HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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Guide to
Electronic Submissions - Human Medicines

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 SCOPE

This guidance applies to all applications for human medicinal products (new and existing) and all other submission types supplied to the Health Products Regulatory Authority (HPRA).

2 INTRODUCTION

The HPRA strongly recommends electronic-only submissions through CESP (Common European Submission Platform, available on the HMA website), as outlined in the European Guidance for eCTD (electronic Common Technical Document) and NeeS (Non-eCTD electronic submissions).

This applies to new applications, including responses to validation queries and review of assessment questions, supplementary information, variations, renewals, periodic safety update reports (PSURs) and active substance master files (ASMFs) and drug master files (DMFs).

For human centralised procedure submissions the use of the common repository is now mandatory, in compliance with the HMA eSubmission Roadmap. Marketing authorisation holders are requested to submit applications only once to the European Medicines Agency and should no longer send CDs/DVDs or CESP submissions to any individual Member State. The European Medicines Agency will electronically transmit submissions to the national competent authorities.

The HPRA is aware that some applications cannot follow the CTD format (e.g. parallel import applications and clinical trial applications) and therefore cannot be submitted in eCTD or NeeS format. For these application types only, electronic submissions in Word or pdf format without paper copies are acceptable.

Please see section 3.3 for a list of submission types accepted in electronic format, either as eCTD/NeeS or in Word/pdf.

The HPRA is not in a position to accept electronic formats other than those mentioned above. Companies who have a particular problem with submitting electronic applications in one of the agreed formats should contact the HPRA at info@hprа.ie to discuss their situation before making an application.

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3 ELECTRONIC SUBMISSIONS

3.1 Definitions

3.1.1 eCTD

The eCTD electronic submission is an electronic version of the Common Technical Document (CTD). The structure corresponds to that of the CTD. In addition, the eCTD contains additional technical components which enable management of the lifecycle of the product.

An eCTD application may comprise several dosage forms and strengths, all under one invented product name.

3.1.2 Non-eCTD (NeeS)

A non-eCTD electronic submission is any submission of electronic information formatted as a set of electronic files, organised into module folders containing pdf or MS Word files as per the CTD guidance. There is no ability to manage the lifecycle of the product in this format.

3.1.3 CESP

CESP - the Common European Submission Platform is a simple and secure mechanism for the exchange of submission information between applicants and HMA agencies.

3.1.4 Other

Parallel import submissions must follow the standard file and folder naming conventions where possible.

3.2 Guidance

1 Technical guidance for eCTD and for NeeS submissions is available on the EMA's eSubmission website http://esubmission.ema.europa.eu/.

2 Guidance for industry on providing regulatory information in electronic format as eCTD electronic submissions is available on the ICH website and also on the EMA website.

3 Guidance for industry on submissions through CESP is available on the HMA website

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3.3 Submission types

Please ensure that national, decentralised and mutual recognition procedure submissions on CD/DVD are accompanied by a signed original paper cover letter. For those submitted through CESP, please ensure that the cover letter is part of the submission.

The HPRA will now accept all human medicinal products in the following submission types in eCTD format and non-eCTD (NeeS) format without paper copies:

- New applications for national, decentralised and mutual recognition procedures
- Variations applications
- Article 61(3) notifications
- Line extension applications
- Responses to validation queries
- Responses to assessment questions
- Supplementary information
- Renewal applications
- PSURs
- Follow-up measures
- Active substance master files (ASMFs)/drug master files (DMFs)
- Vaccine antigen master files (VAMFs)
- Plasma master files (PMFs)

The HPRA will now accept the following submission types in pdf/Word format without paper copies:

- New dual pack registration applications (DPRs)
- DPR annual compliance declarations
- New parallel import applications (PPAs)
- PPA variations
- PPA renewals
- Batch-specific requests
- Transfer before and after authorisation applications
- Withdrawal applications
- Clinical trials
- Clinical trial amendments
- Clinical trial developmental safety reports
- Clinical trial end-of-trial declarations
- Clinical trial end-of-trial reports

Please note that this list is not exhaustive.

