HELLENIC REPUBLIC

MINISTRY OF HEALTH **Holargos, 29.03.2017**

NATIONAL ORGANISATION FOR MEDICINES **Ref. no.: 24179**

284, Messogeion Str., 15562 Holargos

www.eof.gr

Product Control Administrative Services Directorate

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DECISION-CIRCULAR

Subject: Electronic submissions for human and veterinary medicinal products exclusively via the *Common European Submission Portal (CESP)*

Entry into effect: 03.04.2017

Having regard to:

1. the provisions of Law 1316/1983 (Government Gazette 11/13-011983), as amended and currently in force;
2. Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products;
3. the provisions of Joint Ministerial Decision Δ.ΥΓ3α/Γ.Π. 32221/2013 (Government Gazette B 1049/04.29.2013);
4. the provisions of Joint Ministerial Decision 282371/2006 (Government Gazette B 731/16.6.2006);
5. EOF Board Decision no. O-237/6/16.07.2015;
6. the EU guidelines on electronic submissions;

WE DECIDE

As part of the effort to constantly improve the procedures and the services provided by EOF to stakeholders, and also in view of the obligation to implement EU Directives, the electronic submission of applications and documentation exclusively via the Common European Submission Portal (CESP) is hereby introduced, effective from **03.04.2017**, as mandatory for human and veterinary medicinal products.

Specifically:

- All submissions of applications for approvals, variations, renewals, PSURs, ASMFs etc. in a mutual recognition procedure (MRP), decentralised procedure (DCP) or national procedure (NP), as well as the relevant documentation, shall be made exclusively via the CESP. The same method shall be used for responses to

questions from the authorities and for the provision of any additional information and data as may be required by EOF in the context of its review of applications.

For the abovementioned applications, the submission of a CD/DVD shall not be required.

- Each submission shall automatically be assigned a reference number, directly communicated to the applicant.

Following the guidance of the International Conference on Harmonisation (ICH) as adopted by the European Union, electronic submissions shall be accepted only in eCTD (electronic Common Technical Document) format, or NeeS (Non-eCTD electronic submissions) for medicinal products for human use and VNeeS (veterinary neeS) for veterinary medicinal products. Exceptionally from **03.04.2017 to 04.09.2017**, electronic submissions that do not comply with these formats shall also be accepted.

In all cases, only electronic application forms (eAFs) shall be accepted.

It should be noted that every new marketing authorisation application (MAA) shall require the submission of a dossier in eCTD format or NeeS (Human) and VNeeS (Veterinary) as from **03.04.2017**.

According to the eSubmission Roadmap adopted by the European Union countries on 10.03.2017, **the mandatory use of eCTD format** for medicinal products for human use is phased in with the following timeframe:

- for all submissions in CP: already in effect;
- for new MAAs in DCP: already in effect as from 01.01.2016;
- for new MAAs in MRP: already in effect as from 01.01.2017;
- for all other submissions (variations, renewals, PSURs, ASMFs, etc.) in DCP and MRP: as from 01.01.2018;
- for new MAAs in NP: as from 01.07.2018
- for all other submissions (variations, renewals, PSURs, ASMFs, etc.) in NP: as from 01.01.2019.

According to the above eSubmission roadmap, the mandatory use of the VNeeS format for veterinary medicinal products is phased in with the following timeframe:

- for all submissions in DCP and CP: already in effect;
- for new MAAs in DCP and CP: already in effect;
- for new MAAs in NP: first quarter 2018;
- for all submissions (variations, renewals, PSURs, ASMFs, etc.) in NP: first quarter 2019.

Baseline submission

To enable a faster and more efficient processing of applications for variations and renewals, a baseline submission is highly recommended* (Module 3 documents).

* Baseline submission refers to the final approved documentation as at the time of the application.

An accompanying statutory declaration shall state that the baseline submission includes only the already approved Module 3 documentation and not any additional change.

We draw your attention to the following:

- direct administrative review shall no longer be necessary;
- a condition for the start of the dossier evaluation shall be the formal submission to EOF's Protocol department of:

  - a Cover Letter completed in the Greek language in accordance to the HMA templates, bearing original signature(s);

  - proof of payment (original fee), unless the fee has been paid electronically;

  - an eAF drawn up in the Greek language (with the relevant fields filled in, e.g. purpose of application, valid/proposed), in Module 1-Common-el

- Specifically for marketing authorisation transfers, apart from the above documents and the e-submission application via the CESP, please submit in addition all marketing authorization transfer related documents that require original signature via EOF's protocol department , i.e.:

  - page 6 of the transfer application;

  - Document 5 "Letter from the current MAH (transferor) designating the prospective MAH (transferee)"

  - Document 10 "Statement by the prospective MAH"

  - Document 11 "Statement by the current MAH".

In addition, we remind you that:

For all submissions the following additional (local) requirements apply:

- "General Information"
- "Summary Variation Table (for all variations of type IA, IA_{in}, IB, II), stored within the working documents (a template of this table has been specified by a previous circular)"

For the final Greek SPC and PIL texts of medicinal products for human use during an ongoing MRP/DCP, the email address spctrans@eof.gr shall be used.

For the final Greek SPC and PIL texts of medicinal products for veterinary use during an ongoing MRP/DCP, the email address spcvet@eof.gr shall be used.

Finally, for more information on eSubmission, CESP, eAF, eCTD, NeeS, VNeeS, please visit http://esubmission.ema.europa.eu

For further clarifications, queries, etc., please contact esubmission@eof.gr

The President of EOF

Aikaterini Antoniou

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