight of phenols; compounds of phenols with metal, except in substances containing less than the equivalent of 60% weight in weight of phenols |
| 12. | Phosphorus yellow |
| 13. | Strychnine and its salts |
| 14. | Thallium and its salts |
| | |
| | 7C-Reportable explosive precursors |
| 1. | Ammonium nitrate |
| 2. | Acetone |
| 3. | Hexamine |
| 4. | Potassium nitrate |
| 5. | Sodium nitrate |

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| 6. | Calcium nitrate |
| 7. | Calcium ammonium nitrate |
| 8. | Aluminum powders |
| 9. | Magnesium powders |
| 10. | Magnesium nitrate hexahydrate |
| | |
| | 5D-Reportable poisons |
| 1. | Aldicarb |
| 2. | Alpha-chloralose |
| 3. | Ammonia 10% w/w |
| 4. | Arsenic, compounds of, the following: |
| | I. Calcium Arsenates |
| | II. Copper Ace to Arsenite |
| | III. Copper Arsenates |
| | IV. Copper Arsenites |
| | V. Lead Arsenates |
| 5. | Barium, salts of, the following: |
| 6. | I. Barium Carbonate |
| | II. Barium Silicofluoride |
| 7. | Carbofuran |
| 8. | Cycloheximide |
| 9. | Dinitro cresols, their compounds with a metal or a base |
| 10. | Dinoseb its compounds with a metal or a base |
| 11. | Dinoterb |
| 12. | Drazoxolon; its salts |

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| 13. | Endosulfan |
| 14. | Endothall its salts |
| 15. | Endrin |
| 16. | Fentin and its compounds |
| 17. | Formaldehyde 5% w/w |
| 18. | Formic acid 25% w/w |
| 19. | Hydrochloric acid 10% w/w |
| 20. | Hydrofluoric acid and |
| | I. Alkali Metal Bifluorides Ammonium Bifluoride |
| | II. Alkali Metal Fluorides |
| | III. Ammonium Fluoride |
| | IV. Sodium Silicofluoride |
| 21. | Mercuric chloride |
| 22. | Mercuric iodide; organic compounds of mercury except compounds that contain a methyl (CH ₃) group directly linked to the mercury atom |
| 23. | Metallic oxalates |
| 24. | Methomyl |
| 25. | Nicotine its salts; its quaternary compounds (which are not for intended for use in human beings) |
| 26. | Nitrobenzene 0.1% w/w |
| 27. | Ox amyl |
| 28. | Paraquat salts of |
| 29. | Phenols |
| 30. | Phosphoric acid |

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| 31. | Phosphorus compounds, the following: |
| | I. Azinphos-Methyl |
| | II. Clofenvinphos |
| | III. Demephion |
| | IV. Demeton-Smethyl |
| | V. Demeton-S-Methyl Sulphone Dialifos |
| | VI. Dichlorvos |
| | VII. Dioxathion |
| | VIII. Disulfoton |
| | IX. Fonofos |
| | X. Mecarbam, |
| | XI. Mephosfolan |
| | XII. Methidathion |
| | XIII. Mevinphos |
| | XIV. Omethoate |
| | XV. Ox demeton-Methyl |
| | XVI. Parathion |
| | XVII. Phenkapton, |
| | XVIII. Phorate |
| | XIX. Phosphamidon |
| | XX. Perimorphs-Ethyl |
| | XXI. Quinalphos |
| | XXII. Thiometon |
| | XXIII. Thionazin |
| | XXIV. Triazophos |

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| | XXV. Vamidotion |
| 32. | Potassium hydroxide 17% |
| 33. | Sodium hydroxide 12% |
| 34. | Sodium nitrite |
| 35. | Thiofanox |
| 36. | Zinc phosphide |
| | |
| | 5E-Other Laboratory chemicals |
| 1. | 1-Naphthol |
| 2. | 4-Aminobenzoic acid |
| 3. | Acetic acid glacial |
| 4. | Acetic anhydride |
| 5. | Acetone |
| 6. | Acetonitrile |
| 7. | Acetonitrile |
| 8. | Acetyl chloride |
| 9. | Adipic acid |
| 10. | Aluminum (III) ammonium sulfate |
| 11. | Aluminum (III) potassium sulfate |
| 12. | Ammonium acetate |
| 13. | Ammonium carbonate |
| 14. | Ammonium chloride |
| 15. | Ammonium dihydrogen phosphate |
| 16. | Ammonium hydrogen carbonate |
| 17. | Ammonium sulfate |

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| 18. | Ammonium thiocyanate |
| 19. | Antimony (III) chloride |
| 20. | Barium chloride |
| 21. | Benzaldehyde |
| 22. | Benzalkonium chloride |
| 23. | Benzene |
| 24. | Benzethonium chloride |
| 25. | Benzoic acid |
| 26. | Benzoyl chloride |
| 27. | Benzyl alcohol |
| 28. | Benzyl chloride |
| 29. | Benzylamine |
| 30. | Boric acid |
| 31. | Butanol |
| 32. | Calcium carbonate, powder |
| 33. | Calcium chloride |
| 34. | Calcium chloride, anhydrous |
| 35. | Calcium sulfate |
| 36. | Chloroform |
| 37. | Citric acid |
| 38. | Copper (I I) sulfate |
| 39. | Dichloro-2,6-phenol-indophenol sodium salt |
| 40. | Dichloromethane |
| 41. | Diethylamine |
| 42. | Diethylene glycol |

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| 43. | Diethyl ether |
| 44. | Di isopropyl ether |
| 45. | Dimethyl sulfoxide |
| 46. | di-Potassium hydrogen phosphate |
| 47. | EDTA |
| 48. | Ethyl acetate |
| 49. | Ethyl methyl ketone |
| 50. | Ethylenediamine |
| 51. | Formaldehyde |
| 52. | Formamide |
| 53. | Formic acid |
| 54. | Fumaric acid |
| 55. | Glutaraldehyde |
| 56. | Hexamethylenetetramine |
| 57. | Hexane-1-sulfonic acid |
| 58. | Hydrochloric acid |
| 59. | Hydrogen peroxide |
| 60. | Hydroquinone |
| 61. | Hydroxylammonium chloride |
| 62. | Iodine |
| 63. | Iron (III) chloride |
| 64. | Lead (II) acetate |
| 65. | Lugol solution |
| 66. | Magnesium chloride |
| 67. | Magnesium sulfate |

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| 68. | Mercury (I I) iodide |
| 69. | Methane sulfonic acid |
| 70. | Methanol |
| 71. | Methyl salicylate |
| 72. | N, N-Dimethylanilines |
| 73. | N, N-Dimethylformamide |
| 74. | Naphthalene |
| 75. | Nitric acid |
| 76. | Oxalic acid |
| 77. | Perchloric acid |
| 78. | Phosphoric acid |
| 79. | Potassium acetate |
| 80. | Potassium bromide |
| 81. | Potassium chloride |
| 82. | Potassium hydrogen carbonate |
| 83. | Potassium hydrogen phthalate |
| 84. | Potassium hydroxide |
| 85. | Potassium iodide |
| 86. | Potassium nitrate |
| 87. | Potassium permanganate |
| 88. | Potassium sodium tartrate |
| 89. | Potassium sulfate |
| 90. | Potassium thiocyanate |
| 91. | Propanol |
| 92. | Silver chloride |

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| 93. | Silver nitrate |
| 94. | Sodium acetate |
| 95. | Sodium bromates |
| 96. | Sodium bromide |
| 97. | Sodium carbonate |
| 98. | Sodium chloride |
| 99. | Sodium citrate |
| 100. | Sodium dihydrogen phosphate |
| 101. | Sodium disulfate |
| 102. | Sodium dodecyl sulfate |
| 103. | Sodium fluoride |
| 104. | Sodium hexanitrocobaltate (III) |
| 105. | Sodium hydrogen carbonate |
| 106. | Sodium hydroxide |
| 107. | Sodium iodide |
| 108. | Sodium nitrate |
| 109. | Sodium oxalate |
| 110. | Sodium phosphate |
| 111. | Sodium sulfite |
| 112. | Sulfanilamide |
| 113. | Sulfuric acid |
| 114. | Tetrachloroethylene |
| 115. | Tetrachloroethylene |
| 116. | Tetrahydrofuran |
| 117. | Tetra-n-butylammonium bromide |

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| 118. | Tetra-n-butylammonium hydrogen sulfate |
| 119. | Tetra-n-butylammonium iodide |
| 120. | Thioglycolic acid |
| 121. | Trichloroacetic acid |
| 122. | Triethanolamine |
| 123. | Triethylamine |
| 124. | Trifluoroacetic acid |
| 125. | Tween 20, 80 |
| 126. | Urea |
| 127. | Zinc acetate |
| 128. | Zinc chloride, anhydrous |
| 129. | Zinc sulfate |

Annex VIII: Prohibited Chemicals

| | Prohibited Pharmaceuticals |
|----|--|
| 1 | Acetorphine. |
| 2 | Acetyl-Alpha-Methylfentanyl. |
| 3 | Alkoxyamfetamines And Substituted Alkoxyamfetamines Except When Separately Specified In These Schedules. |
| 4 | Alkoxyphenylethylamines And Substituted Alkoxyphenylethylamines Except When Separately Specified In These Schedules. |
| 5 | Alkylthioamfetamines And Substituted Alkylthioamfetamines Except When Separately Specified In These Schedules. |
| 6 | Allylprodine. |
| 7 | Alphameprodine. |
| 8 | Alpha-Methylfentanyl. |
| 9 | Alpha-Methylthiofentanyl. |
| 10 | Alphamethadol. |
| 11 | Alpha-Pyrrolidinovalerophenone *(Alpha-Pvp). |
| 12 | 2-Amino-1-(2,5-Dimethoxy-4-Methyl) Phenylpropane *(Stp Or Dom). |
| 13 | 5-(2-Aminopropyl) Indan And Substituted 5-(2-Aminopropyl)Indans Except When Separately Specified In These Schedules. |
| 14 | Benzethidine. |
| 15 | Benzoylindoles Except When Separately Specified In These Schedules. |
| 16 | Benzylpiperazine *(Bzp). |
| 17 | Betacetylmethadol. |
| 18 | Beta-Hydroxyfentanyl. |
| 19 | Beta-Hydroxy-3-Methylfentanyl. |
| 20 | Betameprodine. |
| 21 | Betamethadol. |
| 22 | Betaprodine. |
| 23 | 1-(8-Bromobenzo[1,2-B;4,5-B]Difuran-4-Yl)-2-Aminopropane *(Bromo-Dragonfly). |
| 24 | 4-Bromo-2,5-Dimethoxyphenethylamine *(Bdmpea). |
| 25 | Bufotenine. |
| 26 | Cannabis (Including Seeds, Extracts, Resins, And The Plant And Any Part Of The Plant When Packed Or Prepared), As Specified In The Narcotic And Psychotropic Substances Act. |
| 27 | Cathinones Except When Separately Specified In These Schedules. |
| 28 | Clonazolam. |
| 29 | Clonitazene. |
| 30 | Coca Leaf. |
| 31 | Codoxime. |
| 32 | 4-Cyano-2-Dimethylamino-4,4'-Diphenylbutane. |

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| 33 | Cyclohexylphenols Except |
| 34 | a) When Separately Specified In These Schedules; Or |
| 35 | b) In Preparations Containing 0.5 Per Cent Or Less Of Cyclohexylphenols. |
| 36 | Deschloroetizolam. |
| 37 | Desomorphine. |
| 38 | N,N-Dialkylaminocyclohexyl Alkyl Benzamides Except When Separately Specified In These Schedules. |
| 39 | N,N-Dialkylaminocyclohexylmethyl Alkyl Benzamides Except When Separately Specified In These Schedules. |
| 40 | Diampromide. |
| 41 | Dibenzopyrans Except When Separately Specified In These Schedules. |
| 42 | 3,4-Dichloro-N-[(1r,2r)-2-(Dimethylamino)Cyclohexyl]-N-Methylbenzamide (U-47700). |
| 43 | 3,4-Dichloro-N-[[1-(Dimethylamino)Cyclohexyl]Methyl]Benzamide *(Ah-7921). |
| 44 | Diclazepam. |
| 45 | Diethylthiambutene. |
| 46 | N,N-Diethyltryptamine *(Det). |
| 47 | Dimenoxadol. |
| 48 | Dimepheptanol. |
| 49 | 2,5-Dimethoxyamfetamine *(Dma). |
| 50 | 2,5-Dimethoxy-4-Bromoamfetamine *(Dob). |
| 51 | 2,5-Dimethoxy-4-Ethyl-A-Amfetamine *(Doet). |
| 52 | 2,5-Dimethoxy-4-Ethylthiophenethylamine *(2c-T-2). |
| 53 | 2,5-Dimethoxy-4-Iodophenethylamine *(2c-I). |
| 54 | 2,5-Dimethoxy-4-(N)-Propylthiophenethylamine *(2c-T-7). |
| 55 | 3-(2-Dimethylaminoethyl)-4-Hydroxyindole *(Psilocine Or Psilotsin). |
| 56 | 3-(1,2-Dimethylheptyl)-1-Hydroxy-7,8,9,10-Tetrahydro-6,6,9- Trimethyl-6h-Dibenzo (B,D) Pyran *(Dmhp). |
| 57 | N, A -Dimethyl-3,4-(Methylenedioxy)Phenylethylamine *(Mdma). |
| 58 | N,N-Dimethylamfetamine (Dimetamfetamine). |
| 59 | Dimethylthiambutene. |
| 60 | N,N-Dimethyltryptamine *(Dmt). |
| 61 | Dioxaphetyl Butyrate. |
| 62 | Ecgonine. |
| 63 | N-Ethyl-A-Methyl-3,4-(Methylenedioxy)Phenethylamine *(N-Ethyl Mda). |
| 64 | Ethylmethylthiambutene. |
| 65 | Eticyclidine *(Pce). |
| 66 | Etonitazene. |
| 67 | Etorphine. |
| 68 | Etoxidine. |
| 69 | Fenetylline. |

