European Medicines Regulatory Network
eSubmission Roadmap

V0.7

Draft for Consultation

Contents

1. Executive Summary

The electronic Submission (eSubmission) Roadmap aims at establishing secure, consistent and efficient electronic submission processes for medicinal products for human and veterinary use across the European Medicines Regulatory Network (ERMN or "the Network"). It aims at defining the way the regulatory information on medicinal products is submitted by applicants electronically and received, validated, processed and distributed by regulatory authorities within the Network. It promotes open international standards and interoperable systems to support them. It should lead to increased efficiency through sustainable fully end to end electronic processing of information, meaning elimination of paper and physical electronic media, to enable and facilitate electronic collaborative processes as well as increased transparency and sharing of information within the Network throughout the medicinal product life-cycle.

The common agreed vision for the objectives on eSubmission outlined in this document underpins the decisions taken by the Network to implement the Roadmap.
The relevant components and milestones of the eSubmission Roadmap as well as the schedule are agreed by the Network, taking into account feedback from pharmaceutical industry associations[1].
The objectives of the Roadmap should be achieved as a result of coordinated development and implementation activities as defined in this document.
Implementation of the eSubmission Roadmap has to be supported by clear and appropriate communication with stakeholders at International, European and National level.

2. Purpose

The eSubmission Roadmap is a high level strategic plan for business and technology change, typically operating across multiple disciplines over several years. It is a tool to align the plans of target groups and help NCA and pharmaceutical industry to prepare themselves to forthcoming changes. It clarifies objectives and activities to reach them. It sets a common timeline for development. It helps supporting resource provisions. It is thus an important communication tool which helps to find a common understanding and commitment. It is therefore addressed to decision makers at executive management level.

The eSubmission Roadmap is the strategic driver and reference that guides the alignment of priorities, resources and commitment put behind implementation for the achievement of the eSubmission objectives.

3. Background

Although electronic submission of applications within the Network has increased, the uptake of a standard electronic format[2] has been slow[3]. In the human sector electronic submission of applications is widespread, but a non-standard electronic submission format[4] is still largely used as an alternative format for submission of applications for medicinal products for human use.
In the veterinary sector paper submissions are still common across the Network , but a specific electronic submission format[5] has become the reference in the European Union for electronic submission of applications for medicinal products for veterinary use.

[1] EFPIA , EGA, AESGP, EuropaBio
[2] Electronic Common Technical Document (eCTD)
[3] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) published its first final version of eCTD in October 2003, allowing for the electronic submission of the Common Technical Document (CTD) from applicants to regulatory authorities. The Network implemented the eCTD EU Module 1 in July 2004, enabling electronic submission of eCTD in Europe.
The Heads of Medicines Agencies (HMA) committed in 2005 to be ready to receive, handle and process eCTD by the end of 2009.
[4] Non-eCTD electronic Submission (NeeS)
[5] Veterinary Non-eCTD electronic Submission (VNeeS)

A number of initiatives have been undertaken to enable and improve the added value of eSubmission within the Network. For instance, EMA has required mandatory eCTD for applications of Centrally Authorised Products (CAP) for human use from 2010, the Network developed structured electronic Application Forms and HMA set up a Common European Submission Platform (CESP). These initiatives have been achieved with the support of the pharmaceutical industry.

The increase of regulatory requirements introduced by legislation has put the Network under strain and interoperability of systems has become the key for efficient use of data and resource. There was a need for the Network to establish a clear roadmap that would enable pharmaceutical industry and regulatory authorities to plan for the necessary investments and organisational changes.

In the current budgetary climate it is paramount for the Network to find ways to save human and financial resources to cope with the increasing regulatory workload and the electronic processes resulting from the implementation of the eSubmission Roadmap shall help the Network to work more efficiently.

4. The eSubmission Vision

In support of administrative, regulatory and scientific activities related to medicinal product regulatory applications the main objectives of the eSubmission Roadmap are:

1. Consistent, efficient, effective and secured electronic handling (submission, reception, validation, processing and distribution) of regulatory information for all procedures throughout the life cycle of medicinal products (One process).

2. Fully electronic processing without paper or any physical media.

3. Implementation of a single electronic exchange message for submission of regulatory information for medicinal products, in line with international standards.

