IPRP
International Pharmaceutical Regulators Programme

Mandate Document

Biosimilars Working Group (BWG)

Version 2.0

endorsed by the MC on 12 November 2018

Document History

Version number	Action	Date of endorsement
v2.0	The IPRP MC confirmed endorsement of the mandate document at the meeting in Charlotte, NC, USA in November 2018.	**12 November 2018**
v2.0	Second version of the Mandate document (dated 29 May 2017) presented to the IPRF MC for endorsement at the meeting in Montreal, Canada in May, 2017.	**1 Sep. 2017**
v1.0	First version of the Mandate document (dated 7 Nov. 2016) presented to the IPRF MC for endorsement at the meeting in Osaka, Japan in Nov, 2016.	**2 Feb. 2017**

1. General Considerations

1.1. Statement of the Perceived Problem

Biosimilars are biotherapeutic products that are generally composed of complex biological substances, which may demonstrate a degree of variability (e.g. microheterogeneity). This variability is may be the potential challenge to develop a highly similar (biosimilar) version of the biological medicine since they are relatively new and further experience needed to be gained in the global environment.

1.2. Expected Benefits

Biosimilars Working Group will contribute to provide meaningful outcome to promote public health through more affordable biosimilar products.

1.3. Background to the proposal

The expiration of patent of original biological products enables the regulatory pathway for follow-on biological products, which were produced to be similar to already licensed original products. EMA was a pioneer for establishing legislation and guidelines from 2005 and called the product according to this process 'biosimilar'. Japan, Canada, Korea as well as WHO published their guidelines for biosimilar product. Many biosimilar products are already licensed in many countries. As a result of the experience for last 7 ~ 8 years, necessity for regulatory convergence arose due to the global development trend of biosimilars. In the ICH meeting held in Osaka, 2013, it was agreed to establish an IPRF Working Group on Biosimilar products to discuss emerging issues and to promote regulatory convergence.

In these circumstances, the need for discussion group for regulatory issues has been increased to promote convergence of review and regulation of biosimilar products.

2. Scope

To discuss regulatory challenges and potential topics/areas for harmonization or convergence regarding biosimilars

To consider how regulatory convergence can be achieved and how regulatory information can be exchanged without compromising confidentiality

To explore work sharing process with other international bodies and to collaborate in terms of training of international regulators

3. Objectives and Key Deliverables

3.1. Objectives

- Objective 1: Regulatory convergence

  For regulatory convergence of technical requirements for biosimilar products in facilitating the regulatory process

- Objective 2: Regulatory frameworks

  To support international regulators develop safe and effective regulatory frameworks for biosimilar products

3.2. Key deliverables

- Deliverable 1: Public Assessment Summary Information for Biosimilar (PASIB)

  Purpose

  - To provide a template to assist NRAs in making available a summary of the review of biosimilar applications in their country in a common language (English)

  Structure

  - Part A: Administrative information
    - Biosimilar Product & Reference Biotherapeutic Product (RBP) Information
    - Summary of outcomes
  - Part B: Submitted data and reviewer summary
    - Quality, Non-clinical & Clinical Data
    - Post-authorization measures
  - Part C: Reviewer conclusions

- Deliverable 2: Reflection Paper on Extrapolation of Indications in Authorization of Biosimilar Products

  Purpose

  - To compile the common features of various biosimilar guidelines and to highlight to NRAs harmonized scientific considerations on the extrapolation of indication(s) for biosimilar products

  Structure

  1. Scope and Application
  2. Executive Summary
  3. Background
  4. General Considerations
     - Principles for Demonstrating Biosimilarity
     - Principles for Extrapolation of Indications
  5. Specific Considerations for the Extrapolation of Indications
     - Evidence from Analytical Comparability Study
     - Evidence from *in vitro* and/or *in vivo* Functional Studies
     - Evidence from Clinical Studies
     - Evidence from Publicly Available Information
     - Evidence to be Provided Where a Residual Uncertainty Remains
  6. References

- Deliverable 3: Training Manual for Regulatory Reviewers : The Basics of Analytical Comparability of Biosimilar Monoclonal Antibody for Regulatory Reviewers

  Purpose

  - To help train quality reviewers with experience in biotherapeutics to review the analytical comparability of biosimilar monoclonal antibodies

  Structure

  1. General concepts of biosimilar
  2. Analytical comparability assessment
  3. Appendix 1 : Additional information

4. Appendix 2 : Case study (Remsima/Inflectra)

4. COMPOSITION

The working group is comprised of international regulatory authorities

- 11 Regulatory authorities [Brazil, Canada (Co-Chair), Europe, Japan, Mexico, Republic of Korea (Chair), Saudi Arabia, Singapore, Switzerland, Taiwan, US] and 3 Organizations [WHO, PANDRH (Pan American Network on Drug Regulatory Harmonization), EAC (East African Community)]

5. SPECIFIC ORGANISATION

5.1. Designation of a Chair Supporteur

To develop a draft longer-term plan of discussion topics

To draft agendas for each meeting

To facilitate and conduct the Forum face-to-face meetings

To organize periodic teleconferences, and/or videoconferences, and to lead the group in making progress on topics or sunsetting those topics in which progress cannot be made

A co-chair will also be appointed from the membership, for the same renewable terms length, and will assist the Chair, sharing the management workload and helping maintain progress on the work undertaken by the Forum.

5.2. Organisation of meetings

Biosimilars Working Group will meets every 3 ~ 4 month from end of March via teleconference.

The Chair will organize the teleconference by providing multi-connecting phone and pin number. The Chair will draft agenda and circulate to members at least one week before teleconference (Co-chair to assist).

The Chair and co-chair will facilitate teleconference to make conclusion, action points, next steps.

The co-chair will draft meeting minute for circulation.

The chair will circulate meeting minute and take comments from members to finalize it.

5.3. Contact with stakeholders

Not available