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| 79 | 4-Fluoro-N-Methylamfetamine. |
| 71 | Flubromazepam. |
| 72 | Flubromazolam. |
| 73 | 1-(5-Fluoropentyl)-3-(2-Iodobenzoyl)Indole *(Am-694). |
| 74 | Furethidine. |
| 75 | Harmala Alkaloids Except In Herbs, Or Preparations, For Therapeutic Use: |
| 76 | Containing 0.1 Per Cent Or Less Of Harmala Alkaloids; Or A) |
| 77 | In Divided Preparations Containing 2 Mg Or Less Of Harmala Alkaloids Per B)Recommended Daily Dose. |
| 78 | Heroin. |
| 79 | 3-Hexyl-1-Hydroxy-7,8,9,10-Tetrahydro-6,6,9-Trimethyl-6h-Dibenzo (B,D) Pyran *(Parahexyl). |
| 80 | 4-Hydroxybutanoic Acid And Its Salts Except For Sodium Oxybate When In Schedule 5a. *(Gamma Hydroxybutyrate (Ghb)). |
| 81 | 2-[(1r,3s)-3-Hydroxycyclohexyl]-5-(2-Methylnonan-2-Yl)Phenol *(Cannabicyclohexanol Or Cp 47,497 C8 Homologue). |
| 82 | 2-[(1r,3s)-3-Hydroxycyclohexyl]-5-(2-Methyloctan-2-Yl)Phenol *(Cp 47,497). |
| 83 | Hydroxypethidine. |
| 84 | Isomethadone. |
| 85 | Ketobemidone. |
| 86 | Levomethorphan (Excluding Its Stereoisomers). |
| 87 | Levophenacymorphan. |
| 88 | Lysergic Acid. |
| 89 | Lysergide. |
| 90 | Meclonazepam. |
| 91 | Mecloqualone. |
| 92 | Metazocine. |
| 93 | Methaqualone. |
| 94 | Methcathinone. |
| 95 | 5-Methoxy- A -Methyltryptamine *(5-Meo-Amt). |
| 96 | 5-Methoxy-3,4-Methylenedioxyamfetamine *(Mmda). |
| 97 | 4-Methoxy- A -Methylphenylethylamine *(Pma). |
| 98 | 2-(2-Methoxyphenyl)-1-(1-Pentylindol-3-Yl)Ethanone *(Jwh-250). |
| 99 | Methyl (2s, 4ar, 6ar, 7r, 9s, 10as, 10br)-9-Acetoxy-6a,10b-Dimethyl-4,10-Dioxo-Dodecahydro-2-(3-Furyl)-2h-Naphtho[2,1-C]Pyran-7-Carboxylate *(Salvinorin A). |
| 80 | 4-Methylaminorex. |
| 81 | Methyl-desorphine. |
| 82 | 3,4-Methylenedioxyamfetamine *(Mda). |
| 83 | 3,4-Methylenedioxypropiovalerone *(Mdpv). |
| 84 | 3-Methylfentanyl. |
| 85 | 4-Methylmethcathinone *(Mephedrone). |

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| 86 | N- A -[Methyl-3,4-(Methylenedioxy)Phenethyl]Hydroxylamine *(N-Hydroxy Mda). |
| 87 | N-Methyl-1-(3,4-Methylenedioxyphenyl)-2-Butanamine *(Mbdb). |
| 88 | 2-Methyl-3-Morpholino-1, 1-Diphenylpropane Carboxylic Acid (Moramide Intermediate). |
| 89 | Methylone *(Mdmc). |
| 90 | 1-Methyl-4-Phenyl-4-Piperidinol Propionate *(Mppp). |
| 91 | 4-Methylthioamphetamine. |
| 92 | 3-Methylthiofentanyl. |
| 93 | Metopon. |
| 94 | Mitragyna Speciosa. |
| 95 | Mitragynine. |
| 96 | Morpheridine. |
| 97 | (1-(2-Morpholin-4-Ylethyl)Indol-3-Yl)-Naphthalen-1-Ylmethanone *(Jwh-200). |
| 98 | Muscimol. |
| 99 | Myrophine. |
| 100 | Naphthoylindoles Except When Separately Specified In These Schedules. |
| 102 | Naphthylmethylindoles Except When Separately Specified In These Schedules. |
| 103 | Naphthoylpyrroles Except When Separately Specified In These Schedules. |
| 104 | Naphthylmethylindenes Except When Separately Specified In These Schedules. |
| 105 | Naphthalen-1-Yl-(1-Butylindol-3-Yl)Methanone *(Jwh-073). |
| 106 | Nicocodine. |
| 107 | Nicodicodine. |
| 108 | Nicomorphine. |
| 109 | Nifoxipam. |
| 110 | Noracymethadol. |
| 112 | Norlevorphanol. |
| 113 | Normorphine. |
| 114 | Norpipanone. |
| 115 | Para-Fluorofentanyl. |
| 116 | 1-Pentyl-3-(4-Methyl-1-Naphthoyl)Indole. *(Jwh-122). |
| 117 | 1-Pentyl-3-(1-Naphthoyl)Indole *(Jwh-018). |
| 118 | Phenadoxone. |
| 119 | Phenampramide. |
| 120 | Phenazocine. |
| 121 | Phencyclidine *(Pcp). |
| 122 | Phenibut. |
| 123 | N-Phenethyl-4-Piperidone. |
| 124 | Phenomorphan. |

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| 125 | Phenylacetylindoles Except When Separately Specified In These Schedules. |
| 126 | 1-Phenylethyl-4-Phenyl-4-Piperidinol Acetate *(Pepap). |
| 127 | Piminodine. |
| 128 | Proheptazine. |
| 129 | Properidine. |
| 130 | Psilocybine. |
| 131 | Pyrazolam. |
| 132 | Racemethorphan. |
| 133 | Racemorphan. |
| 134 | Rolicyclidine *(Php Or Pcpy). |
| 135 | Salvia Divinorum. |
| 136 | Synthetic Cannabinomimetics Except When Separately Specified In These Schedules. |
| 137 | Tenocyclidine *(Tcp). |
| 138 | Tetrahydrocannabinols And Their Alkyl Homologues, Except: |
| 139 | When Included In Schedule 4 Or Schedule 4d; Or A) |
| 140 | Processed Hemp Fibre Containing 0.1 Per Cent Or Less Of Tetrahydrocannabinols, And B)Hemp Fibre Products Manufactured From Such Fibre; Or |
| 141 | In Hemp Seed Oil For Purposes Other Than Internal Human Use Containing 50 Mg/Kg Or C)Less Of Total Cannabinoids, Including 20 Mg/Kg Or Less Of Tetrahydrocannabinols, When Labelled With Either Of The Following Warning Statements: |
| i. | ii. Not For Internal Use; Or |
| iii. | iv. Not To Be Taken. |
| 142 | Thiofentanyl. |
| 143 | 1-(3-Trifluoromethylphenyl)Piperazine *(Tfmpp). |
| 144 | Trimeperidine. |
| 145 | 3,4,5-Trimethoxy- A -Methylphenylethylamine *(Tma). |
| 146 | 3,4,5-Trimethoxyphenethylamine (Mescaline) And Other Substances Structurally Derived From Methoxy-Phenylethylamine Except: |
| 147 | Methoxyphenamine; Or A) When Separately Specified In This Schedule. B) |
| 148 | 1-(3,4,5-Trimethoxyphenyl)-2-Aminobutane. |

Prohibited and Restricted Chemicals

| | Chemical | CAS number | Category |
|---|---|-------------|-----------|
| 1 | <u>2,4,5-T and its salts and esters</u> | 93-76-5 (*) | Pesticide |

| | | | |
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| 2 | <u>Alachlor</u> | 15972-60-8 | Pesticide |
| 3 | <u>Aldicarb</u> | 116-06-3 | Pesticide |
| 4 | <u>Aldrin</u> | 309-00-2 | Pesticide |
| 5 | <u>Azinphos-methyl</u> | 86-50-0 | Pesticide |
| 6 | <u>Binapacryl</u> | 485-31-4 | Pesticide |
| 7 | <u>Captafol</u> | 2425-06-1 | Pesticide |
| 8 | <u>Carbofuran</u> | 1563-66-2 | Pesticide |
| 9 | <u>Chlordane</u> | 57-74-9 | Pesticide |
| 10 | <u>Chlordimeform</u> | 6164-98-3 | Pesticide |
| 11 | <u>Chlorobenzilate</u> | 510-15-6 | Pesticide |
| 12 | <u>DDT***</u> (<i>For Kenya – consented to import</i>) | 50-29-3 | Pesticide |
| 13 | <u>Dieldrin</u> | 60-57-1 | Pesticide |
| 14 | <u>Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt)</u> | 534-52-1 | Pesticide |
| 15 | <u>Dinoseb and its salts and esters</u> | 88-85-7 (*) | Pesticide |
| 16 | <u>EDB (1,2-dibromoethane)</u> | 106-93-4 | Pesticide |
| 17 | <u>Endosulfan</u> | 115-29-7 | Pesticide |
| 18 | <u>Ethylene dichloride</u> | 107-06-2 | Pesticide |
| 19 | <u>Ethylene oxide</u> | 75-21-8 | Pesticide |
| 20 | <u>Fluoroacetamide</u> | 640-19-7 | Pesticide |
| 21 | <u>HCH (mixed isomers)</u> | 608-73-1 | Pesticide |

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| 22 | <u>Heptachlor</u> | 76-44-8 | Pesticide |
| 23 | <u>Hexachlorobenzene</u> | 118-74-1 | Pesticide |
| 24 | <u>Lindane (gamma-HCH)</u> | 58-89-9 | Pesticide |
| 25 | <u>Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds</u> | <u>CAS numbers</u> | Pesticide |
| 26 | <u>Methamidophos</u> | 10265-92-6 | Pesticide |
| 27 | <u>Monocrotophos</u> | 6923-22-4 | Pesticide |
| 28 | <u>Parathion</u> | 56-38-2 | Pesticide |
| 29 | <u>Pentachlorophenol and its salts and esters</u> | 87-86-5 (*) | Pesticide |
| 30 | <u>Phorate</u> | 298-02-2 | Pesticide |
| 31 | <u>Toxaphene (Camphechlor)</u> | 8001-35-2 | Pesticide |
| 32 | <u>Tributyl tin compounds</u> | 1461-22-9, 1983-10-4, 2155-70-6, 24124-25-2, 4342-36-3, 56-35-9, 85409-17-2 | Pesticide |
| 33 | <u>Trichlorfon</u> | 52-68-6 | Pesticide |
| 34 | <u>Dustable powder formulations containing a combination of benomyl at or above 7%, carbofuran at or above 10% and thiram at or above 15%</u> | 137-26-8, 1563-66-2, 17804-35-2 | Severely hazardous pesticide formulation |
| 35 | <u>Methyl-parathion (Emulsifiable concentrates (EC) at or above 19.5% active ingredient and dusts at or above 1.5% active ingredient)</u> | 298-00-0 | Severely hazardous pesticide formulation |
| 36 | <u>Phosphamidon (Soluble liquid formulations of the substance that exceed 1000 g active ingredient/l)</u> | 13171-21-6 | Severely hazardous pesticide formulation |

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| 37 | <u>Actinolite asbestos</u> | 77536-66-4 | Industrial |
| 38 | <u>Anthophyllite asbestos</u> | 77536-67-5 | Industrial |
| 39 | <u>Amosite asbestos</u> | 12172-73-5 | Industrial |
| 40 | <u>Crocidolite asbestos</u> | 12001-28-4 | Industrial |
| 41 | <u>Tremolite asbestos</u> | 77536-68-6 | Industrial |
| 42 | <u>Commercial octabromodiphenyl ether (including Hexabromodiphenyl ether and Heptabromodiphenyl ether)</u> | 36483-60-0, 68928-80-3 | Industrial |
| 43 | <u>Commercial pentabromodiphenyl ether (including tetrabromodiphenyl ether and pentabromodiphenyl ether)</u> | 32534-81-9, 40088-47-9 | Industrial |
| 44 | <u>Hexabromocyclododecane</u> | 134237-50-6, 134237-51-7, 134237-52-8, 25637-99-4, 3194-55-6 | Industrial |
| 45 | <u>Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls</u> | 1691-99-2, 1763-23-1, 24448-09-7, 251099-16-8, 2795-39-3, 29081-56-9, 29457-72-5, 307-35-7, 31506-32-8, 4151-50-2, 56773-42-3, 70225-14-8 | Industrial |
| 46 | <u>Polybrominated Biphenyls (PBBs)</u> | <u>13654-09-6, 27858-07-7, 36355-01-8</u> | Industrial |
| 47 | <u>Polychlorinated Biphenyls (PCBs)</u> | <u>1336-36-3</u> | Industrial |
| 48 | <u>Polychlorinated Terphenyls (PCTs)</u> | 61788-33-8 | Industrial |
| 49 | <u>Short-chain chlorinated paraffins (SCCP)</u> | 85535-84-8 | Industrial |
| 50 | <u>Tetraethyl lead</u> | 78-00-2 | Industrial |
| 51 | <u>Tetramethyl lead</u> | 75-74-1 | Industrial |
| 52 | <u>Tributyltin compounds</u> | 1461-22-9, 1983-10-4, 2155-70-6, 24124-25-2, 4342-36-3, 56-35-9, 85409-17-2 | Industrial |

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| 53 | Tris(2,3 dibromopropyl)phosphate | 126-72-7 | Industrial |
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Prohibited & Restricted Ingredients in Cosmetics

| | Ingredient | Details |
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| 1. | Bithionol | <p>The use of bithionol in cosmetics is prohibited because it may cause photocontact sensitization</p> <p>WHO Comment: Bithionol, which has bactericidal and anthelmintic activity, was formerly available in soaps. By the late 1960s use of such preparations had been associated with a risk of photosensitivity reactions and cross-sensitivity with other halogenated disinfectants. This resulted in their withdrawal in the USA. Oral preparations of bithionol remain available for the treatment of paragonimiasis and fascioliasis.</p> |
| 2. | Chlorofluorocarbon propellants | <p>The use of chlorofluorocarbon propellants in cosmetic aerosol products intended for domestic consumption is prohibited</p> |
| 3. | Chloroform | <ul style="list-style-type: none"> - causes cancer in animals and is likely to be harmful to human health, too. - an exception for residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient <p>WHO Comment: Chloroform was formerly widely used in pharmaceutical preparations as a solvent and preservative as well as for its anaesthetic and flavouring properties. By the late 1970s reservations concerning its safety, including positive results in a carcinogenicity screening programme sponsored by the National Cancer Institute in the USA, had led to considerable restrictions in its use in pharmaceutical preparations. While many pharmaceutical products</p> |

