European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Certification of suitability to the Monographs of the European Pharmacopoeia

Electronic submissions for CEP applications Revised Roadmap 2016-2020

Address: 7 Allée Kastner, CS 30026 F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

1. Introduction

The EDQM is the organisation responsible for the procedure of Certification of Suitability to the monographs of the European Pharmacopoeia (CEP), and therefore receives dossiers describing the manufacture and quality control of substances for pharmaceutical use.

The EDQM has been encouraging the submission of applications in electronic format since 2007 and has provided regularly updated guidance for preparing and submitting eSubmissions (EDQM Guidance for electronic and paper submissions for Certificates of Suitability applications, PA/PH/CEP (09) 108).

This eSubmission Roadmap aims at developing and improving the current processes for submission of electronic data related to CEP applications. The main goals are to have:

- Efficient and secure electronic handling of data related to CEP applications (submission, reception, validation, processing)
- Fully electronic processing without paper or any physical media
- Automation of data transfer and storage
- Alignment with practice in place in regulatory agencies for eSubmission of marketing authorisation applications.

The Roadmap has been revised to align with the European procedures.

2. Current situation

Procedures for the electronic submission of CEP applications have been in place since 2007. The number of eSubmissions has increased regularly, however paper applications, which are still accepted currently, represent about 10% of applications received.
With regards electronic formats, the EDQM has so far accepted several kinds of formats, pdf, NeeS[1]and eCTD, as described in the last version of the respective EDQM guideline. The majority of applications received are in pdf, which is the most basic electronic format. eCTD represent less than 20% of the formats received, regardless of the kind of submission (new application or revision).

The EDQM has decided to use the CESP (Common Electronic Submission Platform) as the preferred way to receive eSubmissions. However, currently the Dropbox remains the transfer system most used by applicants.

3. Goals

This section describes the objectives to reach within the next years.

[1] Non-eCTD electronic Submission (NeeS)

Topic	Objectives
Submission format	Single format for submission of data: eCTD (except for TSE only submissions and for submissions for substances for veterinary use only[2]). For TSE only submissions, PDF continues to be standard format accepted.
Submission media and mechanisms	Single and secure entry point for eSubmission of data: CESP, or alternatively an EDQM dedicated portal
Application form	Implement eApplication form/upload of electronic information from Application form
Content	Consistent information, aligned with eCTD specification
Receipt and validation of data	Automation of data transfer and storage, reduction of manual handling and checks
Use by assessors	Full use of review tool for all kinds of applications

4. Actions and Timetable

This section describes the detailed actions and estimated timeframes for completion of these actions in order to achieve the objectives described above and which have an impact on the preparation of the submissions by applicants.

Topic	Timeframe	Actions
Submission format and content	June 2016	No further acceptance of paper submissions for any kind of application (including TSE only submissions)
	January 2018	Require eCTD submissions for new applications (except for TSE only submissions and for submissions for substances for veterinary use only[3]). For TSE only submissions PDF continues to be standard format accepted.
	January 2018	Stop accepting PDF submissions for revisions and renewals. Therefore, all such submissions need to be in NeeS or eCTD format (except for TSE only submissions and for submissions for substances for veterinary use only[3]). For TSE only submissions PDF continues to be standard format accepted.

[2] For submissions for substances for veterinary use only, VNeeS (Veterinary Non-eCTD electronic Submission) is accepted.

[3] For submissions for substances for veterinary use only, VNeeS (Veterinary Non-eCTD electronic Submission) is accepted.

	January 2020	Require eCTD submissions for all applications including requests for revisions and renewals (except for TSE only submissions and for submissions for substances for veterinary use only[3]). For TSE only submissions PDF continues to be standard format accepted.
Submission media and mechanisms	January 2017	Stop the use of the Dropbox and CDs, and use only the CESP (Common European Submission Portal)