Annex I of the Guideline on Reliance: List of Reference Institutions (RIs)

List of regulatory authorities and regional and international bodies that are acknowledged as reference institutions for the purpose of reliance on / use of relevant Marketing Authorisation decisions, reports or information

The following agencies/institutions/organizations are assigned as reference institutions:

- European Medicines Agency (EMA)
- the National Medicines Regulatory Authorities (NMRA) of 27 Member States of the European Union (EU) and 3 EU associated states of the European Economic Area (EEA) (EU: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden; EEA: Iceland, Liechtenstein, Norway)
- Medicines and Healthcare Products Regulatory Agency (MHRA (UK))
- U.S. Food and Drug Administration (US-FDA)
- Pharmaceuticals and Medical Devices Agency (PMDA (Japan))
- Swissmedic (Switzerland)
- Health Canada
- Therapeutic Goods Administration (TGA (Australia))
- World Health Organization (WHO (Prequalification Programme))
- African Vaccine Regulatory Forum (AVAREF)
- Economic Community of West African States/West African Health Organization (ECOWAS/WAHO)
- NMRAs with WHO global benchmarking maturity level of at least 3

Reliance on a regulatory decision based in itself on reliance should not be acceptable.

The basis for reliance should be an assessment of major parts of the submission.

Partial reliance for Active Pharmaceutical Ingredient (API) assessment to WHO (Certificate of a Pharmaceutical Product (CPP)), WHO Prequalification Team - Medicines (PQTm) (Confirmation of Prequalification (CPQ)) or European Directorate for the Quality of Medicines and Healthcare (EDQM) (Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP)) is acceptable.

Table of **partial to full reliance approaches**:

No reliance	Partial reliance	Work sharing	Full reliance
Any other application	WHO-PQ[1] (no CRP[2])	ECOWAS/WAHO	WHO-PQ (CRP)
	EMA MoUs[3] with Ghana FDA		EU-M4all[4] Swissmedic-MAGHP[5] MoUs[3] with Ghana FDA
	NMRAs: EU+EEA, UK, US, CH, CA, AU, JP		AVAREF
	US-FDA PEPFAR[6]		WHO EUL
	EDQM (CEP), WHO PQTm (CPQ), WHO (CPP)		

[1]: Prequalification
[2]: Collaborative Registration Procedure
[3]: Memorandum of Understanding
[4] previous EMA Article-58
[5]: Marketing Authorization for Global Health Products Procedure
[6]: U.S. President's Emergency Plan for AIDS Relief

This list of reference institutions is based on the WHO approach on the framework for evaluating and publicly designating regulatory authorities as WHO-Listed Authority