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| | | <p>containing chloroform have been withdrawn or reformulated to exclude this substance, it may still be incorporated in toothpastes and other specified products in some countries, subject to statutorily-imposed concentration limits. (Reference: (IARCCD) Chloroform: IARC Monograph, 20(20), 401-427, 1979)</p> |
| 4. | Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide) | <p>Prohibited in cosmetic products because they may cause serious skin disorders</p> <p>WHO Comment: Halogenated salicylanilides, including dibromsalan, metabromsalan, tribromsalan and tetrachlorosalicylanilide, which have antibacterial and antifungal activity, have been used both as active ingredients for antimicrobial purposes and as inactive ingredients (preservatives) in drug and cosmetic products. Their use has been associated with photosensitive eruptions and disabling skin disorders which has resulted in their withdrawal by some national drug regulatory authorities.</p> |
| 5. | Hexachlorophene | <p>Because of its toxic effect and ability to penetrate human skin, hexachlorophene (HCP) may be used only when no other preservative has been shown to be as effective. Where it is required in a cosmetic, the HCP concentration may not exceed 0.1 percent, and it may not be used in cosmetics that are applied to mucous membranes, such as the lips.</p> <p>WHO Comment: Hexachlorophene, an antimicrobial agent, was introduced in 1948 in proprietary liquid preparations and powders and was subsequently used extensively as a topical antiseptic. By the early 1970s its use in infants had been conclusively demonstrated to cause encephalopathy as a result of transdermal</p> |

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| | | <p>absorption. More recently it has been suggested that the drug has a teratogenic potential. Many regulatory authorities have placed rigorous restrictions on the medicinal use of hexachlorophene, particularly in preparations intended for infants. However, its use still commonly remains permissible at low concentrations as a preservative in toiletries and cosmetics. (Reference: (WHODI) WHO Drug Information, 3, 6, 1978)</p> |
| 6. | Mercury compounds | <p>Mercury compounds are readily absorbed through the skin on topical application and tend to accumulate in the body. They may cause allergic reactions, skin irritation, or neurotoxic problems.</p> <p>WHO Comment: Mercuric derivatives were formerly widely available in topical antiinfective preparations. The hazards associated with their use, including hypersensitivity and allergy, outweigh any therapeutic benefit and such preparations have been withdrawn in many countries. Systemic absorption has resulted in chronic mercury poisoning and acrodynia (pink disease) in children.</p> |
| 7. | Methylene chloride | <p>Causes cancer in animals and is likely to be also be harmful to human health</p> |
| 8. | Prohibited cattle materials | <p>To protect against bovine spongiform encephalopathy (BSE), also known as "mad cow disease," cosmetics may not be manufactured from, processed with, or otherwise contain, prohibited cattle materials. These materials include specified risk materials*, material from non-ambulatory cattle, material from cattle not inspected and passed, or mechanically separated beef.</p> |
| 9. | Sunscreens in cosmetics | <p>Use of the term "sunscreen" or similar sun protection wording in a product's labeling generally causes the product to be subject to regulation</p> |

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| | | as a drug or a drug/cosmetic, depending on the claims. However, sunscreen ingredients may also be used in some cosmetic products to protect the products' color. The labelling must also state why the sunscreen ingredient is used, for example, "Contains a sunscreen to protect product color." If this explanation isn't present, the product may be subject to regulation as a drug |
| 10. | Vinyl chloride | <p>vinyl chloride is prohibited as an ingredient of aerosol products, because it causes cancer and other health problems.</p> <p>Vinyl Chloride (chloroethylene) is banned in the USA for use as a pesticide or in pesticidal products. Registration was cancelled for all pesticides containing vinyl chloride, whether as an active or inert ingredient, for uses in the home, food-handling establishments, hospitals, or enclosed areas in April 1974. Vinyl chloride is not allowed in any pesticidal product.</p> <p>Animal studies demonstrated carcinogenic effects of vinyl chloride in rats, mice and hamsters. Moreover, vinyl chloride was causally linked to angiosarcoma of the liver in workers who had close occupational contact with it. Vinyl chloride is also persistent in the air.</p> <p>USA (Reference: (EP1) UNEP/FAO - PIC Circular X - 12/1999, , ,)</p> |
| 11. | Zirconium-containing complexes | <p>The use of zirconium-containing complexes in aerosol cosmetic products is prohibited because of their toxic effect on lungs of animals, as well as the formation of granulomas in human skin.</p> <p>Withdrawn from the market in 1977 and prohibited for export by the US Food and Drug Administration on the basis of negative animal toxicity tests including the development of skin granulomas and toxic effects in the lungs and other organs, and an adverse benefit to-risk ratio for humans.</p> |

Annex IX: Pharmaceutical Raw Materials

| Schedules 7A : Excipients | | | | |
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| 1 | 7A (i) General Excipients | Widely used in pharmaceutical sector without special labelling requirement. | | |
| | | These are general excipients which do not require special warning and are used day to day | | |
| | | <p style="text-align: center;">Examples;</p> Acacia Acesulfame Potassium Almond Oil Ammonium Alginate Alginates/ Alginic Acid Attapulgate Benzyl Alcohol Butylparaben Calcium Acetate Calcium Alginate Calcium Carbonate Calcium Chloride Calcium Lactate Calcium phosphate Calcium Phosphate Calcium Silicate Calcium Stearate Calcium Sulfate Calcium Hydroxide Canola Oil Carbomer Carbon Dioxide Carboxymethylcellulose Calcium Carboxymethylcellulose Sodium Carboxymethylcellulose Sodium Carrageenan Castor Oil Castor Oil Hydrogenated Cellulose Acetate Cellulose Acetate Phthalate | Ceratonia Ceresin Cetostearyl Alcohol Cetrimide Cetyl Alcohol Cetylpyridinium Chloride Chitosan Chlorhexidine Chlorobutanol Chlorocresol Citric Acid Monohydrate Coconut Oil Corn Oil Corn Starch Pregelatinized Starch Cottonseed Oil Cresol Croscarmellose Sodium Crospovidone Cyclodextrins Cyclomethycaine Dextrates Dextrine Dextrose Ethanol Fructose Gélatine Glucose Liquid Glycerin Guar Gum Isopropyl Alcohol Kaolin | Paraffin Peanut Oil Peppermint Petrolatum Potassium Alginate Potassium Alum Potassium Benzoate Potassium Bicarbonate Potassium Chloride Potassium Citrate Saccharin Saccharin Sodium Safflower Oil Saponite Sesame Oil Shellac Silica Simethicone Sodium Acetate Sodium Alginate Sodium Ascorbate Sodium Benzoate Sodium Bicarbonate Sodium Chloride Sodium Citrate Dihydrate Soybean Oil Starch Pregelatinized Starch Sterilizable Maize Sucrose Sucrose Octa acetate Sugar Spheres Sugar |

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| | | Cellulose Microcrystalline Cellulose Microcrystalline Cellulose Powdered Cellulose Silicified Microcrystalline | Lanolin Lanolin Alcohols Lanolin Hydrous Menthol Mineral Oil Olive Oil | Compressible Sugar Confectioner's Sunflower Oil Talc Turmeric |
| 2 | 6A(ii) Special Excipients | Excipients with special labelling requirements or which is controlled | | |
| | | <p>Examples; Acetic Acid, Glacial Acetone, Acetyl tributyl Citrate, Acetyl triethyl Citrate, Adipic Acid, Albumin, Aliphatic Polyesters, Alitame, Alpha Tocopherol Aluminium adjuvants</p> <p>Example AluminiumHydroxide Aluminium Monostearate, Aluminium Oxide, Aluminium Phosphate Ammonia Solution, Ammonium Chloride, Ascorbic Acid, Ascorbyl Palmitate, Aspartame, Bee's wax, Bentonite, Benzalkonium Chloride,</p> | <p>Imidurea, Inulin, Iron Oxides, Isomalt Isopropyl Myristate, Isopropyl Palmitate Lactic Acid Lactitol, lactose, Lactose, Anhydrous, Lactose, Inhalation, Lactose, Monohydrate Lactose, Monohydrate and Corn Starch, Lactose, Monohydrate and Microcrystalline Cellulose, Lactose, Monohydrate and Povidone Lactose, Monohydrate and Powdered Cellulose, Lactose, Spray-Dried Lanolin, Lauric Acid, Lecithin, Leucine,</p> | <p>Polyoxymethylene Sorbitan, Fatty Acid Esters, Polyoxymethylene Stearates Polyoxylglycerides, Polyvinyl Acetate Phthalate, Polyvinyl Alcohol Potassium Hydroxide, Potassium Metabisulfite, Potassium Sorbate Povidone, Propionic Acid, Propyl Gallate, Propylene Carbonate Propylene Glycol, Propylene Glycol Alginate, Propylparaben Propylparaben Sodium, Pyrrolidone, Raffinose, Sodium Borate Sodium Carbonate, Sodium Cyclamate, Sodium Formaldehyde Sulfoxylate Sodium Hyaluronate,</p> |

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| | <p>Benzethonium Chloride, Benzoic Acid Benzyl Benzoate, Boric Acid, Bronopol, Butylated Hydroxy anisole Butylated Hydroxytoluene, Butylene Glycol, Chlorodifluoromethane (HCFC) Chlorofluorocarbons (CFC), Chloroxyleneol, Cholesterol, Colloidal Silicon Dioxide, Colouring Agents, Crosopovidone, Denatonium Benzoate Dibutyl Phthalate, Dibutyl Sebacate, Diethanolamine, Diethyl Phthalate Difluoroethane (HFC), Dimethicone, Dimethyl Ether, Dimethyl Phthalate Dimethyl Sulfoxide, Dimethylacetamide, Disodium Edetate, Docusate Sodium, Edetic Acid, Erythorbic Acid, Erythritol, Ethyl Acetate Ethyl Lactate, Ethyl Maltol, Ethyl Oleate, Ethyl Vanillin, Ethyl cellulose Ethylene Glycol Stearates, Ethylene Vinyl Acetate, Ethyl paraben</p> | <p>Linoleic Acid Macrogol 15 Hydroxy stearate, Magnesium Aluminium Silicate Magnesium Carbonate, Magnesium Oxide, Magnesium Silicate Magnesium Stearate, Magnesium Trisilicate, Maleic Acid, Malic Acid Maltitol, Maltitol Solution, Maltodextrin, Maltol, Maltose, Mannitol Medium-chain Triglycerides, Meglumine, Methanol, Methionine Methylcellulose, Methylparaben, Monoethanolamide, Monosodium Glutamate, Monothioglycerol, Myristic Acid, Myristyl Alcohol Neo hesperidin Dihydrochalcone, Neotame, Nitrogen, Nitrous Oxide Octyldodecanol, Oleic Acid, Oleyl Alcohol, Palmitic Acid, Peanut, Pectin Pentetic Acid,</p> | <p>Sodium Hydroxide, Sodium Lactate Sodium Lauryl Sulphate, Sodium Metabisulfite, Sodium Phosphate, Dibasic Sodium Phosphate, Monobasic Sodium Propionate, Sodium Starch Glycolate, Sodium Stearyl Fumarate, Sodium Sulphite, Sodium Thiosulfate Sorbic Acid, Sorbitan Esters (Sorbitan Fatty Acid Esters), Sorbitol Stearic Acid, Stearyl Alcohol, Sucralose, Sulfobutylether b-Cyclodextrin Sulphur Dioxide, Sulfuric Acid, Suppository Bases, Hard Fat, Tagatose Tartaric Acid, Tetrafluoroethene (HFC), Thaumatococin, Thimerosal, Thymol Titanium Dioxide, Toluene, Tragacanth, Trehalose, Triacetin, Tributyl Citrate, Tricaprylin, Triethanolamine, Triethyl Citrate,</p> | |
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| | | <p>Fumaric Acid, Gelatine, Glyceryl Behenate, Glyceryl Monooleate Glyceryl Monostearate, Glyceryl Palmitostearate, Glycine, Glycofurol Hectorite, Heptafluoropropane (HFC), Hexetidine, Honey, Hydrocarbons (HC), Hydrochloric Acid, Hydrophobic Colloidal Silica, Hydroxyethyl Cellulose, Hydroxyethyl methyl Cellulose, Hydroxypropyl Betadex Hydroxypropyl Cellulose, Hydroxypropyl Cellulose, Low-substituted Hydroxypropyl Starch, Hypromellose, Hypromellose Acetate Succinate Hypromellose Phthalate,</p> | <p>Phenol, Phenoxyethanol, Phenylethyl Alcohol, Phenylmercuric Acetate, Phenylmercuric Borate, Phenylmercuric Nitrate, Phospholipids Phosphoric Acid, Polacrilin Potassium, Poloxamer, Poly (DL-Lactic Acid) Poly (methyl vinyl ether/maleic anhydride), Polycarbophil, Polydextrose Polyethylene Glycol, Polyethylene Oxide, Polymethacrylates, Polyoxymethylene Alkyl Ethers, Polyoxymethylene Castor Oil Derivatives</p> | <p>Triolein, Vanillin Vegetable Oil, Hydrogenated, Vitamin E Polyethylene Gly Succinate Wax, Anionic Emulsifying, Wax, Carnauba, Wax, Cetyl Esters, Wax, Microcrystalline, Wax, Non-ionic Emulsifying Wax, White, Wax, Yellow Xanthan Gum, Xylitol, Zein, Zinc Acetate, Zinc Stearate</p> |
| | Schedule 6B: Active Pharmaceutical Ingredients | | | |
| 3 | Anti-diabetics Thyroid hormone | Alpha glucosidase inhibitors | | |
| | | Examples; Acarbose, Miglitol | | |
| | | Biguanides Examples; Metformin | | |
| | | Dipeptidylpeptidase-4-inhibitors | | |

