# **Terms of reference**

# **Workshop with the International Generic and Biosimilar Medicines Association (IGBA) on Collaborative Registration Procedure (CRP) for generics and biosimilars prequalified by WHO and SRA approved (in-person and virtual)**

# **Date : 05 July 2023 (9-12h CET)**

# **Venue: WHO HQ office (room TBC)**

# **Background**

Although many medical products successfully undergo regulatory review process conducted by reference regulatory authorities or may have been prequalified by the World Health Organization (WHO), each of individual National Regulatory Authority (NRA)'s approvals of the same medical products, consume additional time and resources before these products are made available to patients.

To address this issue, WHO has been promoting the Collaborative Registration Procedure (CRP) between NRAs and manufacturers to accelerate registrations of medical products.  The Procedure provides a tool and mechanism where NRAs have access to the assessment reports of medical products, generated by Stringent Regulatory Authorities (SRAs)/WHO Prequalification programme (WHO PQ), following stringent and international standards. The CRP involves the collaboration between NRAs, SRAs, WHO PQ and pharmaceutical companies, to facilitate and accelerate the registration of medical products in countries.

The WHO CRP covers three (3) different products streams, based on the product type and source of product information:

1. CRP for WHO-prequalified medicines, vaccines and biotherapeutics (PQ CRP);
2. CRP for WHO-prequalified In-Vitro Diagnostics (IVDs CRP);
3. CRP for medicines, vaccines and biotherapeutics assessed and/or approved by Stringent Regulatory Authorities (SRA CRP).

Normally, publicly available versions of assessments, inspections or performance evaluation outcomes do not provide all the necessary information in sufficient detail to enable regulatory decisions to be adopted. Therefore, detailed assessments, inspections and performance evaluation outcomes that include commercially sensitive data are shared among NRAs under strict confidentiality to facilitate regulatory decision, avoid repetitive assessment of the same product and accelerate issuance of marketing authorizations by the NRAs.

The procedure showed to enable faster access to quality-assured, safe and effective medical products for patients in need. It reduces the time from dossier submission to approval, avoids duplication of efforts, and decreases workload and human and financial resources in countries, leading to greater efficiency in the regulatory processes for medical products.

The three CRP procedures are open to NRAs in all WHO Member States and all applicants, on a voluntary basis. By participating in CRP, the applicant will benefit from the opportunity to submit only one single product dossier to multiple CRP participating countries, accelerate the registration of its products in countries, avoid duplication of GMP inspections and testing prior to product registration, to have a more efficient management of post-approval changes, and finally to reduce human and financial resources as well as time needed for making priority medical products available for populations in need.

# **Rationale**

In 2022, the number of participating countries has significantly increased to a total of more than fifty countries (50), (CRP PQ ([link](https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration)) and SRA CRP ([link](https://extranet.who.int/pqweb/medicines/faster-registration-fpps-approved-sras)))which demonstrates a greater interest from countries to use CRP as a tool to enable them to apply reliance principles and accelerate the assessment and registration of essential medical products in their countries. Globally, more than eight hundred (800) registrations for quality-assured priority pharmaceutical products have been granted with the use of PQ CRP and SRA CRP.

While registration through CRP has reduced time needed for registration of products in LMICs, thus facilitating timely access to relevant medical products in those countries, there are several challenges that have been identified in the course implementation of the Procedure. The challenges have been identified both at the WHO, participating National Regulatory Authorities (NRAs) and Applicants through the CRP project evaluation in 2020. One of such identified challenges was the lack of a central platform to facilitate communication and notification of application status to all involved stakeholders (applicants, WHO, participating NRAs and SRAs), including real time data. To address this challenge, WHO is working to launch a new centralized information management platform (ePQS) where CRP applications status will be available for monitoring in real time. The responsible Team is currently in the process of data migration into the new platform, and the new centralized system is expected to be fully operational by the end of 2023.

