

DCVMN manufacturers trigger successful Collaborative Registration Procedure (CRP) for Accelerated Registration of WHO Prequalified Vaccines in Developing Countries



Geneva, 03rd November 2020 - Encouraged by open dialogue between WHO and DCVMN, vaccine manufacturers are actively pursuing the WHO Collaborative Registration Procedure: three companies - Biological E Ltd., Bharat Biotech International Ltd. and Serum Institute of India Pvt. Ltd.- were successful in registering their respective new WHO pre-qualified vaccines in eight developing countries: Democratic Republic of Congo, Eritrea, Ghana, Malaysia, Malawi, Nigeria, Sierra Leone, and Zambia.

The Collaborative Registration Procedure (CRP) was launched in 2013 to facilitate and accelerate the registration process for WHO-prequalified medicines and vaccines in 43 CRP-adopting countries¹. It is based on information sharing between WHO prequalification services and National Regulatory Authorities (NRAs) by leveraging assessment and inspection reports of WHO prequalification, and thereby eliminating duplicative regulatory tasks, for in-country registration of quality-assured products, contributing to their wider availability. This procedure helps harmonize submissions and streamline the licensure process in many developing countries.

There has been a positive change in the registration process for WHO Prequalified vaccines during past few months². The overall process has proceeded well within the stipulated 90 days period, likely due to the active consultation between NRA's and WHO-CRP team, although the greater success of achieving maximum registrations through CRP is yet to come.

DCVMN calls for further support from governments to increase the value of WHO-Prequalification of vaccines towards accelerated global access goals.

¹ <https://extranet.who.int/pgweb/medicines/collaborative-registration-faster-registration>

² https://www.who.int/pg-vector-control/resources/orient_crp.pdf?ua=1