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| | <p>Examples Al gliptin, Linagliptin, Sax gliptin, Sitagliptin, Vildagliptin</p> |
| | <p>Glucagon-like peptide -1 receptor agonists Albiglutide, Dulaglutide, Exenatide, Liraglutide, Lixisenatide, Semaglutide</p> |
| | <p>Meglitinides Example. Nate glinide, Repaglinide</p> |
| | <p>Sodium glucose co-transporter Examples; Canagliflozin, Dapagliflozin, Empagliflozin</p> |
| | <p>Sulfonylureas Examples; Chlorpropamide, Glibenclamide, Gliclazide, Glimepiride, Glipizide, Gliquidone, Tolbutamide</p> |
| | <p>Thiazolidinediones Examples; Pioglitazones,</p> |

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| | Rosiglitazone |
| | Insulins Examples; Biphasic isophane insulin, Isophane insulin, Biphasic insulin asp art, Biphasic insulin lispro, Insulin degludec Insulin detemir, Insulin glargine, Insulin zinc suspension, Protamine zinc insulin, Insulin, Insulin asp art, Insulin glulisine Insulin lispro |
| | Glycogenolytic hormones Examples; Glucagon |
| | Anti-thyroid Examples; Thyrotropin alfa |
| | Sulphur-containing imidazole Examples; Carbimazole |
| | Thiouracils Examples; Propylthiouracil |
| | Vitamins and trace elements Examples; Iodide with iodine |
| | Thyroid hormones Examples; Levothyroxine, Liothyronine |

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| 4 | Antidiuretic hormone disorders | Vasopressin and analogues Examples; Desmopressin, Vasopressin |
| | | Selective vasopressin V2 receptor antagonists' Example. Tolvaptan |
| 5 | Disorders of bone metabolism | Bisphosphonates Examples; Alendronic acid, Cole calciferol, Ibandronic acid, Pamidronate disodium, Residronate sodium, Risedronate with calcium carbonate and Cole calciferol, Sodium clodronate, Zoledronic acid |
| | | Bone resorption inhibitors Examples; Calcitonin (salmon) Strontium ranelate |
| | | Parathyroid hormones analogues Examples; Teriparatide |
| 6 | Dopamine responsive conditions | Non-ergot receptor agonist Examples; Quinagolide |
| 7 | Gonadotrophin responsive conditions | Anti-gonadotrophin-releasing hormone Examples; Cetrorelix, Ganirelix Danazol |

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| | | <p>Gonadotrophin releasing hormone</p> <p>Examples; Buserelin, Goserelin, Leuprorelin, Nafarelin, Triptorelin</p> |
| 8 | Hypothalamic and anterior pituitary hormone related disorders | <p>Corticotrophins</p> <p>Examples; Tetracosactide</p> |
| | | <p>Gonadotrophins releasing hormone</p> <p>Examples; Gonadorelin</p> |
| | | <p>Gonadotrophins</p> <p>Examples; Choriogonadotropin alfa, Chorionic gonadotrophin, Corifollitropin alfa, Follitropin alfa & beta Follitropin alfa with lutropin alfa, Menotrophin, Urofollitropin</p> |
| | | <p>Growth hormone receptor antagonist</p> <p>Examples; Pegvisomant Octreotide</p> |
| | | <p>Human growth hormones</p> <p>Examples; Somatropin</p> |
| 9 | Sex hormone responsive conditions Female | <p>Bone resorption inhibitors</p> <p>Examples; Raloxifene</p> |

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| | | Oestrogens Examples; Diethylstilbesterol, Estradiol, Estriol, | Estrone, Ethinylestradiol, Gestodene, Tibolone, Mestranol |
| | | Progestogens Example ; Desogestrel, Dienogest, Drospirenone, Dydrogesterone Etonogestrel Gestodine Hydroxy progestérone Levonorgestrel, | Lynoestrenol, Medroxyprogesterone, Nomegestrel Norelgestromin, Norethisterone, Norethindrone, Norgestimate Norgestrel, Progesterone |
| | | Ovulation stimulants Examples; Clomiphene, Minotropins, Raloxifen | |
| 10 | Male Hormones | Androgens Examples; Testosterone and Mesterolone | |
| | | Anti-androgens Examples; Cyproterone and Dienogest | |
| | | Cushing's syndrome (Enzyme inhibitors) Examples; Metyrapone | |
| Central Nervous System | | | |
| 12 | Dementia | Centrally acting anticholinesterases Examples; Donepezil, Galantamine Rivastigmine | |

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| | | NMDA receptor antagonists Examples; Memantine | | |
| 13 | Epilepsy & seizure drugs | These drugs are used in the management of the following; Partial seizures and generalized seizures | | |
| | | <table border="1"> <tr> <td>Examples; Brivaracetam, Carbamazepine, Clonazepam, Eslicarbazepine, Ethosuximide Fosphenytoin sodium, Gabapentin, Lacosamide, Lamotrigine, Levetiracetam, Oxcarbazepine,</td> <td>Perampanel, Phenobarbitone Phenytoin, Pregabalin, Primidone, Rufinamide, Sodium valproate, Thiopental sodium, Tiagabine, Vigabatrin, Zonisamide</td> </tr> </table> | Examples; Brivaracetam, Carbamazepine, Clonazepam, Eslicarbazepine, Ethosuximide Fosphenytoin sodium, Gabapentin, Lacosamide, Lamotrigine, Levetiracetam, Oxcarbazepine, | Perampanel, Phenobarbitone Phenytoin, Pregabalin, Primidone, Rufinamide, Sodium valproate, Thiopental sodium, Tiagabine, Vigabatrin, Zonisamide |
| Examples; Brivaracetam, Carbamazepine, Clonazepam, Eslicarbazepine, Ethosuximide Fosphenytoin sodium, Gabapentin, Lacosamide, Lamotrigine, Levetiracetam, Oxcarbazepine, | Perampanel, Phenobarbitone Phenytoin, Pregabalin, Primidone, Rufinamide, Sodium valproate, Thiopental sodium, Tiagabine, Vigabatrin, Zonisamide | | | |
| 14 | Attention deficit hyperactivity disorders | Centrally acting sympathomimetics Example Atomoxetine, Dexamfetamine sulphate, Guanfacine, Lisdexamfetaminemesilate, Methylphenidate Hcl Bipolar disorder and mania Example Asenapine, Lithium carbonate | | |
| 15 | Antidepressants | Tricyclic and related antidepressants Example Amitriptyline Hcl, Clomipramine Hcl, Doxepin, Imipramine Hcl, Lofepamine, | | |

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| | MianserinHcl, Nortriptyline, Trazodone Hcl, Trimipramine | |
| | Mono Amine Oxidase inhibitors (MAO A &B) Example Isocarboxazid, Phenelzine, Tranlycypromine, Moclobemide | |
| | Selective serotonin Reuptake Inhibitors Example Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline | |
| | Serotonin and Noradrenaline Reuptake inhibitors Examples; Duloxetine, Venlafaxine | |
| | Serotonin Uptake inhibitors Examples; Trazodone Hcl | |
| | Tetracyclic antidepressants Examples; Mianserin, Mirtazapine | |
| | Noradrenaline Reuptake inhibitors Examples; Reboxetine | |
| | Melatonin receptor Agonists Examples; Agomelatine | |
| | Other antidepressants Example. Vortioxetine | |
| 16 | First Generation antipsychotics | Pericyazine, |

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| | Pyschoses and schizophrenia | Examples; Benperidol, Chlorpromazine Hcl Flupenthixoldecanoate FluphenazineDecanoate, Haloperidol, Loxapine, | Perphenazine, Pimozide, Promazine, Prochlorperazine, Sulpiride, Trifluoprazine, Zuclopenthixol acetate |
| | | Second Generation Antipsychotics Example Amisulpride, Aripiprazole, Clozapine, | LurasidoneHcl, Olanzapine, Paliperidone, Quetiapine, Risperidone |
| 17 | Movement disorders | CNS stimulant Example ; Piracetam | |
| | | Monoamine depleting drugs Examples; Tetrabenazine | |
| 18 | Muscle relaxants | Peripherally acting Neurotoxin Examples; Botulinum toxin type A and Botulinium toxin Type B | |
| | | Centrally acting Examples; Baclofen, Methocarbamol, Tizanidine | |
| | | Directly acting Examples; Dantrolene sodium | |
| | | Neuroprotective drugs Example ; Tafamidis | |

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| 19 | Parkinson disease | Dopaminergic drugs Examples; Levodopa |
| | | Monoamine B inhibitors Examples; Selegiline, Rasagiline, Safinamide |
| | | Catechol-o- Methyl Transferase Inhibitors Examples; Entacapone, Opicapone, Tolcapone |
| | | Dopamine receptor agonists Example Amantadine, Apomorphine, Bromocriptine, Cabergoline, Pergolide, Pramipexole, Ropinirole Rotigotine |
| | | Dopa-decarboxylase inhibitors Example. Carbidopa |
| 20 | Disease modifying anti-rheumatic drugs (DMARDs) | These drugs are used in management of Rheumatoid arthritis by suppressing the body's immune response Example Abatacept, Apremilast, Etanercept, Hydroxychloroquine sulphate, Leflunomide, Penicillamine, Sodium aurothiomalate |
| 21 | | Xanthine oxidase inhibitors |

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| | Hyperuricaemia and gout | Example Allopurinol Febuxostat |
| | | Plant alkaloids Example. Colchicine |
| | | Uricosurics Example. Sulfinpyrazone |
| 22 | Neuromuscular disorders | Neuroprotective drugs Example ; Riluzole |
| | | Anticholinesterases Examples; Neostigmine methylsulfate, Pyridostigmine bromide |
| | | Cholinergic receptor stimulating drugs Examples; Amifampridine |
| | | Drugs for Muscular dystrophy Examples; Ataluren |
| 23 | Anti-dandruffs/anti-fungal (POM) | Ketoconazole, Miconazole, Clotrimazole, Zinc pyrithione, Selenium sulfide |
| 24 | Respiratory System | |
| | | Beta 2 adrenoreceptor agonists Examples; Bambuterol, Formoterol, Indacaterol, |

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| | <p>Olodaterol, Salbutamol, Salmeterol, Terbutaline</p> |
| | <p>Leukotriene receptor antagonists Example Montelukast Zafirlukast</p> |
| | <p>Phosphodiesterase Type 4 inhibitors Example. Roflumilast</p> |
| | <p>Xanthines Example Aminophylline Theophylline</p> |
| | <p>Drugs used in hereditary Angioedema Example C1-esterase inhibitor, Conestat alfa, Icatibant</p> |
| | <p>Mucolytics Example Carbocysteine, Dornase alfa, Erdosteine, Ivacaftor Lumacaftor</p> |
| | <p>Respiratory Stimulants Example. Doxapram</p> |
| | <p>Antimuscarinics, Example Acetylcholine chloride, Atropine, Cyclopentolate HCL,</p> |

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| | | <p>Homatropine HCL, Pilocarpine, Tropicamide Darifenacin, Fesoterodine fumarate, Oxybutynin, FlavoxateHcl Solifenacin succinate, Trospium chloride, Tolterodine tartrate PropiverineHcl, OrphenadrineHcl, ProcyclidineHcl, TrihexyphenidylHcl (Benzhexol), Aclidinium bromide Glycopyrronium bromide, Ipratropium bromide, Tiotropium Umeclidinium</p> |
| 25 | General Anesthetics | |
| | | <p>Intravenous anaesthetics Example Etomidate, Propofol</p> |
| | | <p>Volatile anesthetics Example Desflurane, Isoflurane , Nitrous oxide Sevoflurane</p> |
| | | <p>Neuromuscular Blockers Example Atracuriumbesilate, Cisatracurium, Mivacurium, Pancuronium bromide, Rocuronium bromide</p> |

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| | | Suxamethonium chloride |
| | | NMDA receptor antagonists Example. Ketamine |
| | | Local Anaesthetics Example Bupivacaine Hcl, ChloroprocaineHcl, Levobupivacaine, Lidocaine Hcl, MepivacaineHcl, PrilocaineHcl RopivacaineHcl, Tetracaine (Amethocaine), Oxybuprocaine hydrochloride (benoxinate hydrochloride) Proxymetacaine hydrochloride |
| 26 | Skin Preparations | |
| | Skin Preparations | Skin preparations Example Calamine , Coal tar , Coconut oil , Dithranol (anthralin), Ichthammol, Tacrolimus |
| | | Interleukin Inhibitors Example. Ixekezumab |
| | | Retinoid Related Drugs Example Acitretin, Adapalene, Alitretinoin, Isotretinoin , Tazarotene, Retinol Palmitate |

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| | <p>Astringents Example. Aluminium chloride hexahydrate</p> |
| | <p>Antipruritic agents Example Crotamiton Levomenthol</p> |
| | <p>Anti acne drugs Example Benzoyl peroxide Co-cyprindiol</p> |
| | <p>Abrasive agents Example. Aluminium oxide</p> |
| | <p>Scalp and hair conditions Example Benzalkonium chloride Selenium</p> |
| | <p>Alopecia drugs Example. Minoxidil</p> |
| | <p>Hirsutism preparations Example. Eflornithine</p> |
| | <p>Antiseptics and disinfectants Example Chlorhexidine, Hydrogen peroxide Potassium permanganate, Povidone – Iodine</p> |
| | <p>Sunscreen Agents Example Amiloxate, Avobenzone, Bemotrizinol, Bisotrizole,</p> |

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| | | Ecamsule, Ensulizole, Enzacamene, Octinoxate Octocrilene, Oxybenzone |
| | Genitourinary Tract | |
| 27 | Nocturnal enuresis | Beta 3 Adrenoreceptor Agonist Example. Mirabegron |
| | Urinary retention | Choline esters Example. Bethanecol |
| | | 5-Alpha Reductase inhibitors Examples: Dutasteride, Finasteride |
| 28 | Urological pain | Urine alkalizing Drugs Examples: Citric acid, Potassium citrate, Sodium citrate Terpenes (Anethol) |
| | | Urological Anti-Inflammatory Drugs Example. Dimethyl sulfoxide |
| 29 | Spermicides | Example: Nonoxinol |
| 30 | Erectile dysfunction | Phosphodiesterase Type 5 Inhibitors Examples: Avanafil, Sildenafil, Tadalafil Vardenafil |
| | | Prostaglandin analogues |

