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*

      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*

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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*
7 Oct 2020	Biowaivers for dosage forms (oral and injectable products)	Submitted manuscript to JPPS for publishing

1.2. Future anticipated key milestones

Expected future completion date	Objective	Key Milestone or Deliverable
Feb 2021	Additional strength biowaivers (modified-release dosage forms)	Submit manuscript to JPPS for publishing
Mar 2021	Alternative comparator product policies	Submit for MC endorsement for publication in JPPS
Jun 2021	Bioequivalence study designs	Finalise draft article and circulate for internal clearances
Jun 2021	Biowaivers by dosage form – Part 2 (topical products)	Review of first draft manuscript
Ongoing	Data integrity in bioequivalence studies	(Standing agenda item)

2. TIMELINE FOR SPECIFIC TASKS

Beginning date	End date	Task / Activity	Details
Oct 2018	Sep 2020	Additional strength biowaivers (modified-release)	Submit for internal clearances Submit for MC endorsement
Oct 2018	Mar 2021	Alternative comparator product policies	Finalise draft article Submit for internal clearances Submit for MC endorsement
Jun 2019	Sep 2021	Bioequivalence study designs	Finalise draft article Submit for internal clearances Submit for MC endorsement
May 2020	-	Teleconferences	Held every 6-8 weeks between face to face meetings
Q1/Q2 2021	-	5th BEWGG meeting	*To be confirmed*