FREQUENTLY ASKED QUESTIONS – COLLABORATIVE REGISTRATION PROCEDURE

1. What is the Collaborative Registration Procedure (CRP)? 2
2. How many CRP pathways are available and which products are eligible? 2
3. Who initiates the procedure? 2
4. Are there any fees for the procedure? 3
5. Are CRP applications exempt from local requirements? 3
6. Does the applicant have to submit the product dossier to the participating country? 3
7. Can the procedure be utilized if the WHO Prequalification (PQ)/ Marketing Authorization (MA) Holder is not the legal entity making the submission in the participating country? 3
8. How do stakeholders know whether a country of interest participates in the Procedure? 3
9. What if a country of interest is not on the list of participating countries? 3
10. Is a WHO Prequalification (PQ)/Marketing authorization (MA) Holder required to submit CRP applications for a product to the different countries at once? 3
11. How can NRAs participate in the procedure? 4
12. What is the role of the CRP Focal points in participating countries? 4
13. Can the CRP Focal points be contacted by the company directly? 4
14. Once an application for registration of a product is submitted to the CRP-participating country, is it automatically assessed using CRP? 4
15. Can the NRA recommend the procedure to an applicant/manufacturer if the product is WHO Prequalified or SRA approved? 4
16. When do the 90 working days start ("start-clock")? 5
17. Who will provide the participating NRA with the assessment/inspection reports from the reference authority/PQT? 5
18. During the assessment, will the company receive questions, if any, from WHO or from the participating NRA? 5
19. What if the NRA requires any clarifications on the assessment or inspection reports? 5
20. How does the WHO follow up on the CRP applications in participating countries? 5
21. Are post-approval changes (variations) also submitted using CRP? 5
22. What happens following the registration of the product using CRP? 5
23. What happens if the NRA deregisters a product registered using CRP? 5
24. What happens if a manufacturer withdraws a product registered using CRP from WHO prequalification or from the SRA market? 6

25. What happens if WHO PQT/reference SRA suspends the registration/de-lists a product registered using CRP? 6

26. Who do we contact for more information on the Procedure? 6

27. What is the current scope of CRP for prequalified medicines and vaccines? 6

28. A medicine or vaccine has been WHO-prequalified using abridged review based on an approval by an SRA. Is it eligible for PQ CRP? 6

29. What is the current scope of CRP for IVDs? 6

30. What is the current scope of CRP for SRA- approved products? 6

31. Which SRAs can be used as reference authorities for this procedure? 7

32. With the transition to WHO Listed Authorities (WLAs), will the procedure include additional reference authorities that have been designated WLA? 7

1. **What is the Collaborative Registration Procedure (CRP)?**

The WHO Collaborative Registration Procedure (CRP) is a reliance mechanism where participating National Regulatory Authorities (NRAs) have access to assessments and inspection reports of medical products, generated by reference NRAs ("stringent regulatory authorities") or WHO Prequalification to facilitate accelerated registration of medical products in countries. The NRAs can accelerate registration by conducting verification/abridged review of the application for registration of the medical products and issue a regulatory decision within 90 working days (recommended time). Participation in the procedure is voluntary, and the final regulatory decision is made by the NRA.

2. **How many CRP pathways are available and which products are eligible?**

There are currently three CRP pathways:

- *PQ CRP Medicines and vaccines* – for WHO-prequalified medicines and vaccines that have been fully assessed by the WHO Prequalification Team
- *PQ CRP In-vitro diagnostics* – for WHO-prequalified In-vitro diagnostics that have been assessed by the WHO Prequalification Team
- *SRA CRP Medicines and vaccines* – for medicines and vaccines that have been assessed by "stringent regulatory authorities"
- *PQ CRP for vector control products* – for vector control products that have been assessed by the WHO Prequalification Team

- If you need further clarification on the applicable pathway for a product, you may contact the WHO Facilitated Product Introduction (FPI) Team on crp@who.int.

3. **Who initiates the procedure?**

The procedure is initiated by the applicant/manufacturer with an expression of interest to either the participating NRA or notifying the WHO Facilitated Product Introduction Team. The relevant

forms are available on the webpage for each pathway Collaborative registration procedure for medical products

4. **Are there any fees for the procedure?**

   There are no fees payable to WHO for participating in the Procedure. The only fees applicable are the relevant fees payable to the NRAs as part of the NRA requirements.

5. **Are CRP applications exempt from local requirements?**

   Applications submitted using the procedure are not exempt from local requirements in the participating country. WHO is continuously engaging with NRAs to streamline requirements for CRP applications. Applicants/manufacturers are encouraged to verify local requirements with the NRA before submitting applications.

