State Agency
of Medicines
Republic of Latvia

INFORMATION ON SUBMISSIONS OF MARKETING AUTHORISATION DOCUMENTATION IN ECTD FORMAT

The State Agency of Medicines (hereinafter – SAM) is issuing a reminder that, in accordance with the European Medicines Regulatory Network eSubmissions Roadmap, starting from 1 January 2019 documentation submitted for marketing authorisation, renewal or variation of medicinal products should be prepared in an eCTD (electronic Common Technical Document) format.

European Medicines Agency and the pharmaceutical regulatory authorities in the European countries have established a Roadmap in order to implement a safe, consistent and effective electronic submission process for human and veterinary medicinal products throughout the network of regulatory authorities for medicinal products in Europe. The objective of the Roadmap is to define and implement a method for submission, receipt, approval, processing and distribution of regulatory information at regulatory authorities. More information regarding preparation and submission of medicinal product documentation is available here – eCTD (electronic Common Technical Document).

Frequently asked questions

1. Has Latvian regulatory agency mandated that baseline eCTD submissions must be prepared for every authorised product which is approved in a paper or NeeS format?

Response:

Baseline submission is not mandatory but recommended, as stated in "Harmonised Technical Guidance for eCTD Submissions in the EU" (Version 4.0, 2016).

If submission of baseline sequence is not possible, the company may use any regulatory activity, e.g., application for variation, to switch from paper or NeeS to eCTD format.

2. Has Latvian regulatory agency mandated that all of the modules for the CTD (Module 1 to Module 5) have to be included within the baseline submission, or is a shorter version acceptable (just Module 3 submission)?

Response:

In accordance with the approved document "Harmonised Technical Guidance for eCTD Submissions in the EU" (Version 4.0, 2016) inclusion of documentation of the full dossier is not mandatory, however it is preferable and is highly appreciated if baseline submission includes all modules (Module 1 – Module 5).

3. For example, if an application for variations is submitted to the SAM using NeeS format on 27 December 2018, is it possible to use NeeS format when additional documentation (e.g., reply to SAM deficiency letter) is submitted on 30 January 2019?

Response:

Yes, it is acceptable. In order to ensure transparency and traceability of documentation, it should be submitted in one format. However, when submitting an application, e.g., for variations, on 15 February 2019 the documentation should be prepared in eCTD format.

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