Annex 4b QIS-RI-BTP

Quality Information Summary (QIS) of the Biotherapeutic Product Approved by a Reference Institution (RI) (QIS-RI-BTP)

A1. Biotherapeutic Product (BTP) or corresponding Similar Biotherapeutic Product (SBP) information (as currently approved by RI)

A1-1. Product reference number (RI number)
A1-2. Reference institution
A1-3. Name of the holder of the Marketing Authorization and official address
A1-4. Proprietary name of the drug product (DP) in the RI country/region
A1-5. International Nonproprietary Name (INN) of drug substance (DS)
A1-6. Dosage form and strength
A1-7. Description of the DP (as in Product Information, e.g. powder for concentrate for solution for infusion; concentrate for solution for infusion, white powder, clear, colourless liquid, excipients)
A1-8. Description of the DS. Brief description of the molecular features (e.g. engineered mouse/humanized/fully human monoclonal antibody, type of IgG), brief description of the manufacturing process (producing cell line, purification methods, presence of viral inactivation steps, etc.)
A1-9. Primary and secondary packaging material(s) and pack size(s) (all pack types)
A1-10. Storage conditions (as in Product Information) and any special precautions for storage (including storage conditions after reconstitution/first opening, where applicable)
A1-11. Shelf-life of the DP (including in-use period and conditions, where applicable)
A1-12. Names of all approved manufacturers of DP, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, primary packaging site and release testing (indicate function of each site)
A1-13. Names of all approved DS manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (indicate function of each site)

A2. Reference Biotherapeutic Product (RBP) information (as approved by the RI at the time of submission of the SBP application)

A2-1. Product reference number (RI number), if applicable.
A2-2. Reference institution
A2-3. Name of the holder of the Marketing Authorization and official address
A2-4. Proprietary name of the drug product (DP) in the RI country/region
A2-5. INN of DS
A2-6. Dosage form and strength

A2-7. Description of the DP (as in Product Information, e.g. powder for concentrate for solution for infusion; concentrate for solution for infusion, white powder, clear, colourless liquid, excipients)
A2-8. Description of the DS. Brief description of the molecular features (e.g. engineered mouse/humanized/fully human monoclonal antibody, type of IgG), brief description of the manufacturing process (producing cell line, purification methods, presence of viral inactivation steps, etc.)
A2-9. Primary and secondary packaging material(s) and pack size(s) (all pack types) if available
A2-10. Storage conditions (as in Product Information) and any special precautions for storage (including storage conditions after reconstitution/first opening, where applicable)
A2-11. Shelf-life of the DP (including in-use period and conditions, where applicable)
A2-12. Names of all approved manufacturers of DP, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, primary packaging site and release testing (indicate function of each site) if available
A2-13. Names of all approved DS manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (indicate function of each site) if available
A2-14. References/source of information with corresponding URL addresses (e.g. labelling, EU SmPC, EPAR – Scientific Discussion, PMDA Review reports, FDA Chemistry review, scientific literature…)

BTP or corresponding SBP information (as currently approved by the RI) that will not be made publicly available

B1. Composition (formulation) information					
Component and quality standard	Function	Unit composition		Batch composition (largest approved size)	
		Quantity per unit or per ml	% (if applicable)	Theoretical quantity/ batch	% (if applicable)
<complete with appropriate title, e.g., active ingredients, excipients>					
Batch size in number of units/L, where applicable					
Additionally approved batch sizes - in number of units or L, where applicable (add as many rows as necessary)					
Excipients with known effects if applicable					

RBP information (as currently approved by the RI) that will not be made publicly available

B2. Composition (formulation) information (Applicable for a SBP submitted for prequalification)
Name of the RBP

Component and quality standard	Function	Unit composition	
		Quantity per unit or per ml	% (if applicable)
<complete with appropriate title, e.g., active ingredients, excipients>			
Excipients with known effects if applicable			

B3. BTP drug product specifications			
Standard (e.g. International Pharmacopoeia, British Pharmacopoeia, United States Pharmacopeia) if available			
Specification reference number and version/effective date			
Test	Acceptance criteria (release)	Acceptance criteria (shelf-life)	Analytical procedure (type/source/ version)
Visual appearance			
Identity			
Potency			
Impurities			
Endotoxin			
Sterility			
etc.			

B4. Pharmacokinetic/safety/efficacy related information used for RI approval of the SBP. Indicate: (Applicable for a SBP submitted for prequalification)		
Name of the RBP		
Name of the holder of the Marketing Authorisation of the RBP		
Type of study		"X" in appropriate box
Comparability exercise/similarity exercise (head-to-head comparability studies with the SBP in order to show similarity in terms of	quality	
	safety/non-clinical	
	efficacy/clinical	
Other (specify) (e.g. pharmaco-toxicological	-	

assessment, design of the use of pharmacodynamic markers, pharmacovigilance studies potentially performed, extrapolation of safety and efficacy)	-	
	-	
Notes/clarifications		

B5. Contact information for communication with RI	
Contact person and postal address	
(International code) Telephone number	
(International code) Fax number	
Email address	

Change history to QIS-RI and product information

Date of preparation of original QIS-RI: .....

Date of revision (reported variation*)	**Revision/variation description**

*Variations approved by the RI after prequalification of the Drug product and affecting only the QIS-RI and/or Product Information should be reported in the change history.