6. **Does the applicant have to submit the product dossier to the participating country?**

   The product dossier should still be submitted to the NRA together with any applicable local requirements. The WHO FPI Team will facilitate the sharing of reports with the CRP Focal points in the participating NRAs.

7. **Can the procedure be utilized if the WHO Prequalification (PQ)/ Marketing Authorization (MA) Holder is not the legal entity making the submission in the participating country?**

   Yes, the applicant in the participating country will need to clearly declare the relationship between the PQ/MA Holder and the applicant in the participating country when submitting the Expression of Interest (Appendix 3a for PQ CRP, Appendix 7 for SRA CRP) to the NRA.

8. **How do stakeholders know whether a country of interest participates in the Procedure?**

   The lists of participating countries for each pathway are available on our webpages and are regularly updated: Collaborative registration procedure for medical products. Participating NRAs are also encouraged to include information on their CRP participation on the NRA website.

9. **What if a country of interest is not on the list of participating countries?**

   The applicant/manufacturer intending to make a submission can contact the WHO FPI Team so that the NRA can be invited to participate in the procedure. The applicant/manufacturer will be informed once the NRA has agreed to participate. The applicant/manufacturer can also notify the NRA of their wish to utilize the procedure so that the NRA can contact the FPI Team for the next steps.

10. **Is a WHO Prequalification (PQ)/Marketing authorization (MA) Holder required to submit CRP applications for a product to the different countries at once?**

    No, the applications can be submitted to the countries at different times depending on the company's product introduction plans.

11. **How can NRAs participate in the procedure?**

    Any NRA that would like to participate in the collaborative registration procedure should send completed NRA participation forms for the relevant pathway (Appendix 1) and a confidentiality undertaking for each of the nominated CRP Focal points (Appendix 1B). The forms are available here: Collaborative registration procedure for medical products. The NRA are also encouraged to send an email to crp@who.int and the forms will be shared by the relevant CRP contact person.

12. **What is the role of the CRP Focal points in participating countries?**

    The CRP focal points are the primary contacts for the procedure within the NRA. Their responsibilities include receiving assessment/inspection reports from WHO, communication on any matters concerning CRP (including NRA's acceptance to use CRP and the status of applications) with WHO, providing guidance on CRP within the NRA and to stakeholders. NRAs are encouraged to nominate focal points for both dossier evaluation and GMP inspections/site audits, and for performance evaluation for CRP IVDs. Any changes to the focal points should be communicated to the WHO FPI Team and the incoming focal points should complete the confidentiality undertaking (PQ CRP Appendix 1B/CRP IVD Appendix 1B).

13. **Can the CRP Focal points be contacted by the company directly?**

    Yes. If they have given consent to share their official contact details, the WHO FPI Team will share the contact details on request. The applicant/manufacturer may contact the focal points directly to seek guidance on the procedure in the local context. NRAs are also encouraged to publish guidance on the procedure on the website or regularly sensitize local stakeholders on the procedure.

14. **Once an application for registration of a product is submitted to the CRP-participating country, is it automatically assessed using CRP?**

    No, once the expression of interest is made, the WHO FPI Team will contact the NRA requesting their acceptance to use the procedure for each product. Alternatively, the NRA, after receiving the expression of interest, may contact the WHO FPI Team communicating their acceptance to use the procedure. Access to the reports is only granted after a positive response is received and confirmation of submission of complete application from the NRA, and that marks the start of assessment by the NRA.

15. **Can the NRA recommend the procedure to an applicant/manufacturer if the product is WHO Prequalified or SRA approved?**

    NRAs are encouraged to use reliance mechanisms such as the CRP as much as possible to facilitate timely processing of applications. Therefore, the NRA may proactively recommend use of the procedure to the applicant/manufacturer and advise of next steps or refer them to the WHO FPI Team for further guidance.

16. **When do the 90 working days start ("start-clock")?**

    The 90 working days start once the NRA has accepted use of the procedure, NRA application requirements have been fulfilled including receipt of the product dossier and the reports from WHO. The 90 working days exclude the applicant's time to respond to any issues raised by the NRA (when the clock is stopped until responses are submitted).

17. **Who will provide the participating NRA with the assessment/inspection reports from the reference authority/PQT?**

    The CRP Focal points in the NRA will receive access to the reports from the WHO FPI Team through a secure platform under confidentiality terms of the procedure.

18. **During the assessment, will the company receive questions, if any, from WHO or from the participating NRA?**

    The applicant/manufacturer may receive any questions directly from the NRA in line with the existing NRA procedures.

19. **What if the NRA requires any clarifications on the assessment or inspection reports?**

    If the NRA has any questions related to the reports issued by the reference authority or WHO prequalification team, they can contact WHO FPI Team for clarification.

