EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

e-Paediatrics

Electronic distribution of application documents to PDCO, and of PDCO opinions and EMA decisions to applicants

2nd EMA-Industry Stakeholders Platform meeting on Paediatric Medicines activities

Presented by Paolo Tomasi on 15 April 2016
Head of Paediatric Medicines, EMA

Submission of applications **to** EMA and PDCO

- EC IAS has made suggestions on how to improve processes and their tracking
- EMA is working to address them
- Current document format of PIP/waiver/modification/CC applications will **not** change (Part A: PDF; parts B-E: word template)
- Current submission procedure (eSubmission Gateway or eSubmission Web Client strongly recommended) will **not** change
- EMA is working to enable direct access to all application files for all PDCO members
- Aim is to abolish the requirement of applicants having to submit the applications to Rapp/Peer (before validation) and all PDCO (after validation) on CD-ROM and/or via Eudralink (in line with current practice for centralised procedures)
- Any comments/foreseen difficulties?

http://esubmission.ema.europa.eu/esubmission.html

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eSubmission Gateway and eSubmission Web Client

eSubmission Gateway and eSubmission Web Client

The European Medicines Agency's Gateway and the Submission Web Client are electronic submission channels that allow the applicants to submit documents supporting all types of applications for human medicines to the Agency securely over the internet in the Electronic Common Technical Document (eCTD) format. The web-based tool may be more suitable for small and medium-sized companies, but is available for all applicants. The Gateway and the Web Client users will benefit from an automated confirmation of the technical validation feedback and an automated upload to the Agency's eCTD review system. The use of the eSubmission Gateway and the Web Client is mdantory for all human medicines eCTD submissions since 1 March 2014.

The use of eSubmission Gateway and the Web Client was extended to include all Referral procedures, all Veterinary Medicines submissions including Veterinary Referrals, and to Paediatric submissions such as Paediatric investigation plans, waivers and modifications on 1st of April 2014.

Announcements

The EMA would like to invite industry representatives to participate in the upcoming User Acceptance Testing (UAT) which is planned to take place with human and veterinary industry representatives:

- From Monday 18/04/16 to Friday 22/04/16

If you wish to participate in the testing of the new functionality, please email turi.salami@ext.ema.europa.eu. Detailed information package for testing and a feedback form for comments will be provided to you following your registration.

From 23 May 2016 it will be possible to use XML delivery files instead of the existing filenaming conventions for all submissions, excluding veterinary PSURs and Maximum Residue Limit (MRL) submissions via eSubmission Gateway/Web Client. More information on the use of the XML delivery files for all submissions can be found here - **New**

- Statement of intent for use of xml delivery files for all submissions - **New**

PSUR submissions using XML delivery files

From 1 September 2015 all PSURs submissions should be sent with an XML delivery file. After this date, it will no longer be possible to send PSUR submissions using the existing filenaming convention. The exclusive use of the PSUR XML delivery file for PSUR submissions is introduced to harmonise the submission mechanism for all PSURs and it will apply to all types of PSUR and PSUR supplementary information submissions. This excludes PSURs for Art. 58 (WHO) procedures.

- Statement of intent for use of xml delivery file
- Statement of Intent
- How to submit Periodic Safety Assessment Reports
- Gateway release II announcement

Referral Procedures to be sent via eSubmission Gateway / Web Client from 1st of November 2014

From 1 November 2014 all submissions for Referral Procedures for human medicinal products should be sent via the eSubmission Gateway or the Web Client. After 1 November 2014, the EMA is no longer accepting electronic submissions for referrals on CD or DVD.

Electronic distribution of documents **by** EMA to applicants

EMA's proposal:

- Replacement of physical by electronic delivery.

Documents affected by the proposed change:

- PDCO opinions (incl. summary report)
- EMA decisions (incl. PDCO opinion and summary report)

Timeframe:

- By June 2016 pilot-phase end (ongoing on internal level), incl. feedback from applicants
- By July 2016 roll out

Electronic distribution of documents **by** EMA to applicants

Current practice

- PDCO opinion
  - hard copy is sent to applicant via courier (Art 25.1: within 10 days of adoption by PDCO)
    - ✓ Art 25.2: D1(/30) = the day following the physical delivery
- EMA decision
  - hard copy is sent to applicant via courier
  - electronic copy is sent to applicant via EudraLink

New proposal

- PDCO opinion
  - PDF file sent to applicant via EudraLink (Art 25.1: within 10 days of adoption by PDCO)
    - ✓ Art 25.2: D1(/30) = the day following the electronic delivery receipt, i.e. EudraLink message was “Accessed by” the applicant
- EMA decision
  - PDF file sent to applicant via EudraLink

Electronic distribution of documents **by** EMA to applicants

Benefits examples:

- Limitation of delivery errors (no involvement of 3rd party)
- Faster access to document (close to zero delivery time)
- Direct delivery to appointed contact person (no time wasted on locating the document around the company / 100% utilisation of time granted by Art 25.2)
- Convenient format (easy to distribute, archive and access in the future)

Electronic distribution of documents **by** EMA to applicants

Procedural implications:

- Procedural timelines, Art 25.2, to be triggered by either:
  - the date the EudraLink was accessed by the applicant;
  - in any case, automatically no later than a fixed number of days after distribution, to avoid procedural delays (opinion definitive triggers decision stage) considered.
- Decision will no longer contain wet signature of EMA Executive Director (or delegated manager)

Electronic submission **from and to** EMA/PDCO

Your feedback needed verbally or at paediatrics@ema.europa.eu

Any questions?

With thanks to Marketa Lisakova and Riitta Measom, who are doing most of the work here!

Thank you for your attention

Further information

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000023.jsp&mid=WC0b01ac05800240cd

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