Further guidance regarding the application process and forms may be found in the specific guidance relating to those application types on the 'Publications and Forms' section of www.hpra.ie.

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4 REQUIREMENTS FOR ELECTRONIC SUBMISSIONS

The requirements for electronic submissions are outlined in the eCTD and NeeS guidance referenced in Section 3.2 above. In addition the HPRA would like to highlight the following items. The requirements of this section are applicable to both eCTD and NeeS submissions.

4.1 Process

It is recommended that MAHs submit applications electronically in either eCTD or NeeS formats or through CESP. Once a submission has been received in eCTD format, all subsequent product information in relation to the submission must be submitted in eCTD format.

4.2 Media and label information

Ideally, there must only be one regulatory activity per medicinal product, per CD; where more than one CD is required please use a DVD. If necessary, multiple eCTD sequences may be submitted for the same medicinal product on the same CD / DVD. This must be clearly indicated on the disc itself and on the signed original cover letter that accompanies the disc.

Each CD or DVD submitted in electronic format must include the following label information, clearly presented and printed on the media as defined in the guidance in Section 3.2 above:

- Format: eCTD or NeeS
- Applicant's name
- Name of the medicinal product
- The allocated MRP/DCP procedure number
- HPRA application number or case number, where known
- Sequence number(s) of the eCTD and NeeS submissions contained on the CD / DVD
- Number of media units per application (full set) and number of copies
- Submission type of each eCTD submission(s) contained on the CD / DVD (e.g. 'initial application decentralised procedure', 'variation Type II'), as per the eCTD envelope information
- Description of each submission type of each submission(s) contained on the CD / DVD (e.g. 'supplementary information following validation')
- Contact e-mail if problems arise with the CD/DVD

4.3 CESP submissions

Please be aware of the following while submitting through CESP:

- Do not drop over the delivery file until the entire submission has fully uploaded to CESP.
- Please refer to our National Requirements which are indicated on the Contacts tab of the CESP Platform prior to submitting documentation.
- CESP supports the upload of zip files using the following software only: Winzip and Microsoft Compressed File Format.

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- Where there are large numbers of products, sequences and procedures, please use an identification matrix that can be filtered to allow ease of tracking of applications that concern Ireland.

Delivery file:
- Must not be renamed or re-used.
- Ensure the type of submission is correctly identified.
- Ensure the appropriate category on the dropdown list is selected.
- For variations the full MRP/DCP procedure number must be provided.
- Specify the zip software used for compression.
- Where possible please provide the Irish product authorisation number (PA).

4.4 Additional information to be included with the submission

- The eCTD or NeeS technical validation report showing the submitted sequence has passed technical validation (with the name and version number of the validation software).
- Tracking table for eCTD sequences, including a description of each submission type.
- Statement that the submission is checked with an up-to-date and state-of-the-art virus-checker (name and version of the anti-virus programme must be mentioned).
- Ensure any covering letter or other documents accompanying a disc are also present electronically within the same disc.

Note: The HPRA does not accept password protected submissions.

4.5 Label and leaflets

Label, leaflet and label-leaflet mock-ups for marketed presentations must be submitted as a set of consolidated pdf documents for all pack sizes and presentations of the product. Single documents in pdf and Word files are not acceptable. For parallel import applications, the PPA holder is still required to submit actual samples in addition to an electronic application.

4.6 Application form information

The application form and related annexes must be clearly labelled including the relevant section as part of the document title, with preferably a clearly labelled separate document for country specific information, for example, as in Annex 5.1, 5.3 and 5.10. On 01 January 2016, the Word based application form was replaced by a mandatory electronic application form for all EU procedures. Please visit http://esubmission.ema.europa.eu/eaf/ for further information.

5 HPRA CONTACT POINTS

If you have a specific query regarding electronic submissions to the HPRA, please contact info@hpra.ie. For information regarding CESP and registration please go to the CESP website www.cesp.hma.eu/.

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