4. One single entry point for submission of applications to all authorities.

5. Identical regulatory information made available to all authorities.

5. Approach

The eSubmission Roadmap describes the current situation of eSubmission in the European Union and issues that need to be addressed. It identifies changes required and defines actions and deliverables with timelines to show progression from the current situation to the target situation in line with the eSubmission vision.
The scope of the eSubmission Roadmap covers electronic submission of regulatory information on medicinal products for human and veterinary use in all marketing authorisation procedures.

The EU Telematics Strategy of the Network has a broader scope and supports other regulatory activities involving electronic exchange of different types of regulatory information throughout the life cycle of medicinal products, e.g. Clinical Trials, Pharmacovigilance, Inspections, etc. It would align legislation, business needs and technical possibilities with available resources and provide open interfaces ensuring interoperability between centralised systems and national systems for data and documents with the aim to minimize total cost of ownership.

The long term objective of the Network is the implementation of a single electronic exchange message for submission of regulatory information for all medicinal products, in line with international standards. Specific approaches for medicinal products for human and veterinary use apply within the period covered by this first version of the roadmap.

The vision applies to all procedures: European (Centralised, Mutual Recognition and Decentralised procedures) and National procedures. In the short term, priority is given to mandatory implementation of single exchange messages for European procedures. In the longer term, the Network might consider mandatory extension to National procedures.

A pre-requisite for successful implementation of the eSubmission Roadmap is that all authorities within the Network adopt the same vision, direction and priorities.

The eSubmission Roadmap is part of the overall EU Telematics Strategy developed and agreed within the Network in the framework of the EU Telematics governance structure. It is a key component for the management of transition as it is incrementally developed throughout the phases that cover organisation, processes, information technology and infrastructure.

5.1. Current Situation

This section provides high-level information on where we are, including identified issues.

Area	Current situation	Issues
Submission format	• Centrally authorised products: eCTD (human) and VNees (veterinary) • MRP/DCP: eCTD, NeeS (human) and VNees (veterinary) • Other non-standard electronic formats	• Various guidance, validation criteria and processes. • Inconsistent life-cycle management • Switch from one format to another
Submission media	• CD/DVD vs. paper • CD/DVD + paper (wet signed paper still required in some NCA) • Electronic messages (documents attached to E-mail or through portals)	• Different handling and means to give access to assessors. • Different processes and infrastructure for archiving • Preventing electronic only submission for all applications
Submission transfer mechanism	• By courier (CD/DVD and paper) • eSubmission through national portals using national specific registration modes and submission forms • Eudralink • eGateway/Web Client for CAP • CESP	• Multiple entry points • Various reception processes

Area	Current situation	Issues
Content format	• Mainly unstructured electronic format for content (PDF) • Parallel templates of application forms for use by applicants (AF in Word and eAF in PDF) • Dynamic eApplication Form does not make full use of controlled vocabularies and requires further structuring. • Different data dictionaries across the Network	• Low data availability for export into databases • Different data quality approach • Low data quality for export into databases • Prevent data exchange between databases (European and National)
Content requirements	• Specific national documents required in some countries. • National regulatory activities in MRP/DCP relevant to only one NCA (translations in national language, MAH transfer, Sunset Clause, etc)	• Prevent full harmonisation of the submission. • Prevent efficient handling of submission life-cycle
Processes across the Network	• Specific technical validation criteria (eCTD, NeeS, VNeeS) • Validation of submissions by multiple NCAs • Differences between technical validation reports • Some NCA do not perform technical validation of electronic submissions • CHMP/CVMP members for CAP and CMS for MRP/DCP receive electronic submissions before technical validation by EMA and RMS, respectively.	• Unnecessary rejection of applications and additional exchanges, source of inefficiency.

5.2. Objectives

This section defines the high-level objectives in priority areas in line with the eSubmission Vision.

