

Goals/ Definition

WHO PQ dossier submission.

WHO PQ meeting data submission, and/or meeting decision and recommendations for product prequalification.

(Note: PQ meeting with QSS conducted at the end phase 2)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ Safety and efficacy demonstrated 	<ul style="list-style-type: none"> a) Safety and efficacy data from all clinical trials b) Product release specifications (including pre-approval inspection of manufacturing facilities) c) Stability data to support expiration dating (e.g., cold chain requirements/suitability for use under field conditions, shelf life and remaining shelf life at time of shipment) 	<ul style="list-style-type: none"> ▪ Notification of submission date
<ul style="list-style-type: none"> ▪ Relevance to target population demonstrated 	<ul style="list-style-type: none"> a) Relevance of the available clinical data to the UN target population b) Specific requirements of UN procurers c) Any specific advisory group recommendations needed/documented/addressed 	<ul style="list-style-type: none"> ▪ Summary of special requirements met
<ul style="list-style-type: none"> ▪ WHO tender specifications met 	<ul style="list-style-type: none"> a) Packaging: Volume of cold space required (if any), primary and secondary packaging characteristics b) Suitability of presentation (e.g., tablets, vials, ampoules or prefilled auto-dispensable syringes) c) Applicability packaging requirements d) Adequacy of information on labels for package: all relevant information is stated, insert reflects product characteristics and does not contradict model inserts and WHO policies; availability in all required languages e) Tertiary packaging prepared according to the WHO shipping guidelines and are properly validated 	<ul style="list-style-type: none"> ▪ Summary of product suitability requirements met
<ul style="list-style-type: none"> ▪ Pharmacovigilance (PV) Plan 	<p>Particularly relevant if the drug is intended for launch only in low income countries where passive PV is insufficient. Plan can include:</p> <ul style="list-style-type: none"> a) Summary of key identified and potential risks b) Action Plan for collecting reports of adverse reaction, active monitoring, evaluating and reporting of safety issues to regulatory authorities (e.g., Periodic Safety Update Reports, ADRs: Adverse Drug Reactions) c) Overall PV plan for the product bringing together the actions for all individual safety issues 	<ul style="list-style-type: none"> ▪ High level plan