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| | | Example. Alprostadil |
| 31 | Priapism | Examples; Metaraminol |
| 32 | Obstetrics | Progesterone receptor modulators Examples; Mifepristone |
| | | Oxytocics Examples: Oxytocin , Carbetocin |
| | | Ergot Examples; Ergometrine Maleate |
| | | Oxytocin receptor antagonist Examples; Atosiban |
| Gastro-Intestinal System | | |
| 33 | Anti-ulcer Agents | Antacids Examples: Aluminum hydroxide Calcium salts, Hydrotalcite, Magnesium hydroxide, Magnesium carbonate. Magnesium triscilicate, Sodium bicarbonate. |
| | | Proton pump inhibitors. Examples: Dexlansoprazole, Esomeprazole, Lansoprazole Omeprazole, Pantoprazole, Rabeprazole |
| | | H ₂ Antagonists. Examples: Cimetidine, Famotidine, Nizatidine, Ranitidine |

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| | | <p>Others</p> <p>Examples: Alginic acid, Bismuth salts, Simeticone , Sucralfate. Carbenoxolone sodium.</p> |
| 34 | Laxatives | <p>Bulk Forming</p> <p>Examples: Bran powder, Carboxymethyl cellulose, Guargum. Ispaghula husk, Psyllium, Sterculia.</p> |
| | | <p>Osmotic</p> <p>Examples: Magnesium Sulphate. Sodium Phosphate Potassium Phosphate. Polyethylene glycol. Lactulose.</p> |
| | | <p>Stimulant</p> <p>Examples: Bisacodyl, Castor oil, Senna, Cascara. Sodium picosulfate.</p> |
| | | <p>Stool softeners</p> <p>Examples: Arachis oil, Docusate sodium, Glycerol. Liquid paraffin.</p> |
| | | <p>Chloride Channel antagonists.</p> <p>Examples:</p> |

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| | | <p>Linaclotide, Lubiprostone.</p> <p>Bowel Cleansing Examples: Citric acid with magnesium carbonate. Macrogols.</p> <p>5HT₄ antagonists Example. Prucalopride.</p> <p>Opioid antagonists Example. Methylnaltrexone bromide.</p> <p>Others Examples: Co-danthramer, Co-danthrusate, Naloxegol</p> |
| 35 | Anti-diarrhoea agents | <p>Activated charcoal, Co-Phenotrope, Kaolin, Loperamide Hydrochloride, Pectin, Racecadotril.</p> |
| 36 | Anti-spasmodics agents | <p>Alverine citrate, Dicycloverinehydrochloride, Hyoscine butylbromide, Mebeverine hydrochloride, Propantheline bromide, Scopolamine.</p> |
| 37 | Rectal and anal disorders. | <p>Examples: Bismuth oxide, Bismuth subgallate, Cinchocainehydrocholride,</p> |

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| | | Hydrocortisone acetate, Peru balsam, Phenol, Pramocaine, Zinc oxide. |
| 38 | Chronic bowel disorders. | Examples: Azathiopurine, Balsalazide sodium, Fragula, Lubiprostone, Magnesium citrate, Mercaptopurine, Mesalazine. Olsalazine sodium, Peppermint oil, Sterculia, Sulfasalazine. Teduglutide. |
| 39 | Liver disorders and related conditions. | Examples: Borneol, Camphene, Cineole, Colestyramine, Menthol. Menthone, Pinene, Terlipressin acetate, Ursodexychoic acid. |
| 40 | Anti-Obesity agents. | Exenatide Example Liraglutide, Lorcaserin, Orlistat, Phentermine, Rimonabant; Example |

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| | | Sibutramine, Topiramate |
| 41 | Reduced exocrine secretions. | Example: Pancreatin. |
| 42 | Anti-Emetics (Anti-vomiting agents.) | Phenothiazines Examples; Methotrimeprazine, Prochlorperazine. |
| | | H ₁ Antagonists Examples; Cyclizine, Dimhydrinate, Diphenhydramine, Meclizine. Promethazine. |
| | | Muscarinic antagonists Example. Glycopyrrolate. |
| 43 | Emetics | Example: Ipecacuanha |
| | Anti-Infectives | |
| 44 | Anthelmintics | Intestinal Antihelminthics Examples; Albendazole, Mebendazole, Niclosamide, Levamisole |
| | | Antifilarials Examples; Diethylcarbamazine (DEC), Ivermectin |
| | | Antischistosomiasis and Antitrematodes Example. Praziquantel |
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| Schedule 3: APIs for anti-infectives | | |
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| 45 | Antibacterials | Beta lactams Examples; Amoxicilin, Ampicillin , Benzylpenicillin, Phenoxymethyl penicillin, Piperacilin, Pivmecillinam, Temocillin, Ticarcillin |
| | | Quinolones Examples; Ciprofloxacin, Floxacin, Levofloxacin ,Moxifloxacin Nalidixic acid, Norfloxacin, Ofloxacin, Lomefloxacin |
| | | Cephalosporins Examples; Cefaclor, Cefadroxil, cefixime cefotaxime, cefradine, ceftaroline, ceftazidime, Ceftriaxone, Cefuroxime Cephalexin, |
| | | Sulphonamides |

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| | <p>Examples; Sulfadiazine, Sulfamethoxazole, Sulfisoxazole</p> |
| | <p>Aminoglycocides Examples; Amikacin, Gentamicin, Neomycin, Streptomycin Framycetin, Tobramycin</p> |
| | <p>Macrolides Examples; Azithromycin, Clarithromycin , Erythromycin</p> |
| | <p>Tetracyclines Examples; Demeclocycline, Doxycycline, Lymecycline Minocycline , Oxytetracycline, Tetracycline , Tigecycline</p> |
| | <p>Others Examples; Chloramphenicol, Fusidic acid, Gramicidin</p> |
| | <p>Nitroimidazoles Examples; Metronidazole, Ornidazole</p> |
| | <p>Antileprotics Examples;</p> |

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| | <p>Clofazamine, Dapsone, Rifampicin</p> |
| | <p>Antituberculosis Examples; Amikacin, Aminosalicylic acid, Bedaquiline, Capreomycin, Cycloserine, Delamanid, Ethambutol, Isoniazid Kanamycin , Prothionamide, Pyrizinamide, Rifabutin, Rifampicin Streptomycin</p> |
| | <p>Carbapenems Examples; Ertapenem, Imipenem , Meropenem</p> |
| | <p>Glycopeptide Examples; Teicoplanin, Telavancin, Vancomycin</p> |
| | <p>Lincosamides Example. Clindamycin</p> |
| | <p>Monobactams Example. Aztreonam</p> |
| | <p>Polymyxins Examples;</p> |

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| | | Colistimethate, Polymixin B |
| 46 | Antifungals | Imidazoles Examples; Clotrimazole, Econazole, Ketoconazole , Miconazole Tioconazole |
| | | Polyenes Examples; Amphotericin, Nystatin |
| | | Echinocandins Examples; Anidulafungin, Caspofungin, Micafungin |
| | | Triazoles Examples; Fluconazole, Itraconazole, Posaconazole, Voriconazole |
| | | Others Examples; Flucytosine, Griseofulvin |
| 47 | Antivirals | Anti-Herpes Examples; Acyclovir , Famciclovir, Inosine Pranobex Valaciclovir |
| | | Neuclosides Reverse Transcriptase inhibitors Examples, |

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| | <p>Abacavir, Didanosine, Emtricitabine, Ganciclovir, Lamivudine, Stavudine, Tenofovir, Valganciclovir, Zalcitabine Zidovudine</p> | |
| | <p>Non nucleosides inhibitors Examples; Efavirenz, Etravirine, Nevirapine, Rilpivirine</p> | |
| | <p>Protease Inhibitors Examples; Atazanavir, Darunavir, Fosamprenavir, Indinavir Lopinavir, Nelfinavir, Ritonavir, Saquinavir, Simeprevir Tipranavir</p> | |
| | <p>Integrase inhibitors Examples; Dolutegravir, Elvitegravir, Raltegravir</p> | |
| | <p>Antihepatitis Examples; Adefovir,</p> | <p>Ombitasvir, Paritaprevir, Peginterferon</p> |

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| | | Daclatasvir, Desabuvir, Elbasvir, Entecavir Grazoprevir, Ledipasvir, | alpha, Ribavarin, Ritonavir, Sofosbuvir, Telbivudine, Velpatasvir |
| | | HIV Fusion Inhibitors | |
| | | Example. Enfuvirtide | |
| | | Others Examples; Amantadine, Tromantadine | |
| 48 | Antiprotozoals | Anti amoebic Examples; Chloroquine, Diloxanide, Metronidazole, Paramomycin Ornidazole | |
| | | Anti-giardial Examples; Nitazoxanide, Tinidazole | |
| | | Anti leshmaniasis Examples; Amphotericin B, Paramomycin, Pentamidine isethionate Sodium Stibogluconate | |
| | | Anti-malarial Examples; ArtemetherLumefantrine, Chloroquine , Dihydroartemisinin, | Mefloquine, Piperaquine, Primaquine Proquanil, PyrimethamineSulphadoxine, Quinine |

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| | | Anti-trypanosomiasis Examples; Benznidazole, Nifurtimox, Pentamidine, Suramin | |
| | Anticancer Agents | | |
| 49 | Anticancer | Cytotoxics Examples; Alkylating agents, Busulfan, Carboplatin, Carmustine Chlorambucil, Cisplatin, Cyclophosphamide, | Dacarbazine Ifosfamide, Lomustine, Melphalan, Oxaliplatin, Procarbazine Streptozocin, Temozolomide, Thiotepa |
| | | Antihormones Examples; Tamoxifen, Anastrozole | |
| | | Antimetabolites Examples; 5-Fuorouracil, 6-mercaptopurine, Capecitabine | Decitabine, Fludarabine, Gemcitabine, Methotrexate, Thioguanine |
| | | Anti-tumor Antibiotics Examples; Actinomycin, Bleomycin, Dactinomycin, Dactinomycin | Daunorubicin, Doxorubicin, Idarubicin, Mitomycin, Mitoxantrone Plicamycin |
| | | Vinka Alkaloids Examples; Vinblastine, | |

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| | | Vinorelbine, Vincristine, Vindesine |
| | | Epipodophylotoxins Examples; Etoposide, Teniposide |
| | | Taxenes Examples; Cabazitaxel, Docetaxel, Paclitaxel |
| | | Camptothecins Examples; Irinotecan, Topotecan |
| | | Cytokines Example. Interleukin-2 |
| | | Immunomodulation agents Examples; Filgastrim, Thalidomide, Zoledronic acid |
| 50 | Diagnostic Agents | Radio Contrast Media Examples; Barium sulphate, Iohexol, Iopromide Meglumineiotroxate |
| | | MRI Contrast Media Examples; Gadobutrol, Gadodiamide, Gadopentatedimeglumine |
| 51 | Neonatal care | Examples: Caffeine citrate, |

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| | | Surfactant | |
| | Vaccines | | |
| 52 | Diagnostics agents | Tuberculin Purified protein Derivative (PPD) | |
| 53 | Vaccines Antigens | Live Attenuated Examples; BCG, Chicken Pox, Herpes Zoster, | Measles, Mumps OPV, Rubella, Yellow fever, Rota |
| | | Killed Inactivated Examples; Cholera, Hepatitis A, Inactivated polio virus (IPV) | Plague, Typhoid, Whole-cell pertussis (wP), Rabies |
| | | Sub unit Examples; Acellular pertussis (aP), Haemophilus Influenze type b Hepatitis B, | HPV, Pneumococcal (PCV-7, PCV-10, PCV-13) Meningococcal, Typhoid |
| | | Toxoids/anatoxins Examples: Diphtheria, Tetanus toxoid (TT) | |
| | Active Pharmaceutical Ingredients for eye Preparations | | |
| 54 | Mast cell stabilizers | Lodoxamide Examples: Nedocromil, Sodium chromoglycate | |
| 55 | Antineovascularization | Aflibercept,. Pegaptanib sodium | |
| 56 | Diagnostic dyes | Example: Fluorescein sodium | |
| | Anti-oxidants | Example: Idebenone | |

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| 57 | Ocular lubricants and decongestants/Sympat homimetics | Naphazoline Examples; Oxymetazoline, Phenylephrine, Synephrine Tetrahydrazoline, Verteporfin, Xylometazoline |
| 58 | Immunosuppressants | Ciclosporin Examples; Azathioprim, Mycophenolate mofetil |
| 59 | Anti-glaucoma | B-blockers Example. Timolol |
| | | Alpha agonists Examples; Apraclonidine, Brimonidine |
| | | Carbonic Anhydrase inhibitors Examples; Acetazolamide, Brinzolamide, Dorzolamide |
| 60 | Recombinant proteolytic enzymes | Example: Ocriplasmin |
| Antidotes | | |
| 62 | Toxicant | Class of antidote/ Description |
| 63 | Unspecific | Intestinal absorbents Example. Activated charcoal |
| 64 | Cyanide | Examples; Dicobaltdetate, Sodium thiosulfate, |

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| | | Sodium nitrite |
| 65 | Organophosphates | Examples; Obidoxime, Pralidoxime chloride |
| 66 | Benzodiazepines | Example: Flumazenil |
| 67 | Digoxin toxicity | Example: Digoxin-specific antibody |
| 68 | Heparins | Example: Protamine sulphate |
| 69 | Opioids | Example: Naloxone |
| 70 | Paracetamol | Examples; Acetylcysteine, Methionine |
| 71 | Methemoglobinemia | Example: Methylthioninium chloride (methylene blue) |
| 72 | Methanol | Examples; Folinic acid , Fomepizole |
| 73 | Iron salts | Examples; Deferasirox, Deferiprone, Desferrioxaminemesilate |
| 74 | Carbon monoxide | Example: Oxygen |
| 75 | Alcohol | Example: Thiamine |
| 76 | Lead | Examples; Chelators, Calcium disodium edetate(EDTA) Dimercaprol, Oral succimer |
| CARDIOVASCULAR DRUGS | | |
| 77 | APIs for medicines for heart and blood vessel conditions | Inotropes Examples; Adenosine, Dobutamine, Dopamine, Dopexamine HCL |

