

## TABLE FOR COMMENTS



**COMMENTS ON WHO WORKING DOCUMENT:** QAS/20.851/Rev.1

**TITLE OF THE DOCUMENT:** GOOD RELIANCE PRACTICES IN REGULATORY DECISION-MAKING FOR MEDICAL PRODUCTS: HIGH-LEVEL PRINCIPLES AND CONSIDERATIONS

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*Kindly complete the table without modifying the format of the document - thank you.*

General comment(s) if any:	Originator of the comments
The title of the document could be made more concise as follows: “Good reliance practices for regulation of medical products: high level principles and considerations”.	ISPE

Section	Line	Comment/rationale	Proposed change/suggested text	Classification L= low, M= medium, H= high	Originator of the comments (for WHO use)
2	97	Editorial: spelling error	Change “heath” to “health”	L	
3	155	It would be useful to give an example of a recent MRA.	Suggest adding at end of sentence: “... such as the MRA on the Inspection of Manufacturers of Medicines between US and EU”.  (if this proposed change is agreed, a reference to this MRA will need to be added).	M	
4	184	It would be useful to mention that these practice guides, case studies, etc. will be in future editions of the document.	Suggest amending to read: “It will be complemented in future editions of this document by a ....”.	L	
4	184	We suggest using the term “good practice guides” instead of “practice guides”.	... consisting of good practice guides, case studies ...	M	
6.1	233	Rephrase sentence for better flow and clarity.	... relevant internationally recognized standards	M	

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			and guidelines such as those of ISO, ICH, PIC/S and the pharmacopoeias.		
6.1	252	For clarity, replace “institution” with “scheme”, and add “program”	... a trusted scheme such as WHO pre-qualification (WHO PQ) program, being relied upon by ...	M	
6.1	298	Editorial: Maintain style used for each definition by deleting “A” at the start.	Amend to read: “joint activity. A joint activity is a form of ...”	L	
6.2.5	386	Include ASEAN Sectoral MRA on GMP Inspection in addition to EU processes.	... is binding on the member states (e.g. ASEAN Sectoral MRA on GMP Inspection and EU processes).	H	
8	488	We suggest using the term “good practice guides” instead of “practice guides”.	... Case studies, good practice guides and the ...	M	
8	489	It would be useful to mention that the practice guides and reliance repository will be in future editions of the document.	... reliance repository in future editions of this document.	L	
8.1.1	523	We suggest emphasizing that NRAs should also monitor and evaluate the “benefits” of regulatory reliance.	WHO encourages NRAs to monitor and evaluate the impact, including benefits, of regulatory reliance in their country and ...	M	
8.1.2	554	Trust should also be built with industry.	Trust should also be built with the public, healthcare professionals and industry in order ...	M	
8.1.4	566	Rephrase the sub-heading for consistency with other sub-headings under Section 8.1	Investment of resources and time in implementing reliance	M	
8.1.4	574	It also is important to establish communication links and networks with other regulators.	... Information sharing platforms, communications links and networks with other NRAs.	M	
8.1.6	608	We propose that transparent publication of an NRA’s reliance framework and strategies, as well as the metrics used and benefits achieved, will provide industry with encouragement to support and promote the NRA’s approach.	Suggest adding a new paragraph: “Transparent publication of an NRA’s reliance framework and strategies, as well as the metrics used and benefits achieved, will provide industry with encouragement to support and promote the NRA’s approach”.	H	
8.1.7	609	Rephrase the sub-heading for consistency with	Invoking reliance during public health emergency	M	

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		other sub-headings under Section 8.1			
8.2.3	645	We suggest rephrasing the sub-heading for greater clarity	Other potential barriers	M	
8.3.3	684	Change “between” to “among” as multiple regulators are involved	Information-sharing and dialogue among regulators	M	
8.3.3	687	Change “between” to “among” as multiple regulators are involved	The increasing dialogue among regulators is seen ...	M	
8.3.3	696	We suggest including PIC/S because this organisation promotes and disseminates regulatory information internationally among more than 50 NRAs.	... Such as ICH, ICDRA and PIC/S conferences, meetings, are also platforms that promote the ...	M	
Annex 1	749	Please elaborate description of Annex 1 for greater clarity.	Annex 1: Examples of applications of regulatory reliance	M	
Annex 1 (f)	919	Provide a specific example from ASEAN.	... (USA), ASEAN Sectoral MRA on GMP Inspection.	M	