PLANNED ECTD IMPLEMENTATION IN SINGAPORE

Dear Stakeholders,

We would like to provide an early announcement on HSA's plans on the implementation of the electronic Common Technical Document (eCTD) for your information.

The eCTD serves as an interface for the transfer of regulatory information in a structured format from pharmaceutical companies to the regulatory agency. Apart from enabling a faster data transfer by applicants to HSA and maintain better oversight of the product's life-cycle, companies would also be able to make use of the eCTD dossier already prepared for another eCTD enabled agency for submissions to HSA.

HSA plans to commence the development phase in 2019 in order to allow eCTD submissions in Singapore by the end of 2020. The following are HSA's planned approaches:

1. The implementation will adopt a phased-in approach to allow industry more time to adapt to the new process:
    a) eCTD submissions will start with new original marketing applications (NDAs and GDAs). Products which are originally registered via eCTD submissions are expected to continue in eCTD format for the rest of its life-cycle.
    b) eCTD submissions will be voluntary during the initial implementation period. The requirement for mandatory submissions will be reviewed at a later date.
2. HSA intends to implement eCTD version 3.2.2 and applicants should note that eCTD submissions will be applicable for the ICH CTD format only.
3. The requirements for baseline submissions (quality dossiers) for currently registered products will be reviewed at a later date.

We will continue to share more details as the information becomes available. The industry will also be invited to provide input during the development phase to facilitate a smooth transition. This is expected to include consultations concerning the validation requirements and draft guidelines, as well as opportunities to be involved in User Acceptance Testing.

Thank you.

Health Products Regulation Group
Health Sciences Authority