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| | Milrinone | |
| | Cardiac Glycosides Examples; Deslanoside, Digitoxin, Digoxin, Ouabain | |
| | Sodium Channel Blockers Examples; Disopyramide, Flecainide , Mexiletene, | Moricizine, Procainamide , Propafenone, Quinidine, Tocainide |
| | Potassium Channel Blockers Examples; Amiodarone, Bretylium, Dofetilide, Dronedarone Ibutilide | |
| | B-Adrenergic Receptor Blockers Examples; Acebutolol, Atenolol, Betaxolol, Betunolol, Bisoprolol, Buccidolol, Carteolol hydrochloride, Carvedilol, Celiprolol, | Esmolol Labetalol, Levobunolol, Metoprolol,Nadolol, Nevibolol, Oxprenolol Pindolol, Propranolol, Sotalol, Timolol |
| | Centrally acting Antiadrenergics Examples; Clonidine, | |

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| | Methyldopa, Moxonidine, Rilmenidine | |
| | Peripherally acting antiadrenergics Example Guanethidinemonosulphate | |
| | Angiotensin Converting Enzyme Inhibitors (ACEIs) Examples; Captopril, Enalapril, Fosinopril, Imidapril, Lisinopril | Moexipril, Perindopril arginine, Perindopril erbumine, Quinapril, Ramipril Trandolapril |
| | Angiotensin Receptor Blockers (ARBs) Examples; Azilsartan medoxomil, Candesartan cilexetil, Eprosartan | Irbesartan, Losartan, Olmesartanmedoxomil, Telmisartan, Valsartan |
| | Renin Inhibitors Example. Aliskren | |
| | Vasodilators Examples; Cinnarizine, Glyceryl trinitrate, Hydralazine, Isosorbide mononitrate, Isosorbide Dinitrate, Minoxidil, | Moxisylyte(Thymoxamine) Naftidrofuryl oxalate, Nicorandil, Oxerutins, Pentoxifylline(oxyptentifylline), Sacubitril, Sodium nitroprusside, Diazoxide |
| | Alpha Receptor Blockers Examples; Doxazosin, Indoramin, | Phentolamine Prazosin, Tamsulosin, Terazosin, |

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| | Phenoxybenzamine, | AlfuzosinHcl |
| | Ganglion blockers Example. Trimethorphan | |
| | Calcium Channel Blockers Examples; Amlodipine, Clevidipine, Diltiazem, Felodipine, Isradipine | Lacidipine, Lercanidipine, Nicardipine, Nifedipine, Nimodipine, Verapamil |
| | Endothelial Receptor Antagonists Examples; Ambrisentan, Bosentan, Macitentan | |
| | Guanylate Cyclase Stimulators Example. Riociguat | |
| | Vasoconstrictors Examples; Adrenaline, Metaraminol, Midodrine HCL, Noradrenaline/Norepinephrine, Ornipressin | |
| | Phosphodiesterase Type 3 Inhibitors Example. Enoximone | |
| | 3-KAT Inhibitor Example. Trimetazidine | |
| | Piperazine Derivatives | |

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| | | <p>Example. Ranolazine</p> |
| | | <p>Rauwolfia Alkaloids/Dopamine depleters Example. Reserpine</p> |
| | | <p>Ergot Alkaloids Example. Dihydroergocristine</p> |
| | | <p>Selective sinus node I_f inhibitors Example. Ivabradine</p> |
| | | <p>Sclerosants/Endothelial wall stabilizers Examples; Diosmin, Ethanolamine oleate, Hesperidin Sodium tetradecyl sulphate</p> |
| 78 | Diuretics | <p>Potassium Sparing Examples; Amiloride, Eplerenone, Spironolactone, Triamterene</p> |
| | | <p>Osmotic Diuretics Examples; Mannitol</p> |
| | | <p>Thiazides Examples; Bendrofluazide, Chlorthalidone, Clopamide, Cyclopentiazide Hydrochlorothiazide,</p> |

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| | | Indapamide, Metolazone, Xipamide |
| | | Loop Examples; Bumetanide, Furosemide, Torasemide |
| 79 | Anti-haemorrhage | Antifibrinolytics Example. Tranexamic acid |
| | | Plasma Products Example. Fresh Frozen Plasma |
| | | Haemostatics Examples: Etamsylate, Factor VIII inhibitor bypassing |
| | | Coagulation Proteins Examples; Factor IX fraction, Factor VIIa (recombinant), Factor VIII fraction, Factor XIII, Fibrinogen fraction, Protein C concentrate Prothrombin complex (Human Prothrombin complex) |
| 80 | Antithrombotics | Antidotes and Chelators Example. Idarucizumab |
| | | Antiplatelets Examples; Cangrelor, |

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| | <p>Cilostazol, Clopidogrel, Dipyridamole, Prasugrel Selexipag, Ticagrelor, Ticlopidine</p> |
| | <p>Glycoprotein IIb/IIIa inhibitors Examples; Abciximab, Eftifibatide, Tirofiban</p> |
| | <p>Factor X_{IIa} Inhibitors Examples; Apixaban, Edoxaban, Fondaparinux, Rivaroxaban</p> |
| | <p>Heparinoids Examples; Danaparoid</p> |
| | <p>Héparines Examples; Dalteparin, Enoxaparin, Heparin, Nadroparin, Tinzaparin</p> |
| | <p>Thrombin Inhibitors Examples; Argatroban, Bivalirudin, Dabigatran etexilate</p> |

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| | | <p>Tissue Plasminogen Activators</p> <p>Examples; Urokinase, Retepase, Anistreplase, Tenecteplase, Streptokinase</p> |
| | | <p>Vitamin K Antagonists</p> <p>Examples; Acenocoumarol, Phenidione, warfarin</p> |
| 81 | Antilipidemics | <p>Bile Acid Sequestrants</p> <p>Examples; Colesevelam HCL, Colestipol, cholestyramine</p> |
| | | <p>Cholesterol Absorption Inhibitors</p> <p>Example; Ezetimibe</p> |
| | | <p>Fibrates</p> <p>Examples; Bezafibrate, Ciprofibrate, Gemfibrozil, Fenofibrate</p> |
| | | <p>Nicotinic acid derivatives</p> <p>Examples; Acipimox, Nicotinic acid, Inositol nicotinate</p> |
| | | <p>Statins</p> <p>Examples ;</p> |

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| | | Atorvastatin, Fluvastatin, Simvastatin, Rosuvastatin Pravastatin | |
| | | LDL receptor modifiers Examples; Alirocumab, Evolocumab | |
| | | MTP(microsomal triglyceride transfer protein) inhibitors Example Lomitapide | |
| | | Others Example; Omega -3-acid-ethyl esters | |
| | Schedule 4: Hormonal Based APIs | | |
| 82 | Corticosteroids | Examples; Aclometasone, Beclomethasone, Betamethasone, Budesonide Ciclesonide, Clobetasol, Deflazacort, Dexamethasone, Diflucortolone Fludrocortisone , Fludroxycortide, Fluocinoloneacetone, | Fluocinonide Fluocortolone, Fluorometholone, Fluticasone, Hydrocortisone Loteprednoletabonate, Methylprednisolone, Mometasone, Prednisolone Prednisone, Rimexolone, Nandrolone, Oxymetholone, Tibolone |
| | Non-opioid analgesics | | |

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| 83 | Non-opioid analgesics and Antipyretic Properties | <p>Examples: Nefopam, Paracetamol</p> <p>Analgesic, Anti-inflammatory Antipyretic properties (NSAIDS)</p> <p>Examples; Aceclofenac, Acemetacin, Aspirin, Celecoxib Dexibuprofen Dexketoprofen, Diclofenac potassium , Diclofenac sodium, Etodolac Etoricoxib, Felbinac, Fenoprofen,</p> | <p>Flurbiprofen, Ibuprofen , Indomethacin Ketoprofen, Mefenamic acid , Meloxicam , Nabumetone, Naproxen Piroxicam, Sulindac, Tenoxicam, Tiaprofenic acid, Nepafenac, Diclofenac Flurbiprofen, Bromfenac, Ketorolac trometamol, Nepafenac</p> |
| Monoclonal antibodies | | | |
| 84 | Monoclonal antibodies | <p>Examples; Mepolizumab, Omalizumab, Reslizumab, Denosumab Bevacizumab, Cetuximab, Ipilimumab, Lituximab, Nimotuzumab Ofatumumab,</p> | <p>Panitumumab, Pertuzumab, Trastuzumab, Ranibizumab Eculizumab, Adalumab, Golimumab, Infliximab, Ustekinumab, Tocilizumab Certolizumab</p> |
| 85 | ANTIEMETICS | | |
| | | Serotonin antagonists | |

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| | | <p>Examples; Azesetron, Dolasetron Granisetron, Ondanesttron, Aprepitan Cinnarazine, Fosaprepitan, Levomepromazine (methotrimeprazine) Palonosetron</p> |
| | | <p>Dopamine antagonists. Examples; Cisapride, Domperidone, Droperidol, Metoclopramide.</p> |
| | | <p>Cannabinoids. Examples; Dronabinol, Nabilone.</p> |
| | | <p>Neurokinin blockers Example. Aprepitant.</p> |
| 86 | Vitamins | <p>Fat soluble Examples; Vitamin A, Vitamin D & Ana logues Examples; alfacalcidol, calcitriol, cholecalciferol, dihydratichysterol, Ergocalciferol,</p> |

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| | | <p>paricalcitol Vitamin E (Tocopherol) Vitamin K (Phytomenadione) Zinc carnosine</p> |
| | | <p>Water soluble Examples; Vitamin B1 (Thiamine), Vitamin B2 (Ribiflavine) Vitamin B3 (Niacin/ nicotinamide), Vitamin B6 (pyridoxine) Vitamin B12 Examples; cyanocobalamin, mecobalamin, methylcobalamin hydroxocobalamin Calcipotriol; Calcitriol, Tacalcitol Vitamin C (ascorbic acid)</p> |
| | | Folate's Examples; Folic acid |
| 87 | Minerals and trace elements | <p>Examples; Calcium , Zinc sulphate , Potassium , Sodium , Magnesium Phosphate , Selenium</p> |
| | | <p>Iron preparations Examples; Ferric carboxymaltose, Ferric maltol, Ferrous fumarate Ferrous gluconate, Ferrous sulphate, Iron dextran, Iron isomaltoside</p> |

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| | <p>Iron sucrose, Polysaccharide iron complex, Sodium ferredetate</p> |
| | <p>Minerals & fluids Examples; Calcium chloride, Calcium Chloride dehydrate, Disodium hydrogen citrate, Potassium bicarbonate, Potassium chloride, Sodium chloride, Sodium citrate</p> |
| | <p>Glucose Example. Dextrose monohydrate</p> |
| | <p>Management of acidosis Examples; Potassium bicarbonate, Sodium bicarbonate, Sodium lactate</p> |
| | <p>Plasma expanders Examples; Albumin, Dextran 70, Gelatin, Hydroethyl starch, Tetrastarch</p> |
| | <p>Bone resorption inhibitors Examples; cinacalcet</p> |
| | <p>Minerals Examples; Calcium, Calcium carbonate, Calcium gluconate Calcium lactate gluconate, Calcium phosphate</p> |

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| | | <p>Magnesium supplements Examples; Magnesium glycerophosphate, Magnesium lactate Magnesium sulphate</p> |
| | | <p>Electrolytes & minerals Examples; Aluminium hydroxide, Calcium acetate, Lanthanum Magnesium carbonate, Sevelamer, Sucroferricoxy hydroxide</p> |
| | | <p>Antidotes and chelators (cation exchange resins) Examples; Calcium polystyrene sulfonate, Sodium polystyrene sulfonate</p> |
| | | <p>Supplements Examples; Potassium acid tartrate</p> |
| | | <p>Proteins Examples; Aminoacid concentrate, Intravenous fat emulsion</p> |
| 88 | Hormones | <p>Epoetins Examples; Darbepoetin alfa, Epoetin alfa, Epoetin Beta, Epoetin Zeta Erythropoetin, Methoxy polyethylene glycol-epoetin beta</p> |
| 89 | PROSTAGLANDINS | |

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| | | <p>Examples; Misoprostol, Dinoprostone, carboprost, Misoprostol Gemeprost, Prostaglandin E1 (alprostadil), Bimatoprost, Latanoprost Tafluprost, Travoprost, Epoprostenol(prostacyclin), Iloprost</p> |
| | <p>Schedule 5: Active Pharmaceutical Ingredients for Controlled Drugs</p> | |
| 90 | <i>Least controlled APIs</i> | <p>The drug or other substance has a low potential for abuse. The drug or other substance has a currently accepted medical use in treatment in Kenya, and abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule 9 (c).</p> |

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| | | Examples; Alfaxalone, Alprazolam, Barbital, Bromazepam, BuspironeHcl, Butorphanol Camazepam, Carisoprodol, Cathine, Chloral betaine, Chloral hydrate, Chlordiazepoxide, ChlordiazepoxideHcl, Clobazam, Clonazepam Clorazepate, Clotiazepam, Cloxazolam, Delorazepam, Dexfenfluramine , Dextropropoxyphene, Diazepam, Dichloralphenazone, Diethylpropion | Eluxadoline, Estazolam, Ethchlorvynol, Ethinamate, Ethyl loflazepate, Fencamfamin, Fenfluramine, Fenproporex, Fludiazepam, Flunitrazepam Flurazepam, Fospropofol, Halazepam, Haloxazolam, Ketazolam Loprazolam, Lorazepam , Lorcaserin, Lormetazepam, Mazindol Mebutamate, Medazepam, Mefenorex, Meprobamate, Methohexital | Methylphenobarbital, Midazolam, Modafinil, Nimetazepam,Nitrazepam, Nordiazepam, Oxazepam, Oxazepam, Oxazolam, Paraldehyde, Pemoline, Pentazocine, Petrichloral, Phenobarbital, Phentermine, Pipradrol Prazepam, Quazepam, Sibutramine, Suvorexant, Temazepam, Tetrazepam Tramadol, Triazolam, Zaleplon, Zopiclone |
| 91 | Strictly controlled APIs | APIs that have the following characteristics; i. The drug or other substances have a high potential for abuse, ii. The drug or other substances have currently accepted medical use in treatment in Kenya, or currently accepted medical use with severe restrictions iii. Abuse of the drug or other substances may lead to severe psychological or physical dependence | | |
| | | Examples; 1-Phenylcyclohexylamine, 1-Piperidinocyclohexanecarbonitrile 4-Anilino-N-phenethyl-4-piperidine (ANPP), Alfentanil, Alphaprodine, Amobarbital, | Levomethorphan, Levorphanol Lisdexamfetamine, Meperidine, Metazocine, Methadone,Methamphetamine, Methylphenidate, | |