20. **How does the WHO follow up on the CRP applications in participating countries?**

    The WHO FPI Team is in regular contact with the CRP Focal points to receive updates on CRP applications including timelines.

21. **Are post-approval changes (variations) also submitted using CRP?**

    Yes, any post-approval changes that have been approved by the reference authority or by the WHO prequalification team that require prior authorization by the NRA should also be submitted to the participating NRAs in line with the NRA's submission requirements. NRAs will conduct an abridged review/verification and provide a regulatory decision within 30 working days of submission. MA holders are encouraged to clearly indicate variation applications for products initially approved using CRP when submitting to the NRA.

22. **What happens following the registration of the product using CRP?**

    After a product has been issued with a market authorization by the NRA, WHO will add the product to the list of prequalified/SRA approved products that have been registered using the CRP. The lists are updated regularly and are publicly available on the WHO FPI webpages.

23. **What happens if the NRA deregisters a product registered using CRP?**

    The NRA will inform WHO of the deregistration within 30 days, or as soon as possible in cases where patient safety may be affected. WHO encourages NRAs to request a consultative meeting with WHO FPI Team/reference SRA before de-registering a prequalified/SRA approved product so

experts from both the NRA and WHO/SRA can deliberate on any concerns. If WHO/SRA remains assured about product quality, safety and/or efficacy, de-registration will not affect the prequalification/SRA approval status.

24. **What happens if a manufacturer withdraws a product registered using CRP from WHO prequalification or from the SRA market?**

    If the manufacturer decides to withdraw the product either for reasons related to the quality, safety, efficacy, performance or for marketing reasons, the manufacturer is expected to notify the NRAs and WHO of the decision including the reasons for the withdrawal. The NRAs are also encouraged to check the WHO Prequalification and SRA websites regularly to confirm the most up-to-date status of the products.

25. **What happens if WHO PQT/reference SRA suspends the registration/de-lists a product registered using CRP?**

    If the suspension or de-listing of a WHO prequalified/SRA approved product by the WHO PQT/SRA due to quality, safety, efficacy or performance concerns, the WHO and the manufacturer will notify all the NRAs that have approved the product using CRP. In addition, any related additional information/findings will be shared by WHO with the NRAs including recommendations, if any.

26. **Who do we contact for more information on the Procedure?**

    You can contact the Facilitated Product Introduction Team at WHO Headquarters by sending an email to crp@who.int or to the Team Lead, Marie Valentin, valentinm@who.int.

27. **What is the current scope of CRP for prequalified medicines and vaccines?**

    Medicines and vaccines that have been prequalified by WHO PQT through full assessment are eligible for CRP. The therapeutic areas that are within the scope of CRP for medicines are available here: https://extranet.who.int/prequal/medicines/fpps-apis-eligible-prequalification-eois

28. **A medicine or vaccine has been WHO-prequalified using abridged review based on an approval by an SRA. Is it eligible for PQ CRP?**

    The product can utilise SRA CRP pathway using the SRA as a reference authority.

29. **What is the current scope of CRP for IVDs?**

    In-vitro diagnostics that have been evaluated by the WHO PQT are eligible for CRP. The scope of these IVDs is available here: https://extranet.who.int/prequal/vitro-diagnostics/vitro-diagnostics-eligible-who-prequalification

30. **What is the current scope of CRP for SRA- approved products?**

    Any medicine or vaccine that has been assessed by an SRA for which assessment and GMP inspection reports are available is eligible for SRA CRP. This includes products that have been

assessed and granted a positive recommendation via global health procedures such as the EMA's EU-Medicines-4-All and Swissmedic's Marketing Authorisation for Global Health Products (MAGHP).

31. **Which SRAs can be used as reference authorities for this procedure?**

    In principle, any SRA that has conducted full assessment of the product can be a reference authority for SRA CRP. According, the WHO definition of SRA, the following NRAs are within the scope of the Procedure: Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, Switzerland, United Kingdom, United States of America. There are a number of SRAs that have already participated in the Procedure such as the European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA, UK), Therapeutic Goods Administration (TGA, Australia), Finish Medicines Agency (FIMEA) and the Medicines Evaluation Board (MEB, The Netherlands). You can contact the WHO FPI Team if there is an SRA that you wish to engage as a reference authority and to also notify the SRA of the intention. Please note that currently the US FDA does not participate in SRA CRP due to limitations with sharing reports,

32. **With the transition to WHO Listed Authorities (WLAs), will the procedure include additional reference authorities that have been designated WLA?**

    The procedure is currently still using the list of SRAs as provided above. The SRA CRP guidelines will be reviewed using a consultative process to incorporate the concept of WLA and stakeholders will be informed once the revision process begins.

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