EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2018
EMA/466102/2007 Rev. 33
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 Medicinal Products for Veterinary use (CVMP)

Application / Submission Type	Dossier Requirements for: EMA, (Co-)Rapporteurs and CVMP Members/Alternates
Full application	Electronic submission via the EMA e-Submission Gateway or Web Client is mandatory since 1 January 2017. 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/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 and IG procedures**, the complete dossier should be submitted via the Gateway/Web Client for **each** centrally authorised product included in the worksharing/IG procedure.
Extension	
Type IB variation	
Type II variation	
Renewal	
MRL application	
Periodic Safety Update Report (PSUR)	
Post-Authorisation Measures (PAMs)	

[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.

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Application / Submission Type	Dossier Requirements for: EMA, (Co-)Rapporteurs and CVMP Members/Alternates
Annual Re-Assessment	For technical issues with the submissions visit the EMA Service Desk portal
Referrals	
Type IA	
Transfers	
Active Substance Master Files (ASMFs) new submissions and updates	

The above requirements apply also to the submission of responses to list of questions (LoQ) and list of outstanding issues (LoOI).

The use of the **Common Repository by NCAs is mandatory since the 1st of June 2018**, which means that the following process is applicable:

- the applicant sends their dossier via the EMA Gateway/ 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 NAPs, additional submission to the NCAs 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 / 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. Submission via CD/DVD should be accompanied with signed hard-copy cover letter.

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
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)	NO (please refer to the CESP portal for updated status) https://cespportal.hma.eu/Public/Contacts
Croatia (HR)	NO (please refer to the CESP portal for updated status) 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
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.

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
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** 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).
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

National Competent Authority	Submission via Portal for worksharing procedures involving NAPs
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] Submissions to the co-opted member Dr Gerrit Johan Schefferlie should be made directly to the Medicines Evaluation Board - Veterinary Medicinal Products Unit (CBG-MEB).
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)	NO (please refer to the CESP portal for updated status) 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@mpa.se For CD-Roms and dossiers, the address is: Medical Products Agency, Registration Office, P.O. Box 26, SE-75103 Uppsala, Sweden.
United Kingdom (UK)	YES: submission via CESP accepted https://cespportal.hma.eu/Public/Contacts Alternatively, if sent via Eudralink, to: s.response@vmd.defra.gsi.gov.uk Paper submissions to be sent to: Information Services Veterinary Medicines Directorate Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS, United Kingdom Submissions to the co-opted member Prof Jason Weeks should be made directly to the Veterinary Medicines Directorate (VMD).