HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Electronic Submissions - Veterinary Medicines

1 SCOPE

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

2 INTRODUCTION

From 28 January 2022, electronic submissions are mandatory for veterinary applications in line with Article 6(3) of Regulation (EU) 2019/6. Exceptions can be made for applications made under Article 5(6) and Article 86 of the Regulation although electronic submissions are strongly recommended.

The HPRA accepts submissions in non-eCTD electronic submission (VNeeS) format without paper copies or through CESP (Common European Submission Platform) available on the HMA website.

The HPRA is not in a position to accept other electronic formats. Companies which have a particular problem with submitting electronic applications in VNeeS format should contact the HPRA at info@hpra.ie to discuss their situation before making an application.

3 ELECTRONIC SUBMISSIONS

3.1 Definitions

Non-eCTD (VNeeS)
A veterinary *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 European guidance (see below).

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

3.2 Guidance

Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal products can be located on the EMA eSubmission website.

3.3 Submission types

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

- New applications for centralised, decentralised, mutual recognition and national procedures
- Variations applications
- Line extension applications
- Responses to validation queries
- Responses to assessment questions
- Supplementary information
- Renewal applications
- Follow-up measures
- Batch-specific requests
- Active substance master files (ASMFs)/drug master files (DMFs)
- Referrals
- Application withdrawals
- Transfers

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 HPRA website at www.hpra.ie.

4 REQUIREMENTS FOR ELECTRONIC SUBMISSIONS

The requirements for electronic submissions are outlined in the guidance referenced in section 3.2 above. In addition the HPRA would like to highlight the following items.

4.1 Media

Ideally, there should only be one regulatory activity per medicinal product, per CD; where more than one CD is required please use a DVD. It is recommended that file sizes are reduced where possible; however the HPRA does not accept ZIP files as electronic submissions.
Please ensure that all national, decentralised and mutual recognition procedure submissions on CD/DVD are accompanied by a signed original paper cover letter.
Ensure that any cover letter or other documents accompanying a disc are also present electronically within the same disc.

4.2 Media label information

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

- Format: VNeeS
- Applicant's name
- Name of the veterinary medicinal product
- The allocated MRP/DCP procedure number, if applicable
- HPRA application number or case number, where known
- Number of media units per application (full set) and number of copies

- Description of each submission type of each submission(s) contained on the CD/DVD (e.g. 'supplementary information following validation')
- Contact email if problems arise with the CD/DVD
- 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 should be mentioned)
- Statement that the submission is in line with the guidance document and that it has been put through a 'VNeeS checker' with acceptable results

4.3 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. The PDF file should be unprotected.

4.4 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.

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.

HPRA
7 February 2022