

NATIONAL



AUTHORITY

25th June 2020

Ref: 2128/DR/NDA-6/2020

To: All Licence Holders
: Manufacturers
: Pharmacies
: Local Technical Representatives

CIRCULAR NO. 001/DPAR/2020

EXTENSION OF THE DEADLINE FOR SUBMISSION OF CTD DOSSIERS FOR RENEWAL OF REGISTRATION

This is to notify all Marketing Authorization Holders, Manufacturers and Local Technical Representatives for human pharmaceutical products registered before January 2015 that the deadline for submission of the renewal of registration CTD dossiers has been **extended** to **30th April 2021**.

You are requested to submit complete CTD dossiers for the affected products as per the requirements of the current registration guidelines. If the applicant adopts Option 3 (Full details in the PD) to submit active pharmaceutical ingredient (API) information, the submission should include complete information on both the restricted and open part of the Active Pharmaceutical Ingredient Drug Master Files (DMF).

Applicants who fail to obtain complete API Drug Master Files from their API manufacturers should declare the name and address of their API manufacturers in the dossier and proceed to submit the complete Finished Product information in CTD format. Such applicants will be required to pay for inspection of their API manufacturer(s) in due course.

Yours faithfully,

David Nahamya

SECRETARY TO THE AUTHORITY

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OUR MISSION

Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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