Another critical challenge identified was lack of applicants’ awareness on CRP procedures, which was associated with the observed low number of product applications submitted through CRP. In addition, the narrowed scope of therapeutic areas covered by CRP was adding limitations to an expanded use of the procedure by the applicants. This again has been addressed by implementation of the new CRP strategic plan which is centred at increased CRP advocacy meetings with NRAs, individual manufacturers, and industry associations as well as SRAs. In addition, to address the limited scope in therapeutic areas covered by CRP, the SRA CRP has been expanded to cover any therapeutic area without restrictions, for any product (medicines or vaccines). This way, applicants have a pathway that can cover all their priority products.

Examples indicated above are among a few other challenges that both WHO, NRAs and Applicants have identified and have been working together to ensure the efficient implementation of the Procedure and improve the registration turnround time for the needed medical products. In addition to the above strategies, over the years, WHO has organized and participated in meetings, conferences, and workshops with stakeholders to provide progress, brainstorm opportunities and provide recommendations on how to address effectively emerging challenges in the Procedure.

Despite these innovative strategies, it is recognised that CRP has now evolved to become a reliable global tool for regulatory reliance and needs and expectations of all CRP stakeholders will change over time. Understanding of the challenges, needs and expectations of all stakeholders will facilitate efficient implementation of CRP by all parties for the wider public health benefits. It is with this background, that WHO and IGBA are planning to conduct a half day’s workshop on the collaborative registration procedure for generics and biosimilars for the purpose of further understanding best practices and challenges faced by both parties, but also strategizing on how to discuss on the ways and recommendations to further improve further the Procedure.

**Objectives of the workshop**

The aim of the proposed workshop with IGBA is to share updates and discuss remaining challenges and bottlenecks and jointly explore practical solutions for further improvement of the Collaborative Registration Procedure as an instrument for accelerated introduction of generics and biosimilars prequalified by WHO and/or approved by SRAs.

# Specific objectives of the proposed workshop are:

* To take note of the progress made so far in implementation of CRP and identify/discuss the challenges faced by WHO and industry.
* To discuss and jointly explore further actionable solutions and recommendations with specific activities and realistic timelines to address the identified challenges/bottlenecks.

# **Methodology of the Workshop, agenda, venue, and date**

The workshop is expected to be conducted for half day on the 5th of July 2023 from 9am to 12pm in a hybrid format combining in-person and remote participation allowing maximum number of interested participants to listen and contribute to the discussions. The venue for those attending in person will be in Geneva at WHO. The link for those attending virtually will be provided at later stages of organization of the workshop.

The workshop will include presentations from WHO and IGBA members, followed by a panel discussion on the recommendations for the challenges identified and way forward. The draft agenda of the workshop is presented below.

# **Proposed Participants**

The relevant WHO staff from Regulation and Prequalification Department (four (4) from PQT and six (6) from REG) are expected to attend this workshop (RPQ/REG/FPI, RPQ/PQT), as well as the relevant members and representatives of IGBA.

# **Facilitators**

The facilitators will be from RPQ/REG.

**Language**

The language of the meetings will be English.

# **Draft Agenda**

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Moderator: Unit Head, Regulation and Safety, Department of Regulation and Prequalification (RPQ)

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| Time | **Agenda** | **Responsible** |
| 09:00 – 09:20 | Welcome remarks  Overview of the workshop objectives and agenda | Director RPQ, WHO |
| 09:20 – 09:45 | WHO PQ Medicines and Biotherapeutics programme and sharing of PQ assessment reports to enable CRP | Team Lead, RPQ/PQT  WHO |
| 09:45 – 10:15 | Overview of Collaborative Registration Procedure: progress in implementation and identified challenges | Team Lead, RPQ/REG/FPI  WHO |
| 10:15 – 10:45 | Coffee Break |  |
| 10:45 – 11:20 | * Industry experience with the implementation of CRP for generics and biosimilars prequalified by WHO and approved by SRAs * Challenges experienced by industry with the implementation of CRP for generics and biosimilars prequalified by WHO and approved by SRAs | IGBA |
| 11:20 – 11:50 | Plenary discussion and recommendations to overcome the challenges identified | ALL |
| 11:50 - 12:00 | Conclusions and close of the Workshop | Director RPQ, WHO |