IPRP
International Pharmaceutical Regulators Programme

Work Plan
Bioequivalence Working Group for Generics (BEWGG)

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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
March 2023	Biowaivers for dosage forms (oral and injectable products)	Commenced drafting and review of assessment report templates
30 May 2023	Biowaivers for dosage forms (topical products)	First detailed review of draft manuscript
31 May 2023	BCS-based biowaivers	Reviewed updated draft assessment report template (aligned to ICH M9 guideline)
13 October 2023	Bioequivalence study designs	Obtained MC endorsement for publication of manuscript

1.2. Future anticipated key milestones

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

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
Nov 2021	Sep 24 (?)	Data integrity issues in bioequivalence studies	Nov 23: survey of current requirements Jan 24: Discussion of survey outcomes Feb 24: First review of updated report with appendices on GCP and data analysis approaches May 24: finalise report Jun 24: circulate report to MC Sep 24: 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 23: Review of first batch of assessment report templates Mar 24: Finalise templates Jun 24: IPRP website publication
May 2023	Mar 24	BCS-based biowaivers	May 2023: Initiate updates to assessment report template according to ICH M9 requirements Jan 2024: Finalise template Mar 2024: IPRP website publication
Jan 2024	Jun 2024	Support for ICH harmonisation	Jan 24: initiate assessment of work areas to be covered (work already completed + gaps to be addressed by BEWGG) Jun 24: Summarise data collected from members for sharing with ICH M13 EWG
Jul 24	Sep 24	Foreign comparator products in BE studies	Jul 24: initiate survey to capture updated requirements Sep 24: Discuss next steps (publication?)
Sep 2024	Jan 2026	Biowaivers by dosage form – Part 3 (nasal and inhaled products)	Sep 24: Review of first draft manuscript Sep 25: Finalise draft article for agency clearance Nov/Dec 25: Obtain MC endorsement for publication Jan 26: Submit manuscript to journal
Sep 2024	Sep 2024	Face-to-face meeting	Hosted by HSA, Singapore
	-	Teleconferences	Held every 6-8 weeks between face to face meetings