IPRP
International Pharmaceutical Regulators Programme

Work Plan
Bioequivalence Working Group for Generics (BEWGG)

Date: 16 November 2022

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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*

      iii. *Orally inhaled and nasal products*

   c. *Otic and ophthalmic products will also be included*

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*

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
8 Nov 2019	Bioequivalence study designs	Completed survey of requirements *N.B. this spreadsheet was shared with ICH M13 on 24 April 2020*
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

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
Jan 2023	Bioequivalence study designs	Submit for MC endorsement for publication in JPPS
Nov/Dec 2022	Biowaivers by dosage form – Part 2 (topical products)	Review of first draft manuscript

March 2023	Biowaivers by dosage form – Part 1 (oral and injectablel products)	Review of first draft assessment report templates
Ongoing	Data integrity in bioequivalence studies	(Standing agenda item)

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	**End date**	**Task / Activity**	**Details**
Oct 2021	Jan/Feb 2022	Bioequivalence study designs	Finalise draft article Submit for internal clearances Submit for MC endorsement Submit for publication
Jan 2022	Sep 2023	Biowaivers by dosage form – Part 2 (topical products)	Review of first draft manuscript Finalise draft article
May 2022	May 2023	Biowaivers by dosage form – Part 1 (oral and injectablel products)	Review of first batch of assessment report templates Finalise templates IPRP website publication
Nov 2022	-	Teleconferences	Held every 6-8 weeks between face to face meetings
To be confirmed	-	5th BEWGG meeting	*To be confirmed*