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| | | Amphetamine, Anileridine, Benzoylcegonine, Bezitramide Carfentanil, Cocaine, Codeine, Dextropropoxyphene, Dihydrocodeine, Dihydroetorphine, Diphenoxylate, Diprenorphine, EcgonineEthylmorphine Etorphine, Fentanyl, Glutethimide, Hydrocodone, Hydromorphone, Isomethadone, Levo-alphaacetylmethadol, | Metopon, Morphine,Opium, Oripavine, Oxycodone, Oxymorphone, Pentobarbital, Phenazocine, Phencyclidine, Phenmetrazine, Phenylacetone, Piminodine, Racemethorphan, Racemorphan, Remifentanil, Secobarbital, Sufentanil, Tapentado, Thebaine, Thiafentanil |
| 92 | Highly controlled APIs | The drug or other substance has a high potential for abuse. The drug or other substance has no currently accepted medical use in treatment in Kenya. There is a lack of accepted safety for use of the drug or other substance under medical supervision. | |
| | | Examples Aminorex, Benzethidine, Levomoramide, Levophenacymorphan Lysergic acid diethylamide, Marijuana, Cannabis, Mecloqualone, Mephedrone, Mescaline, Methaqualone, Methyldihydromorphine Morpheridine, Morphine methylbromide, | Ibogaine, Morphine methylbromide, Cyprenorphine, Desomorphine, Dextromoramide Diampromide, Diethylthiambutene, Allylprodine, Alpha-Ethyltryptamine Alphamethadol, Alpha-Methylfentanyl, Phenadoxone, Phenampramide Phenomorphane, Phenoperidine, |

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| | | Norlevorphanol, Normethadone Heroin, Hydromorphanol, Hydroxypethidine, | Pholcodine, Piritramide, Proheptazine, Properidine |
| 93 | Restricted veterinary APIs | Ketamine Sodium pentobarbital Buprenorphine Butorphanol | |
| 94 | Nicotine and related substances including substances used in e-Cigarettes | Nicotine refers to the alkaloid substance derived from tobacco plant or synthetically prepared. Electronic cigarettes, also known as e-cigarettes or e-vaporizers, are battery-operated devices that deliver nicotine with flavourings and other chemicals to the lungs in vapor instead of smoke. Examples Nicotine Propylene Glycol Glycerine | |
| 95 | APIs used in manufacture of special cosmetics | Alpha-lipoic acid Vitamin C Nicotinamide (vitamin B3) Vitamin E (alpha tocopherol) N-Acetyl-Glucosamine (NAG) Ubiquinone (CoQ10) Glycolic acid Lactic acid Citric acid Mandelic acid Malic acid Tartaric acid Lactobionic acid Gluconolactone Salicylic acid Tretinoin / retinoic acid Retinol Retinaldehyde | Hydroquinone Kojic acid Azelaic acid Licorice extract (glabridin) Soy Curcumin Silymarin Pycnogenol Ginkgo biloba Green tea extract Grape seed extract Aloe vera Witch hazel Allantoin Ferulic acid pentapeptide Pal-KTTKS |
| 96 | APIs with potential for illicit use in | 1-Androstenediol (5 α -androst-1-ene-3 β , 17 β -diol) 1-Androstenedione (5 α -androst-1-ene-3, 17-dione) 1-Androsterone (3 α -hydroxy-5 α -androst-1-ene-17-one) | |

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| <p>sporting activities (see latest list as maintained by WADA)</p> | <p>1-Epiandrosterone (3β-hydroxy-5α-androst- 1-ene-17-one) 1-Testosterone (17β-hydroxy-5α-androst-1- en-3-one) 4-Androstenediol (androst-4-ene-3β,17β- diol) 4-Hydroxytestosterone (4,17β-dihydroxyandrost-4-en-3-one) 5-Androstenedione (androst-5-ene-3,17- dione) 7α-hydroxy-DHEA 7β-hydroxy-DHEA 7-Keto-DHEA 19-Norandrostenediol (estr-4-ene-3,17-diol) 19-Norandrostenedione (estr-4-ene-3,17- dione) Androstanolone (5α-dihydrotestosterone, 17β-hydroxy-5α-androstan-3-one) Androstenediol (androst-5-ene-3β,17β-diol) Androstenedione (androst-4-ene-3,17- dione) Bolasterone Boldenone Boldione (androsta-1,4-diene-3,17-dione) Calusterone Clostebol Danazol ([1,2]oxazolo[4',5':2,3]pregna-4-en- 20-yn-17α-ol) Dehydrochlormethyltestosterone (4-chloro- 17β-hydroxy-17α-methylandrosta-1,4-dien- 3-one) Desoxymethyltestosterone (17α-methyl-5α- androst-2-en-17β-ol and 17α-methyl-5α- androst-3-en- 17β-ol) Drostanolone Epiandrosterone (3β-hydroxy-5α-androstan- 17-one) Epi-dihydrotestosterone (17β-hydroxy-5β- androstan-3-one) Epitestosterone Ethylestrenol (19-norpregna-4-en-17α-ol) Fluoxymesterone Formebolone Furazabol (17α-methyl [1,2,5] oxadiazolo[3',4':2,3]-5α-androstan-17β-ol) Gestrinone Mestanolone Mesterolone Metandienone (17β-hydroxy-17α- methylandrosta-1,4-dien-3-one) Metenolone Methandriol Methasterone (17β-hydroxy-2α,17α- dimethyl-5α-androstan-3-one)</p> |
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| | <p> Methyl-1-testosterone (17β-hydroxy-17α- methyl-5α-androst-1-en-3-one) Methylclostebol Methyldienolone (17β-hydroxy-17α- methylestra-4,9-dien-3-one) Methylnortestosterone (17β-hydroxy-17α- methylestr-4-en-3-one) Methyltestosterone Metribolone (methyltrienolone, 17β-hydroxy- 17α-methylestra-4,9,11-trien-3-one) Mibolerone Nandrolone (19-nortestosterone) Norboletone Norclostebol (4-chloro-17β-ol-estr-4-en-3- one) Norethandrolone Oxabolone Oxandrolone Oxymesterone Oxymetholone Prasterone (dehydroepiandrosterone, DHEA, 3β-hydroxyandrost-5-en-17-one) Prostanozol (17β-[(tetrahydropyran-2-yl) oxy]-1'H-pyrazolo[3,4:2,3]-5α-androstane) Quinbolone Stanozolol Stenbolone Testosterone Tetrahydrogestrinone (17-hydroxy-18α- homo-19-nor-17α-pregna-4,9,11-trien-3- one) Trenbolone (17β-hydroxyestr-4,9,11-trien-3- one) Clenbuterol Selective androgen receptor modulators [SARMs, Example. andarine, LGD-4033 (ligan- drol)enobosarm (ostarine) and RAD140] Tibolone Zeranol Zilpaterol Darbepoetins (dEPO) Erythropoietins (EPO) EPO-based constructs [Example. EPO-Fc, methoxy polyethylene glycol-epoetin beta (CERA)] EPO-mimetic agents and their constructs (Example. CNTO-530, peginesatide) Cobalt Daprodustat (GSK1278863) IOX2 Molidustat (BAY 85-3934) Roxadustat (FG-4592) </p> |
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| | <p>Vadadustat (AKB-6548)</p> <p>Xenon</p> <p>K-11706</p> <p>Luspatercept</p> <p>Sotatercept</p> <p>Asialo EPO</p> <p>Carbamylated EPO (CEPO)</p> <p>Buserelin</p> <p>Deslorelin</p> <p>Gonadorelin</p> <p>Goserelin</p> <p>Leuprorelin</p> <p>Nafarelin</p> <p>Triptorelin</p> <p>Cortimorelin</p> <p>rowth hormone fragments, Example. AOD-9604 and hGH 176-191</p> <p>growth hormone-releasing hormone (GHRH) and its analogues, Example. CJC-1293, CJC-1295, sermorelin and tesamorelin</p> <p>growth hormone secretagogues (GHS), Example. lenomorelin (ghrelin) and its mimetics, Example. anamorelin, ipamorelin, macimorelin and tabimorelin</p> <p>GH-releasing peptides (GHRPs), Example. alexamorelin, GHRP-1, GHRP-2 (pralmorelin), GHRP-3, GHRP-4, GHRP-5, GHRP-6, and examorelin (hexarelin)</p> <p>Fibroblast growth factors (FGFs)</p> <p>Hepatocyte growth factor (HGF)</p> <p>Insulin-like growth factor 1 (IGF-1) and its analogues</p> <p>Mechano growth factors (MGFs)</p> <p>Platelet-derived growth factor (PDGF)</p> <p>Thymosin-β4 and its derivatives Example. TB-500</p> <p>Vascular endothelial growth factor (VEGF)</p> <p>Arformoterol</p> <p>Fenoterol</p> <p>Formoterol</p> <p>Higenamine</p> <p>Indacaterol</p> <p>Levosalmeterol</p> <p>Olodaterol</p> <p>Procaterol</p> <p>Reproterol</p> |
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| | <p> Salbutamol Salmeterol Terbutaline Tretiquinol (trimetoquinol) Tulobuterol Vilanterol 2-Androstenol (5α-androst-2-en-17-ol) 2-Androstenone (5α-androst-2-en-17-one) 3-Androstenol (5α-androst-3-en-17-ol) 3-Androstenone (5α-androst-3-en-17-one) 4-Androstene-3,6,17 trione (6-oxo) Aminoglutethimide Anastrozole Androsta-1,4,6-triene-3,17-dione (androstatrienedione) Androsta-3,5-diene-7,17-dione (arimistane) Exemestane Formestane Letrozole Testolactone Bazedoxifene Clomifene Cyclofenil Fulvestrant Ospemifene Raloxifene Tamoxifen Toremifene Activin A-neutralizing antibodies ACE-031 Bimagrumab Follistatin Myostatin propeptide Domagrozumab Stamulumab Landogrozumab AICAR SR9009 -(2-methyl-4-((4-methyl-2-(4-(trifluoromethyl)phenyl)thiazol-5-yl)methylthio)phenoxy) acetic acid </p> |
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| | | Meldonium Trimetazidine Desmopressin Probenecid Acetazolamide Amiloride Bumetanide Canrenone Chlortalidone Etacrynic acid Furosemide Indapamide Metolazone Spironolactone Bendroflumethiazide, Triamterene Tolvaptan Albumin Dextran Hydroxyethyl starch Mannitol Hydrochlorothiazide Chlorothiazide |
| 97 | Schedule 6B(iii) : <i>Controlled precursor chemicals</i> | |
| | <i>Precursor Chemicals</i> | These are substances that are used in preparation of conventional drugs but have potential for diversion for illicit use. Examples; <u>Table I:</u> Acetic anhydride N-Acetylanthranilic acid 4-Anilino-N-phenethylpiperidine (ANPP) Ephedrine Ergometrine Ergotamine Isosafrole Lysergic acid 3,4-Methylenedioxyphenyl-2-propanone 3,4-MDP-2-P methyl glycidate |

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| | <p>3,4-MDP-2-P methyl glycidic acid Norephedrine N-Phenethyl-4-piperidone (NPP) Phenylacetic acid Alpha-Phenylacetoacetamide (APAA) Alpha-Phenylacetoacetonitrile (APAAN) 1-Phenyl-2-propanone Piperonal Potassium permanganate Pseudoephedrine Safrole</p> <p><i>Table II:</i> Acetone Anthranilic acid Ethyl ether Hydrochloric acid Methyl ethyl ketone Piperidine Sulphuric acid Toluene</p> |
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Annex X: Medical Devices

General Sales Medical devices

| | Device trade name | Category | Class |
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| 1 | Adult diapers | Non-Invasive Medical Devices | A |
| 2 | Non-woven Facemask | Non-Invasive Medical Devices | A |
| 3 | Bathroom scale | Non-Invasive Medical Devices | A |
| 4 | Cotton roll | Non-Invasive Medical Devices | A |
| 5 | Cotton wool | Non-Invasive Medical Devices | A |
| 6 | Foam bath | Non-Invasive Medical Devices | A |
| 7 | Pain relief heat patch | Non-Invasive Medical Devices | A |
| 8 | Disposable protective face mask | Non-Invasive Medical Devices | A |
| 9 | Elbow shoulder supports | Non-Invasive Medical Devices | A |
| 10 | Personal protective equipment | Non-Invasive Medical Devices | A |
| 11 | Hand & body sanitizer HOCL liquid | Exceptional Classes -Medical Devices- used for sterilizing or Disinfecting Medical Devices | A |
| 12 | Hand Gel Sanitizer with Aloe Vera | Non-Invasive Medical Devices | A |
| 13 | Hot/cold pack | Non-Invasive Medical Devices | A |
| 14 | Male condoms | Exceptional Classes -Medical Devices for Contraception or the prevention of STDS | C |

Over the counter medical devices

| | Group | Example | Class |
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| 1 | Non-invasive device to be used as a mechanical barrier or for compression or for absorption of exudates | Absorbent pads Island dressings Cotton wool Wound strips and gauze dressings | A |
| 2 | Non-invasive device used to channel or store body liquids or tissues, liquids or gases that are to be infused, administered or introduced into a patient | Administration sets for gravity infusion, Syringes without needles. | A |

