

Mandate Document

Quality Working Group (QWG)

Version 2.0
endorsed by the MC on 28 May 2020

Document History

| Version number | Action | Date of endorsement |
|----------------|---|----------------------|
| v1.0 | Draft version of the Mandate document (dated 2018-11-05) presented to the MC for endorsement at the meeting in Charlotte, USA in November 2018 | November 2018 |
| V1.1 | Revised version reflecting changes to the Mandate format and inclusion of a third objective clarifying the activities of the WG, aligning with the IPRP strategic objectives. Presented to the MC for endorsement at the meeting in Singapore in November 2019. | November 2019 |
| V2.0 | Revision of mandate to reflect the removal of the term Generic from the Working Group title and to incorporate minor revisions | May 2020 |

1. GENERAL CONSIDERATIONS

1.1. Statement of the Perceived Problem

The medicines industry operates at a global level. Drug product manufacturers seek authorisation for the same, or similar, drug product in multiple jurisdictions. Moreover, a single drug substance manufacturer may be supplying multiple drug product manufacturers with the same drug substance, supported by the same or essentially similar Active Substance Master File (ASMF)/Drug Master File (DMF).

Significant pressures are placed on regulatory authorities and organisations (RAs) tasked with the review and authorisation of these drug products. In addition to an increased workload associated with the growing number of drug applications, RAs must also contend with more sophisticated drug products and issues associated with complex global production and distribution chains.

Different procedures and technical requirements among RAs, together with limited operational mechanisms for effective information sharing among RAs, can present challenges to bringing safe, effective and high-quality medicines to the market in a timely manner.

Despite these pressures, the timely availability of quality medicines, plays an important role in helping to address rising health care costs and in promoting access to essential medicines worldwide.

Quality issues that may arise for a specific drug product or drug substance often have widespread consequences across multiple RAs and a collaborative regulatory response to issues is beneficial.

Given these challenges, the benefits of regulatory cooperation, convergence and information sharing have long been recognised.

The strategic priorities of the IPRP create a pathway to respond to the challenges faced by RAs. They are relevant to information sharing; facilitating collaboration towards harmonisation and promoting regulatory convergence for the assessment of drug substance information (e.g., in ASMFs/DMFs) and drug product applications, to enhance the effectiveness and efficiencies of regulatory programmes.

1.2. Expected Benefits

As a standing regulator-only working group, the IPRP Quality Working Group (QWG) serves as a forum in which quality-related issues can be discussed confidentially, including important emerging quality-related issues that arise. In turn, this facilitates the implementation of ICH guidelines and, in a reciprocal manner, the QWG may also identify topics that are suitable for broader discussions within the ICH environment.

The QWG seeks to increase the efficiency and effectiveness of drug substance and drug product review processes by: developing and making common Quality-assessment tools available to medicine regulators; and reducing differences in the interpretation of quality issues between regulators.

As well as providing greater consistency in the interpretation and application of technical requirements for the pharmaceutical industry, the increased convergence and availability of common assessment tools also increases opportunities for RAs to benefit from information sharing. The identification of the circumstances and mechanisms under which this might best occur seeks to maximise these opportunities and thereby reducing the overall regulatory burden of regulatory authorities and organisations.

1.3. Background to the Proposal

The QWG was formed in May 2013 within the International Generic Drug Regulators Pilot (later named the International Generic Drug Regulators Programme) (IGDRP) to establish a framework and mechanisms for enhanced information sharing for ASMFs/DMFs assessments, and the possible future reliance on the assessments of the participating regulatory authorities/organisations. In 2016 the decision was taken to expand its scope to enable discussions and activities on Quality information associated with applications for generic drug products, while continuing to focus on ASMFs/DMFs. Further to direction from the IPRP Management Committee in November 2019 and supported by the QWG members, the identifier “Generic” was removed from the working group name in recognition that work of the QWG and the discussions on Quality issues are applicable beyond generic pharmaceutical products.

