IPRP
International Pharmaceutical Regulators Programme

# Mandate Document
# Bioequivalence Working Group for Generics (BEWGG)

Version 2.0

endorsed by the MC on 20 November 2019

Document History

| Version number | Action | Date of endorsement |
|---|---|---|
| **v2.0** | Revision of the Mandate document based on the updated template presented to the MC for endorsement at the meeting in Singapore in November 2019. | **November 2019** |
| **v1.0** | First version of the Mandate document (dated 17 November 2018) presented to the MC for endorsement at the meeting in Charlotte, USA in November 2018. | **November 2018** |

# 1. General Considerations

## 1.1. Statement of the Perceived Problem

The availability of quality generic medicines plays an increasingly important role in helping to address rising health care costs and in promoting access to essential medicines worldwide. This, however, places significant pressures on regulatory authorities (RAs) tasked with the review and authorisation of these drug products. In addition to an increased workload associated with the growing number of generic drug applications, RAs must also contend with more sophisticated generic drug products and issues associated with complex global production and distribution chains.

Apart from manufacturing being spread across the globe, companies have to grapple with different regulatory requirements and procedures among regulators. This has resulted in companies having to perform multiple sets of bioequivalence studies to support a single product in multiple jurisdictions, resulting in inefficiencies and unnecessary delays and costs to patients. Given these challenges, the benefits of regulatory cooperation, convergence and information sharing have long been recognised.

The strategic priorities identified by the IPRP create a pathway for its goals to be achieved in responding to the challenges faced by RAs. These are relevant for information sharing, facilitating collaboration in efforts towards harmonisation and promoting regulatory convergence in the area of bioequivalence in support of generic drug products.

## 1.2. Expected Benefits

The BEWGG was formed to provide a platform for open discussions and information sharing among generic drug regulators relating to bioequivalence issues in the generics space.

The work of the BEWGG has been shown to result in greater collaboration and regulatory convergence since its inception. This is achieved through information-sharing related to the implementation of existing regulatory guidelines and sharing of best practices, as well as a collective awareness of ongoing international developments and initiatives. In the longer term, these activities are expected to increase the efficiency and effectiveness of the generic drug review process while reducing regulatory burden for RAs and the generics industry.

## 1.3. Background to the proposal

The Biowaivers Working Group was formed in May 2013 within the International Generic Drug Regulators Pilot (IGDRP) to establish a framework and mechanisms for enhanced information sharing for biowaivers, and the possible future reliance on the assessments of the participating regulatory authorities/organisations. In 2016, the scope of the working group was expanded to enable discussions and activities on Bioequivalence information associated with applications for generic drug products, while continuing to focus on biowaivers. The Biowaivers Working Group was renamed to the Bioequivalence Working Group. Under the IGDRP, the working group produced an assessment report template for BCS-based biowaivers and this was published on the IGDRP website.

To date, the BEWGG has completed a number of key projects, including publications highlighting opportunities and challenges to the harmonisation of technical requirements in the field of bioequivalence and biowaivers for generic medicines.

## 2. SCOPE

The scope of the BEWGG is aligned with the scope of activities as outlined in the IPRP Terms of Reference. It covers the implementation and interpretation of bioequivalence requirements, procedures and tools for the assessment of bioequivalence in generic drug products.

The BEWGG's areas of work will complement and not duplicate established international initiatives and developments that are in progress.

## 3. OBJECTIVES

The BEWGG identifies opportunities for regulatory convergence and harmonisation by surveying and collating information from each member agency/organisation regarding issues of common interest related to the bioequivalence assessment of generic drug products. Where appropriate, the BEWGG also develops tools to aid in the assessment of bioequivalence in generic drug products applications.

- Objective 1: Facilitate regulatory convergence and identify opportunities for harmonisation in the area of bioequivalence supporting generic drug applications

  To identify areas of commonalities and differences in existing technical and regulatory requirements concerning bioequivalence (and biowaivers) in order to highlight opportunities for regulatory convergence and harmonisation.
- Objective 2: Support bioequivalence assessment of generic drug applications

  To engage in information sharing to highlight best practices, international regulatory requirements and sharing of technical issues of interest encountered in day to day work.

## 4. COMPOSITION

The regulatory authorities/organisations involved in the group are listed below.

- Argentina: Administración Nacional de Medicamentos, Alimentos y Tecnología Medica (ANMAT)
- Australia: Therapeutic Goods Administration (TGA)
- Brazil: Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada
- Colombia: Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)
- European Union (EU) / CMDh
- Japan: Ministry of Health, Labour and Welfare (MHLW)/Pharmaceuticals and Medical Devices Agency (PMDA)
- Republic of Korea: Ministry of Food and Drug Safety (MFDS)
- Mexico: Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
- New Zealand: Medsafe
- Singapore: Health Sciences Authority (HSA) – **Co-chair**
- South African Health Products Regulatory Agency (SAHPRA)
- Swissmedic
- Taiwan Food and Drug Administration (TFDA)
- US Food and Drug Administration (USFDA)
- World Health Organization (WHO) – **Co-chair**

# 5. SPECIFIC ORGANISATION

## 5.1. Designation of a Chair Supporteur

None – the co-chairs are responsible for secretariat support, e.g. setting up teleconferences, writing meeting agenda, records of discussions.

## 5.2. Organisation of meetings

The BEWGG meets on a regular basis by teleconference (about every 6-8 weeks) and at face-to-face meetings (normally twice a year). The BEWGG and the Quality Working Group for Generics (QWGG) usually hold parallel face-to-face meetings in the same week and in the same venue.

## 5.3. Contact with stakeholders

Public symposia may be organised in the margins of BEWGG face-to-face meetings in order to communicate public information on progress made and to gather feedback from the stakeholders on particular projects. These symposia are organised by the regulatory agency/organisation which hosts the BEWGG meeting in conjunction with the relevant local industry association.

The IPRP website will also be used for external communication of the BEWGG (posting documents, publications, updates, tools etc).