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| 3 | Non-invasive device to channel blood, to store or channel other body liquids, or to store an organ, parts of an organ or body tissue that is to be later introduced into a patient | Tubes for blood transfusion, devices to temporarily store and transport of organs for transplant or for long-term storage of biological substances and tissues such as corneas, sperm and human embryos. | B |
| 4 | Not active and is intended to record x-ray diagnostic images | X-ray films, photo-stimulable phosphor plates. | B |
| 5 | Non-invasive device to channel or store a liquid or gas that is to be infused, administered or introduced into a patient and may be connected to an active medical device | Oxygen tubing and masks; anaesthetic tubing and breathing circuits; Syringes and tubing for infusion pumps. | B |
| 6 | Non-invasive device to modify the biological or chemical composition of blood, other body liquids, or other liquids to be infused in the patient | Hemodialyzers. Auto transfusion systems and devices | C |
| 7 | Devices used to collect body liquid where a return flow is unlikely. | Urine collection bottles, Ostomy pouches, Wound drainage collection bottles Incontinence pads. | A |
| 8 | Devices used to immobilise body parts and/or to apply force or compression. | Non-sterile dressings, Plaster bandages, Cervical collars Gravity traction devices compression hosiery. | A |
| 9 | Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only | Handheld dental mirrors Dental impression materials Exam gloves, Prostatic balloon dilation catheters. | A |
| 10 | Invasive devices that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity | Dressing for nose bleeds, dentures removable by the patient | A |
| 11 | Surgically invasive device | Suture needles, Hypodermic needles and syringes, Suckers, Surgical swabs, Surgical gloves. | B |
| 12 | Invasive reusable surgical instrument | Scissors, Artery forceps, Tissue forceps, Tissue clamps, | A |

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| | | Excavators, Osteotomes, Chisels. | |
| 13 | Surgically invasive device for transient use to supply energy in form of ionizing radiation | Catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body | C |
| 14 | Active medical device for therapy to administer energy to a patient, or exchange energy to or from a patient | Magnetic and electromagnetic energy muscle stimulators, External bone growth stimulators, TENS devices, Electrical acupuncture; Cryosurgery equipment, Heat exchangers; Dermatomes, drills and dental hand pieces; Phototherapy for skin treatment and for neonatal care; Hearing aids. | B |
| 15 | Active medical devices | Magnetic resonance equipment, pulp testers, 16Evoked response stimulators, dia17gnostic ultrasound. Gamma cameras, positron emission tomography, single photon emission computer tomography. Electrocardiographs, electroencephalographs, cardio scopes with or without pacing pulse indicators, electronic thermometers. | B |
| 16 | Active device to administer or remove medicine, body liquids or other substances | Suction equipment, feeding pumps, jet injectors for vaccination. | B |
| 17 | Active devices general | Examination lights, Surgical microscopes, Diagnostic devices for thermography, Active devices for recording, processing or viewing of diagnostic images, Devices intended in general for external patient support (e.g., Hospital beds, patient hoists, wheelchairs, dental patient chairs); Active diagnostic devices intended for thermography - Dental curing lights | A |
| 18 | Device specifically for sterilising medical devices, or disinfecting as the end point of processing | Hard contact lens solutions, comfort solutions. | C |
| 19 | | Sterilizers specifically intended to sterilize medical devices in a medical environment | B |

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| | | Washers-disinfectors intended specifically for disinfecting non-invasive medical devices. | |
| 20 | Device specifically for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses | Denture disinfecting products; Washers-disinfectors for endoscopes; Disinfectants for the fluid pathways of haemodialysis equipment; Disinfectants for ocular prosthesis, intraosseous transcutaneous amputation prosthesis, surgical equipment and invasive dental equipment | C |
| 21 | Dressings | Adhesive dressing strip—sterile | B |
| | | Compression bandage used for sprains | A |
| | | Adhesive dressing strip—not sterile | A |

Prescription only medical devices

| | Group | Example | Class |
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| 1 | Invasive devices that contain a medicine | Antibiotic bone cements, condoms with spermicide, heparin coated catheters, dressings incorporating an antimicrobial agent. | D |
| 2 | Contains viable OR nonviable animal tissues or derivatives | Biological heart valves, Porcine xenograft dressings, catgut sutures, Implants and dressings made from collagen, Intra-ocular fluids, Meniscule joint fluid replacement, Anti-adhesion barriers, Tissue fillers based on hyaluronic acid derived from bacterial fermentation processes. | D |
| 3 | Active implantable medical device | Implantable pacemakers, defibrillators and nerve stimulators, | D |
| 4 | An active device to control, monitor, or directly influence the performance of an active implantable medical device | Clinician's programming devices for pacemakers, patient control devices for nerve stimulation devices. | D |
| 5 | Mammary implant | Mammary / breast implants. | D |
| 6 | Blood bag | Blood bags (including those containing or coated with an anticoagulant). | C |
| 7 | Non-invasive device to be used in contact with injured skin (including a device the principal | Adhesives for topical use, Polymer film dressings, | B |

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| | intention of which is to manage the microenvironment of a wound)— | Hydrogel dressings and Non-medicated impregnated gauze dressings. | |
| 8 | Non-invasive device to be used for wounds that have breached the dermis and where the wounds can only heal by secondary intent | Dressings for chronic extensive ulcerated wounds, severe burn, severe decubitus wounds, or dressings providing a temporary skin substitute. | C |
| 9 | Non-invasive device to be used in treatment consisting of filtration, centrifugation or exchanges of gas or heat— | Devices for particulate filtration of blood in an extracorporeal circulation system, Devices for centrifugation of blood for transfusion or auto transfusion, Devices for removal of carbon dioxide from the blood and/or adding oxygen, and Devices for warming or cooling blood in the extracorporeal circulatory system. | B |
| 10 | Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only | Hard contact lenses Urinary catheters Tracheal tubes Stents Vaginal pessaries Perineal reduction devices. | B |
| 11 | Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for long term use | Long-term urinary catheters, Artificial eyes, Urethral stents, Contact lenses for long-term continuous use | C |
| 12 | Invasive devices for long-term use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and are not liable to be absorbed by the mucous membrane | Orthodontic wire, Fixed dental prostheses, Fissures sealants | B |
| 13 | Invasive device with respect to body orifices, to be connected to an active medical device that is classified as Class B or higher | Tracheostomy tubes connected to a ventilator, Powered nasal irrigators, nasopharyngeal airways, Heat and moisture exchangers, Suction catheters or Tubes for stomach drainage. | B |
| 14 | Surgically invasive devices that have a biological effect or be wholly or mainly absorbed | Bone wax | C |

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| 15 | Surgically invasive device for use to administer medicine via a delivery system, and where the administration is potentially hazardous to the patient | Personal insulin injectors Insulin pens | C |
| 16 | Surgically invasive device for transient use to diagnose, monitor, control or correct a defect of the CNS, heart, or central circulatory system through direct contact | Cardio vascular catheters, Angioplasty balloon catheters Coronary artery probes. | D |
| 17 | Surgically invasive devices for short term use | Clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors for example, chest retractors for cardiac surgery. | B |
| | | Surgical / tissue adhesives. Brady therapy devices Intravenous cannulae. | C |
| | | Haemostatic sponge. Absorbable sutures. Neurological catheters, Cortical electrodes, Connonoid paddles. | D |
| | | To be placed in the teeth and to undergo a chemical change in the body i.e., dental adhesives used for root canal therapy | B |
| 18 | Surgically invasive devices for long term use | All implantable devices such as implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, bone cements, maxillo-facial implants. | D |
| | | To be placed in the teeth such as crowns and bridges | B |
| | | Prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures. Pacemakers | D |
| | | Implantable accessory to an active implantable medical device such as electrode leads associated with pacemakers, defibrillators, nerve stimulators. | D |
| | | Active device to control, monitor or directly influence the performance of an active implantable medical device Rechargeable non-active drug delivery systems. | D |

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| | | Implants claimed to be bioactive | |
| | | Dentine adhesives and Surgical adhesives | D |
| | | Absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine | D |
| 19 | Active device to administer or exchange energy in a potentially hazardous way, | Lung ventilators; Infant incubators, Warming blankets for unconscious patients, blood warmers and heat exchangers used in intensive care; High-frequency electrosurgical generators, electrocautery, External defibrillators, Electroconvulsive therapy equipment; surgical lasers; Lithotripters, physiotherapy ultrasound devices; Radioactive sources for after loading therapy, Therapeutic cyclotrons, Linear accelerators, therapeutic X-ray sources. External feedback systems for active therapeutic devices, after-loading control devices. | C |
| 20 | Device to diagnose and or monitor vital physiological parameters of a patient, | Intensive care monitoring systems, biological sensors, Blood gas analysers used in open heart surgery, Cardio scopes and apnoea monitors including those in home care | C |
| 21 | Device to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology or monitoring | Diagnostic x-ray sources, Linear accelerators. Auto exposure control systems, radiotherapy after loading controls systems. | C |
| 22 | Active device to administer or remove medicine, body liquids or other substances in a way that is potentially hazardous to the patient | Infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers, pressure regulators for medical gases, medical gas mixers, moisture exchangers in breathing circuits, nebulisers | C |
| 23 | Device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body | Antibiotic bone cements, Condoms with spermicide, Heparin-coated catheters, Dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound. | D |

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| | | Endodontic materials with antibiotics Ophthalmic irrigation solutions principally intended for irrigation, which contain components which support the metabolism of the endothelial cells of the cornea Dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound Contraceptive intrauterine devices (IUDS) containing copper or silver – Drug eluting stents | |
| 24 | Devices that contain animal or human cells or tissues or derivatives Devices that contain tissues, cells or substances of microbial or recombinant origin | Biological heart valves, Porcine xenograft dressings, Catgut sutures, biological implants, dressings made from collagen. Devices utilising hyaluronic acid of animal origin Intra-ocular fluids, meniscule joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes. Leather straps associated with limb prostheses. | D |
| 25 | Device for contraception | Contraceptive diaphragms | C |
| | | Contraceptive intrauterine devices (IUDS), surgically implanted contraceptive devices Implantable or invasive device for long term use | D |
| 26 | Dressings | Adhesive dressing strip—with silver | D |
| | | Wound dressing including materials of biological origin, such as collagen, sodium hyaluronate, chondroitin sulphate | D |
| | | Dressing is coated in a gel containing anaesthetic | D |

Annex XI: Invitro Diagnostics

Over the counter IVD

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| 1 | Self-testing devices which do not determine a serious condition or the result is purely preliminary, | HCG strips | B |
| | | Glucose meter | A |
| | | Lancet | B |

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| | | Fertility self-testing kits | B |
| 2 | Reagents | Microscope counting chambers such as haemocytometers and chambered urinalysis slides labelled as being intended for the microscopic examination of urine and other body fluids | A |
| 3 | Cell or tissue specimens for subsequent in vitro examination | | A |
| 4 | Non-assay specific instrument consumable reagents | | A |

Prescription only IVD

| | IVD GROUP | IVD EXAMPLE | CLASS |
|---|---|---|-------|
| 1 | All assays used to determine suitability for transfusion or transplantation (in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin) | All assays for diagnosis of HIV 1 & 2, Hepatitis C virus, Hepatitis B virus and HTLV I/II | D |
| 2 | All assays to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation. | All assays for the diagnosis of SARS-COV, highly virulent pandemic influenza, Variola virus (Smallpox virus) and viral haemorrhagic fevers such as Ebola virus or Marburg virus a | D |
| 3 | All assays for the detection of biological markers in order to assess the immunological compatibility | ABO system Rhesus system Kell system. Kid system Duffy system | D |
| 4 | All IVDS; used in tissue typing | To test for human leukocyte antigens and antibodies | C |
| 5 | IVDS; for testing for red blood cell antigens or antibodies | CW or V from the Rhesus system; Cellano (k) from the Kell blood group system; or Any markers from MNS or Cartwright blood group systems | C |
| 6 | IVDS; for detecting the presence of, or exposure to, a sexually transmitted agent; | C. Trachomatis or N. Gonorrhoea | C |
| 7 | | Chlamydia pneumoniae | B |

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| 8 | Detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation; | N. Gonorrhoea antigens Cryptococcus neoformans antigens; Tests for the detection of Haemophilus influenza type B (Hib) antigen; Tests for the detection of IGM antibodies to malaria parasites. | C |
| 9 | IVDS; for pre-natal screening of women in order to determine their immune status towards transmissible agents; | TORCH screen, Measles virus and Treponema pallidum. | C |
| 10 | To monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient | All tests used for human genetic testing Tests to predict metabolism of warfarin, Cytochrome P450 oxidative enzymes Troponin I, Troponin T and CKMB Viral load and genotyping assays for HIV and Hepatitis C virus. | C |
| 11 | Screening for congenital disorders in the foetus | Pre- and post-natal tests for trisomy 13, trisomy 18, trisomy 21 or Klinefelter's syndrome; tests for alpha-fetoprotein (AFP) | C |
| 12 | For selective therapy and management; or for disease staging; or in the diagnosis of cancer; | Viral genotyping assays Her2/neu testing Free prostate specific antigen | C |
| 13 | Self-test devices | System for self-monitoring of blood glucose i.e., glucose reagent test strips for use in self-testing | C |
| | | Urine self-test strips to detect glucose and other general urine chemistry analytes | B |
| | | Malaria antigen tests | B |
| 14 | IVD medical device that is intended to be used as non assay-specific quality control material | Non-assay specific control serum containing multiple biochemical analytes. DNA or RNA probe supplied for use as a non-assay specific control | B |
| 15 | IVD instruments | Specimen receptacle; microbiological culture medium. All instruments intended to be used for in vitro diagnostic examination. | A |
| 16 | Tests | Tests to detect; | B |

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| | | Helicobacter pylori, Clostridium difficile, Adenovirus, Rotavirus and Giardia lamblia | |
| 17 | Reagents | General Stains such as Grams iodine solution | A |
| | | Keilhauer stain kits | B |
| | | Romanowski staining kit A non-assay specific bacterial or viral RNA nucleic acid extraction kit intended for the extraction of pathogenic nucleic acid from a clinical specimen | B |
| 18 | Instruments | Manual, automated or semi-automated instruments such as an enzyme immunoassay analyser, an ESR analyser, or a thermal cycler for performing nucleic acid amplification | A |
| 19 | IVDS; for performing coagulation testing | Activated partial thromboplastin time (APTT), factor assays and prothrombin time testing (other than prothrombin time for self-testing, | B |

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