2. SCOPE

The scope of the QWG is aligned with that of activities as outlined in the IPRP Terms of Reference, but with a focus on: the implementation and interpretation of Quality requirements, the development of common assessment procedures and tools, the sharing of information related to ASMFs/DMFs and applications for drug products. This work is focused on small molecule/chemical entities and their associated drug products.

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

3. OBJECTIVES

The QWG identifies opportunities for regulatory convergence and information sharing by exchanging and discussing information from members’ organisation regarding issues of common interest related to Quality information. The QWG also develops tools and templates and identifies best practices for the assessment of ASMFs/DMFs and drug product applications.

3.1. Objectives

- Objective 1: To develop common assessment tools and approaches for the assessment of quality information related to drug substances and drug products.

This includes information on best practices and technical requirements,

- Objective 2: To identify opportunities and mechanisms to facilitate the sharing of information related to drug substances and drug products.

This includes the availability and visibility of information maintained by regulatory authorities and organisations in relation to regulatory procedures, technical guidance, ASMFs/DMFs and drug product submission data. To investigate also potential opportunities for sharing of Quality Assessments Reports from other members’ organisations without compromising confidentiality (e.g. where enabled by existing information sharing agreements). These initiatives may lead to the potential for work sharing among agencies who have an ability and interest in doing so.

- Objective 3: To create and foster a forum of regulatory authorities and organisations to discuss best practices, regulatory or technical challenges, and to support convergence of regulatory practices, by identifying and resolving barriers to the implementation of ICH guidelines. To share and seek feedback on current and emerging quality-related issues of importance to the respective

organisation or globally (e.g., actions in response to APIs or drug products with quality issues).

The list of specific on-going projects and deliverables under preparation is available in the QWG Workplan. Consistent with the IPRP Terms of Reference, it should be noted that members may “opt-out” from some activities as the IPRP operates on a voluntary basis. Similarly, members are not obliged to adopt or implement the outputs of the working group.

4. COMPOSITION

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

- Administracion Nacional de Medicamentos, Alimentos y Tecnologia Médica (ANMAT), Argentina
- Agência Nacional de Vigilância Sanitária (ANVISA), Brazil
- European Directorate for the Quality of Medicines and Healthcare (EDQM)
- European Commission (EC) / European Medicines Agency (EMA)
- Federal Commission for the Protection against Sanitary Risk (COFEPRIS), Mexico
- Health Canada, Canada
- Health Sciences Authority (HSA), Singapore
- Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), Colombia
- The Institute for Standardization and Control of Pharmaceuticals (ISCP), Israel
- Ministry of Food and Drug Safety (MFDS), Republic of Korea
- Ministry of Health, Israel
- Ministry of Health, Labour and Welfare (MHLW)/Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- South African Health Products Regulatory Agency (SAHPRA), South Africa
- Swissmedic, Switzerland
- Taiwan Food and Drug Administration (TFDA), Chinese Taipei
- Therapeutic Goods Administration (TGA), Australia
- US Food and Drug Administration (USFDA), United States of America
- World Health Organization (WHO)

5. SPECIFIC ORGANISATION

5.1. Designation of a Chair Supporteur

A Chair or two Co-chairs are responsible for secretarial support services (teleconferences, agendas, reports, etc) and liaise with the IPRP Management Committee (MC) as needed. There is no chair supporteur.

5.2. Organisation of meetings

The QWG operates by holding regular teleconferences (about every 2 months) and, subject to MC agreement, face to face meetings which are hosted by a participating regulatory authority/organisation without additional costs to the IPRP. The QWG and the Bioequivalence Working Group (BEWG) 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 following QWG 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 typically organised by the regulatory authority/organisation which hosts



the QWG meeting without additional costs to the IPRP (potentially in conjunction with the relevant local industry association or a not-for-profit conference organiser). These symposia are subject to MC approval.

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