

Annex 1: 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/organisations are assigned as reference institutions:

- Authorities as per the **List of WHO-Listed Authorities (WLA)**
<https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas>
- Authorities as per the **List of transitional WHO-Listed Authorities**
<https://www.who.int/publications/m/item/list-of-transitional-wlas>
- African Vaccine Regulatory Forum (AVAREF)
- Medicines Regulation Harmonization Programme of the Economic Community of West African States/West African Health Organization (ECOWAS/WAHO)
- World Health Organization (WHO) Prequalification Programme

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 Swiss-medic-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 framework for evaluating and publicly designating regulatory authorities as WHO-Listed Authorities and transitional WHO-Listed Authorities:

<https://www.who.int/initiatives/who-listed-authority-reg-authorities>