Area	Vision	Objectives
Submission format	• Single electronic exchange message for submission of regulatory information for medicinal products	• Streamline life cycle management of submissions
Submission media	• Fully electronic processing of submissions	• Eliminate all physical media (paper, CD/DVD) and other electronic messaging systems • Eliminate wet signed paper submitted with electronic submissions and minimize/eliminate the need of any kind of signatures
Submission transfer mechanism	• One single entry point for secure electronic submission of applications to all authorities for downloading or for automatic transfer to the national systems.	• Eliminate all physical media (paper, CD/DVD) • Implement single electronic submission forms
Content requirements	• Identical regulatory information available to all authorities	• Handle eSubmission of national specific documents and regulatory activities.
Content format	• Consistent electronic handling of regulatory information	• Reduce data inconsistency by implementing full systematic use of controlled terminology • Automate the extraction of structured information into databases
Processes across the Network	• Consistent validation of eSubmissions • Efficient and secure electronic handling of regulatory information	• Common approach to technical validation • Validation by EMA/RMS • Implement common repository for remote access to dossiers for review and download dealing with all procedure types

5.3. Roadmap

This section provides high-level information on how the eSubmissions vision will be implemented, including detailed actions and estimated timeframes for completion of these actions.

Area	Objectives	Action	Deliverable	Timeframe
Submission format (Human use)	• Streamline the handling of submissions and life cycle management	• Require single electronic format for applications of medicinal products for human use	• eCTD only for New MAA's in DCP • eCTD only for New MAA's in MRP • eCTD only for Variations in MRP • Phasing out Nees for EU procedures	• **2015 Q1*** • **2016 Q1*** • **2017 Q1*** • **2017 Q4***
Submission format (Veterinary use)	• Streamline the handling of submissions and life cycle management	• Require single electronic formats for applications of medicinal products for veterinary use	• VNeeS only for all EU procedures	• **2016 Q4***
Submission media and transfer mechanism	• Eliminate all physical media and implement single submission form	• Implement Single EMA-NCA eSubmission Portal Project	• Single EU eSubmission portal for human and veterinary use	• **2014 Q4* (Human)** • **2016 Q4* (Veterinary)**
Content requirements	• Identical content of eSubmission to the Network	• Handle eSubmission of specific national documents and regulatory activities	• Update eSubmission guidance together with relevant regulatory groups (CMDh, CMDv)	• **2014 Q4* (Human)** • **2016 Q4* (Veterinary)**
Content format	• Enable automated extraction of data into databases	• Complete the technical restructuring of eAF	• Replace current AF template in word format published by the Commission with eAF	• **2015 Q1***

- Tentative timeframes

5.4. Critical Success Factors

Factors that would enable timely implementation of the roadmap

Factor	Comments
Common understanding and agreement of National Competent Authorities and EMA to create consistent eSubmission architecture for the Network.	Consolidation of EMA and HMA EU Telematics development plans and programs in the framework of the EU Telematics governance structure.
Coordination between technical and regulatory work in order to find common solutions for eSubmission	Interfaces between technical groups and regulatory groups, such as CMDh, CMDv, and NtAWG should ensure sharing of eSubmission objectives and adapt guidance to support technical and regulatory implementation consistently.
Agreement of the Network to deal with specific national documents and regulatory activities in eSubmission	Alternative ways to link specific national documents and regulatory activities submitted electronically in order to handle the full life cycle management should be found.
Pharmaceutical industry awareness and readiness to implement the milestones within the given time frames	The Network should broadly communicate on the roadmap at National, European and International level.
Implementation of standard terminology related to medicinal product information, e.g. active substances, pharmaceutical forms, routes of administration, MedID, etc.	International implementation of the maintenance process of ISO-IDMP standards for medicinal products for human use is underway. EUTCT database incorporates standard terminology relevant to the EU. The EUTCT maintenance process needs to be implemented across the Network before eSubmission can fully benefit from it.
Coordinated implementation of international exchange standards.	eCTDv4.0 is under development at HL7 and is being tested at ICH and in Europe for submission of regulatory information on medicinal products for human use. It is expected to become an ISO standard. The date of final adoption depends on the Standard Development Organisations processes (HL7, ISO) and ICH. This new version uses a technology that would allow implementation for medicinal products for veterinary use.

6. About this document

6.1. Document location

6.2. Definitions, acronyms, and abbreviations

6.3. Referenced documents

6.4. Document history

Version	Date	Review
0.1	November 2012	TIGes, Industry associations feedback, TSG, HMA
0.2	March 2013	TIGes, TSG
0.3	April 2013	TIGes, TSG, HMA
0.4	May 2013	TIGes
0.5	June 2013	TIGes
0.6	June 2013	TIGes, TIGes Vet