IPRP
International Pharmaceutical Regulators Programme

Work Plan

Biosimilar Working Group (BWG)

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1. Key Milestones and Deliverables

1.1. Current status of key milestones and deliverables

Completion date	Objective	Key Milestone or Deliverable
Aug. 2016	To provide a template to assist NRAs in making available a summary of the review of biosimilar applications in their country in a common language (English)	Public Assessment Summary Information for Biosimilar (PASIB)
Mar. 2017	To help train quality reviewers with experience in biotherapeutics to review the analytical comparability of biosimilar monoclonal antibodies	Training Manual for Regulatory Reviewers : The Basics of Analytical Comparability of Biosimilar Monoclonal Antibody for Regulatory Reviewers
Nov. 2017	To compile the common features of various biosimilar guidelines and to highlight to NRAs harmonized scientific considerations on the extrapolation of indication(s) for biosimilar products	Reflection Paper on Extrapolation of Indications in Authorization of Biosimilar products
Dec. 2018	To establish an IT platform for regulatory convergence on biosimilars by collecting regulatory information and sharing experiences between regulators on NRA's activities in order to enhance transparency and provide information to the members and the public	IPRP BWG Regulatory Information Sharing Platform

Dec. 2019	To help train reviewers with experience in biotherapeutics to review the nonclinical comparability of biosimilar monoclonal antibodies	Training Manual for Regulatory Reviewers: The Basics of Nonclinical Comparability of Biosimilar Monoclonal Antibody for Regulatory Reviewers
Dec. 2020	To help train reviewers with experience in biotherapeutics to review the clinical comparability of biosimilar monoclonal antibodies	Training Manual for Regulatory Reviewers: The Basics of Clinical Comparability of Biosimilar Monoclonal Antibodies for Regulatory Reviewers

1.2. Future anticipated key milestones

Expected future completion date	**Objective**	**Key Milestone or Deliverable**
Dec. 2021	To educate regulatory reviewers about current approaches with respect to specific scenarios in the regulation of biosimilar biotherapeutic products	1) Primer on Specific Regulatory Issues/Topics a. When a different strength is proposed b. When a different presentation is proposed c. When a different route of administration is proposed d. When a new condition of use or dosing regimen is proposed e. When a foreign-sourced reference biotherapeutic product is proposed for use in comparability studies f. Additional topics as raised by working group members

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	**End date**	**Task / Activity**	**Details**
Mar. 2021	Oct. 2021	1. Drafting of materials 2. Teleconferences - 1st TC (March) - 2nd TC (June) - 3rd TC (Sept-Oct)	1. Pre-Tcon, Firm up work plan details with BWG, receive initial input for first draft to be discussed at March tcon 2. March Tcon: discuss clarifications / concerns / next steps

		No face-to-face meeting currently planned	3. Post-Tcon: capture discussion in minutes and revise document(s) accordingly; receive next section input 4. June Tcon: discuss clarification / concerns / next steps 5. Post-Tcon: capture discussion in minutes and revise accordingly; receive next section input 6. Fall Tcon: discuss clarifications / concerns / final edits / next steps
Nov. 2021	Dec. 2021	Finalization of Primer and submission to MC (Nov.) Publication at IPRP's homepage (Dec.)	7. Nov 2021: Finalize document and refer to IPRP MC 8. Dec 20/21: Publish on IPRP website