IPRP
International Pharmaceutical Regulators Programme

Work Plan
Bioequivalence Working Group for Generics (BEWGG)

Date: 30 October 2024

Co-Chair: Clare Rodrigues, HSA, Singapore

Co-Chair: Matthias Roost, Swissmedic, Switzerland

1. Key Milestones and Deliverables

i. Deliverable 1: BCS-based biowaivers

   a. *Concerning biowaiver applications where* in vitro *data based on the Biopharmaceutics Classification System (BCS) may replace* in vivo *bioequivalence study data*

ii. Deliverable 2: Additional strength biowaivers

   a. *Concerning biowaiver applications where* in vivo *bioequivalence studies conducted in certain strengths of the generic product can be extended to the remaining 'additional strengths'*

iii. Deliverable 3: Biowaivers by dosage form

   a. *Concerning biowaiver applications where certain dosage forms may be accepted without* in vivo *bioequivalence study data*

   b. *This deliverable has been split into 3 parts in order to allow discussions of sufficient detail for each dosage form:*

      i. *Oral and injectable products*

      ii. *Topical products (including otic and ophthalmic products, enemas, suppositories and vaginal pessaries)*

      iii. *Orally inhaled and nasal products*

iv. Deliverable 4: Acceptability of foreign comparator products in bioequivalence studies

   a. *Concerning situations where an in vivo bioequivalence study involves a foreign-sourced comparator product as the reference instead of the locally-sourced comparator product*

v. Deliverable 5: Alternative comparator product policies

   a. *Concerning the identification of the appropriate comparator product when the innovator product is no longer registered or marketed locally*

vi. Deliverable 6: Bioequivalence study design

   a. *Concerning the policies and approaches for the selection of type and number of BE studies*

vii. Deliverable 6: Data integrity issues in bioequivalence studies

a. Concerning information sharing on inspection findings related to data integrity and data-based approaches for detecting signals of data manipulation

1.1. Current status of key milestones and deliverables

Past completion date	**Objective**	**Key Milestone or Deliverable**
28 Feb 2017	BCS-based biowaivers	Published assessment report template on IGDRP website
25 Jan 2018	BCS-based biowaivers	Published gap analysis survey results in JPPS and IGDRP website
27 Dec 2018	Acceptability of foreign comparator products in bioequivalence studies	Published gap analysis survey results in JPPS and IPRP website
5 Feb 2019	Additional strength biowaivers (immediate-release dosage forms)	Published assessment report template on IPRP website
29 Sep 2019	Additional strength biowaivers (immediate-release dosage forms)	Published gap analysis survey results in JPPS
14 March 2021	Biowaivers for dosage forms (oral and injectable products)	Published gap analysis survey results in JPPS
25 October 2021	Additional strength biowaivers (modified-release dosage forms)	Published gap analysis survey results in JPPS
8 October 2022	Alternative comparator product policies	Published gap analysis survey results in JPPS
21 March 2024	Bioequivalence study designs	Published gap analysis survey results in JPPS
November 2024	Biowaivers for dosage forms (topical products)	Draft manuscript presented to IPRP Management Committee for endorsement
November 2024	BCS-based biowaivers	Updated draft assessment report template (aligned to ICH M9 guideline) presented to IPRP Management Committee for endorsement to publish on IPRP website
November 2024	Biowaivers for dosage forms (oral and injectable products)	Draft assessment report templates presented to IPRP Management Committee for endorsement to publish on IPRP website

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
Dec 2024	Biowaivers by dosage form – Part 2 (topical products)	Submit manuscript for publication
Jan 2025	BCS-based biowaivers	Publish updated assessment report template on IPRP website
Jan 2025	Biowaivers by dosage form – Part 1 (oral and injectable products)	Publish updated assessment report templates on IPRP website
Jan - Jun 2025	Support for ICH harmonisation	Assessment of work areas to support ICH M13C and future EWG on BE for modified release products
Feb 2025	Data integrity issues in bioequivalence studies	Circulate short report for IPRP member regulators
Mar 2025	Biowaivers by dosage form – Part 2 (topical products)	Submit draft assessment report templates to IPRP Management Committee for endorsement to publish on IPRP website
Sep 2025	Foreign comparator products in BE studies	Finalise draft manuscript for agency clearance
Sep 2026	Biowaivers by dosage form – Part 3 (nasal and inhaled products)	Finalise draft manuscript for agency clearance
End 2026	Biowaivers by dosage form – Part 3 (nasal and inhaled products)	Initiate assessment report templates

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
Nov 2021	Nov 2025	Data integrity issues in bioequivalence studies	Nov 2023: survey of current requirements Jan 2024: Discussion of survey outcomes Feb 2024: First review of updated report with appendices on GCP and data analysis approaches Jan 2025: finalise report

			Feb 2025: circulate report to MC Mar 2025: initiate planning for content of manuscript for publication
Mar 2023	Jun 24	Biowaivers by dosage form – Part 1 (oral and injectable products) – assessment report templates	Mar 2023: Review of first batch of assessment report templates Mar 2024: Finalise templates Jun 2024: IPRP website publication
May 2023	Jan 2025	BCS-based biowaivers	May 2023: Initiate updates to assessment report template according to ICH M9 requirements Sep 2024: Finalise template Nov 2024: Submission to IPRP MC for endorsement to publish on IPRP website Jan 2025: IPRP website publication
Sep 2024	Jun 2024	Support for ICH harmonisation	Sep 2024: initiate assessment of work areas to be covered (work already completed + gaps to be addressed by BEWGG) Jan 2025: Summarise data collected from members for sharing with ICH M13 EWG
Aug 2024	Jan 2026	Foreign comparator products in BE studies	Aug 2024: initiate survey to capture updated requirements Sep 2024: Discussion of information to be included Sep 2025: Finalisation of draft manuscript and start of agency clearance process Nov 2025: Submission to IPRP MC for endorsement to publish Jan 2026: Submit manuscript to journal
Sep 2025	Jan 2027	Biowaivers by dosage form – Part 3 (nasal and inhaled products)	Sep 2025: Review of first draft manuscript Sep 2026: Finalise draft article for agency clearance Nov/Dec 2026: Obtain MC endorsement for publication Jan 2027: Submit manuscript to journal

2025	2025	Face-to-face meeting	Exact dates and venue to be confirmed
	-	Teleconferences	Held every 6-8 weeks between face to face meetings