Updated: Notice - Mandatory use of the Electronic Common Technical Document (eCTD) format

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Health Canada has been accepting regulatory activities in eCTD format since 2004. As of December 2016, 84 percent of regulatory activities for Part C, Division 8 of the Food and Drug Regulations, for human drugs, have been provided in eCTD format. As Health Canada moves closer towards a common submission intake process to standardize and improve its business processes and tools, Sponsors are encouraged to take advantage of the many benefits of using the eCTD format.

In efforts to stay aligned with other regulatory authorities, in July of 2016, Health Canada announced **January 1st, 2018** as the proposed date for mandatory filing of specified regulatory activities in eCTD format. This notice serves as a confirmation of this date.

Please be advised that exemption from the mandatory eCTD format requirement will be considered on a case by case basis. A request for an individual product exemption should be submitted, by email, to ereview@hc-sc.gc.ca. The subject line of the email should be "Mandatory eCTD Format - Exemption". The content of the email request should contain the company name, product name, regulatory activity type, anticipated date of filing, rationale for the exemption as well as an intended plan for converting to eCTD format.

As of **January 1st, 2018**, the following regulatory activity types, as well as all additional information and subsequent regulatory activities/transactions (as per section 1.3 of the Guidance Document Preparation of Drug Regulatory Activities in eCTD Format) for human drugs, must be filed in eCTD format:

- New Drug Submission (NDS);
- Supplement to a New Drug Submission (SNDS);
- Abbreviated New Drug Submission (ANDS); and
- Supplement to an Abbreviated New Drug Submission (SANDS).

Regulatory activities for the following are recommended, however, not mandatory for filing in eCTD format:

- Master Files;
- Clinical Trial Applications (eCTD CTA pilot only);
- Drug Identification Number (DIN) Applications and Post-Authorization Division 1 Changes (PDC) for Human drugs.
- Administrative Licensing Agreement* (i.e. NDS, ANDS),
- Non-Prescription Human Drugs* regulated under Division 1 of the Food and Drug Regulations (i.e. DINA, DINB, DIND, DINF and PDC), and
- Labelling Only* (i.e. NDS, ANDS, SNDS, SANDS)

* For details refer to the Question and Answer Document Regulatory Activities in eCTD Format.

Regulatory activities for the following currently remain out of scope for filing in eCTD format; they must be filed in "non-eCTD electronic-only":

- Medical Devices;
- Veterinary Drugs.

When applicable, regulatory transactions must be sent via the Common Electronic Submissions Gateway (CESG). Refer to the Frequently Asked Questions - Common Electronic Submission Gateway (CESG FAQ) and the Notice - Mandatory Requirements for using the Common Electronic Submissions Gateway (CESG) documents for requirements and utilization of the CESG.

Questions regarding this notice can be sent to ereview@hc-sc.gc.ca.

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