



REPUBLIC OF KENYA
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

LIST OF STRINGENT REGULATORY AUTHORITIES

The Pharmacy and Poisons Board recognizes the following
Regulatory Authorities as part of the implementation of the
Guidance on Reliance for Regulatory Decision making in Kenya.

(HPT/PER/GUD/034 Rev No.0)

SRA ¹	COUNTRIES
A member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) ²	Austria
	Belgium
	Czech Republic
	Denmark
	Finland
	France
	Germany
	Greece,
	Ireland
	Italy
	Luxembourg
	Poland
	Portugal
	Spain
	Sweden
	The Netherlands
	United Kingdom
	United States of America

¹ A member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); or an ICH observer, or a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, (as before 23 October 2015).

² ICH member being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015);

	Japan
Observers ³	Switzerland,
	Canada
Associates ⁴	Australia,
	Norway,
	Iceland
	Liechtenstein
Joint Assessments-EAC MRH	EAC
Joint Assessments-IGAD MRH	IGAD
WHO Collaborative procedure	WHO HQ
Swiss Medic MAGHP Procedure	Swiss Medic
European Medical Agency (EMA) including European Medical Agency Article 58	EMA
PIC/S ⁵	Argentina
	Australia
	Austria
	Belgium
	Canada
	Croatia
	Cyprus
	Czech Rep
	Denmark
	Estonia
	Finland
	France
	Germany
	Greece
	Hong Kong
	Hungary
	Iceland

³ European Free Trade Association (EFTA) represented by Swiss Medic of Switzerland, and Health Canada as before 23 October 2015.

⁴ Associates through mutual recognition agreements: (as before 23 October 2015).

⁵ For GMP reference only

	Ireland
	Israel
	Italy
	Japan
	Korea Republic
	Latvia
	Liechtenstein
	Lithuania
	Malta
	Netherlands
	New Zealand
	Norway
	Poland
	Portugal
	Romania
	Singapore
	Slovak Republic
	Slovenia
	Spain
	Sweden
	Switzerland
	United Kingdom
	United States of America
African Vaccine Regulatory Forum (AVAREF) ⁶	

Signed by:



Dr. F. M Siyoi

CHIEF EXECUTIVE OFFICER

⁶ *Clinical Trials Only*