WHO AND UNITED STATES FOOD AND DRUG ADMINISTRATION EXTEND THE CRP-LITE PILOT

19 June 2024 - Following the initial pilot phase, the World Health Organization (WHO) and the United States Food and Drug Administration (FDA) agreed to further extend the Collaborative Registration Procedure-Lite (CRP-Lite) pilot that helps faster registration of medicines in countries and accelerate access to HIV treatment.

The CRP-Lite pilot was started in 2018 and led to the facilitation of the prequalification of two HIV products – HA741 (ritonavir 25 mg tablets, Cipla) and HA743 (abacavir/ lamivudine 600 mg/300 mg tablets, Cipla) – using minimally redacted FDA reports shared with the WHO Prequalification Team.

FDA provides the WHO Prequalification Programme with reviews of HIV medicines that have been either approved or tentatively approved by the agency under the USA President's Emergency Plan for AIDS Relief (PEPFAR). Use of existing FDA reviews helps WHO expedite its assessments of the medicines, producing reports which can then be shared with regulators in resource-limited countries to speed up their own regulatory review processes, which makes life-saving drugs available to patients faster.

Currently, FDA and WHO-supported CRP-Lite process is proposed only for HIV antiretroviral medicines for an additional three HIV products. If the results are encouraging, the model could be expanded for other therapeutic areas in the future.

The CRP-Lite pilot process builds on the collaborative registration procedure (CRP) introduced by WHO in 2013. With CRP, product registration time in countries were reduced from a few years to less than 90 days, for over 1200 registrations. The CRP is currently used in 66 countries across all regions and one regional economic community (CARICOM).

Most regulatory authorities in low-income countries are under-resourced and over-stretched, resulting in long delays in approvals of medicines that are desperately needed by patients. Initiatives such as CRP and CRP-Lite are vital to improve regulatory efficiency and to deliver life-saving medicines to communities as rapidly as possible.

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