World Health Organization

WHO Prequalification of In Vitro Diagnostics

Q&A: Collaborative Registration Procedure for IVDs

Based on Q&A session of webinar "WHO Collaborative Registration Procedure - Update for IVD manufacturers", 15 March 2023.

	Question	Response
1	Where can I find the information to prepare a WHO Collaborative Registration Procedure (CRP) application?	All the information needed for a manufacturer to apply for CRP can be found on this link: https://www.who.int/publications/m/item/collaborative-procedure-between-the-who-and-nra-s-in-the-assessment-and-accelerated-national-registration-of-who-prequalified-ivd-s-annex4
2	Is the CRP open to all manufacturers?	All manufacturers of WHO Prequalified IVDs can participate in the CRP.
3	What are the fees involved to participate in the CRP?	WHO does not charge fees for manufacturers wanting to participate in the CRP but individual NRAs may charge fees based on the fees and charges regulation in force.
4	Where can I find the list of the NRAs that are part of the CRP program?	Link will be shared once the list has been placed on the website.
5	Is it possible to apply to one or two specific NRAs instead of applying to all NRAs that are part of the CRP?	Yes. The decision belongs entirely to the prequalification holder on where they wish to market their product(s).
6	Will WHO share the prequalification dossier reports with NRAs before consultation with manufacturers?	No. Participation in the CRP is voluntary and WHO will not share PQ assessment reports with any NRA without the written consent of the manufacturer.
7	Under the CRP process, is the communication and document sharing from the manufacturer directly with the NRA or via WHO?	The communication takes place directly between the manufacturer and the NRA, with all correspondence being copied to WHO.
8	The PQ dossier of our product was prepared a few years ago and since then we have had some changes, including a product name change and an updated intended use. Will these changes affect our participation in the CRP?	For changes made to the IVD since prequalification, such as a name change or an updated intended use, the manufacturer would have applied for a change request with the WHO PQ team. If the change request(s) has been approved by WHO, the resulting reports will be

		shared with the NRA along with the initial PQ assessment reports. So prequalified IVDs with approved changes are eligible for the CRP.
9	If the Product submission to WHO was done a few years ago, is the expectation that we bring that Dossier up to date?	Products that were prequalified some time ago can use the CRP. It is the manufacturer's responsibility to apply for change requests with WHO to update the dossier with supporting information as needed.
10	We have Prequalified products both via the full and abridged PQ pathway. Are they all eligible for CRP?	Yes, IVDs prequalified by either the full or abridged assessment pathway are eligible for CRP.
11	We have more than one pre-qualified product. Can we use the CRP for only one (or a few but not all) of our pre-qualified products?	Yes, WHO encourages manufacturers to leverage the CRP across all the IVDs that are prequalified but it is the decision of the manufacturer which product(s) to include in their CRP application.
12	We have a product that is currently undergoing WHO PQ assessment. Some prequalification activities have been completed but others are still ongoing. Does the product qualify for CRP?	No. A product is only eligible for CRP once it has been prequalified.
13	My NRA is listed on the WHO CRP list but has not communicated this to the industry. How can I be confident we can use the CRP process in country?	If an NRA is listed on the WHO CRP program, that is a guarantee that an agreement has been signed between the NRA and WHO. Manufacturers can also confirm this directly with the NRA.
14	Under CRP the NRA has 90 days to make a decision on the application. Are these 90 working days or 90 consecutive days?	The NRA has 90 consecutive days to decide on the application.
15	Under the CRP would an NRA support local Distributor interaction and identify recognised distribution channels?	Yes, this is a collaborative work between all participating parties – manufacturers, NRAs and WHO.
16	During the CRP process, does WHO monitor the NRA's commitment to post enrolment of the product?	Yes, during CRP WHO monitors the implementation of the product timeline, including via specific sessions with the NRAs to assist with any potential issues.
17	Does the work undertaken by WHO on the SARS-CoV-2 assessments for EUL impact on CRP timelines?	No. Emergency Use Listing (EUL) and CRP are two separate programs, the CRP timelines are not affected by EUL assessments.

Manufacturers are welcome to send any questions about the Collaborative Registration procedure for IVDs to diagnostics@who.int