18 November 2022
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Veterinary Medicines Division

Dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency (EMA) and to members of the Committee for Veterinary Medicinal Products (CVMP)

Dossier Requirements for:
EMA, (Co-)Rapporteurs and CVMP Members/Alternates

The below requirements apply to all submissions to the EMA related to applications for central marketing authorisation, centrally authorised products and MRLs.

Electronic submission via the EMA e-Submission Gateway or Syncplicity Web Client is mandatory. Dossiers submitted electronically should follow the current version of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product, published on the Vet e-Submission website:
http://esubmission.ema.europa.eu/tiges/vetesub.htm

All VNeeS submission for Centrally Authorised Products (CAP) sent to EMA via Gateway/Syncplicity Web Client will be considered **delivered to all National Competent Authorities (NCA)' representatives[1], alternates and scientific experts**.

Do not submit any additional copies of CAP submissions directly to the NCAs on CD/DVD or via CESP as this might lead to validation issues and cause delays.

For **worksharing procedures**, the complete dossier should be submitted via the Gateway/Syncplicity Web Client for **each** centrally authorised product included in the worksharing procedure.

For technical issues with the submissions visit the EMA Service Desk portal

[1] From 1 January 2021 this will no longer include UK authorities. However, in view of the validity of Union authorisations in the territory of Northern Ireland, the marketing authorisation holders are advised to also submit the dossier to the UK authorities. With regards to the modalities of such submissions the marketing authorisation holders are advised to contact directly the UK authorities.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The above requirements apply also to the submission of responses to requests for supplementary information (e.g. lists of questions (LoQ), lists of outstanding issues (LoOI)).

The use of the **Common Repository by NCAs is mandatory**, which means that the following process is applicable:

- the applicant sends their dossier via the EMA Gateway/ Syncplicity Web Client;
- the submitted dossier is made available in the Common Repository;
- for CVMP members, no further submissions via any other channels is necessary, as they will retrieve the dossier via the Common Repository.

For worksharing procedures involving nationally authorised products (NAPs), additional submission to the NCAs where the concerned marketing authorisations are authorised will be required as per table below:

Example: for a worksharing procedure involving three CAPs and four NAPs, the procedure will be:

- Applicant sends the same completed dossier 3 times (1 submission per CAP) via EMA Gateway/Syncplicity Web Client
- Applicant sends the NAPs as detailed below

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
Austria (AT)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Eudralink cannot be used for Austria.
Belgium (BE)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink, the address should be: Post.authorisation.v@fagg-afmps.be for worksharing variations including NAPs
Bulgaria (BG)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Croatia (HR)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Cyprus (CY)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Czech Republic (CZ)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Denmark (DK)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
Estonia (EE)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Finland (FI)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively e-submission should be used: applications to be sent on 2 identical CD/DVD media along with signed cover letter and application form on paper (read more at www.fimea.fi). Eudralink cannot be used for Finland.
France (FR)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink: **Immunologicals** applications: E-submission to be addressed to esubimmuno@anses.fr **Pharmaceuticals** and **homeopathics** applications: E-submissions to be addressed to esubpharma@anses.fr
Germany (DE)	*Paul-Ehrlich-Institut (PEI)* YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)* YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Greece (GR)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Hungary (HU)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Iceland (IS)	YES: submission via CESP is very much preferred https://cespportal.hma.eu/Public/Contacts Alternatively CD/DVD submission is accepted. Please note that Eudralink/email submission is not accepted.
Ireland (IE)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Submissions to the co-opted member Dr Rory Breathnach should be made directly to the Health Products Regulatory Authority (HPRA).

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
Italy (IT)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Latvia (LV)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink to vzr@pvd.gov.lv
Lithuania (LT)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Luxemburg (LU)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Malta (MT)	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Netherlands (NL)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts **Pharmaceuticals response dossiers** sent via Eudralink to be addressed to case@cbg-meb.nl, mentioning the word 'case' followed by the procedure number in the email heading.[2]
Norway (NO)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink: CVMP member: to post@legemiddelverket.no CVMP alternate: to Vet.Felles@legemiddelverket.no
Poland (PL)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Portugal (PT)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Romania (RO)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Slovakia (SK)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts

[2] The procedure number should be quoted for centralised procedure. Information on responses by e-submissions is available on their website: http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/e-submission/how-should-response-documents-be-submitted/default.htm

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
Slovenia (SI)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Spain (ES)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts
Sweden (SE)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively if sent via Eudralink, use the address ric@lakemedelsverket.se
United Kingdom (UK-Northern Ireland)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink, to: s.response@vmd.defra.gsi.gov.uk