EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2010
EMA/22383/2010
Human Medicines Development and Evaluation

Electronic submission of applications for orphan designation

Starting with the 18th February 2010 submission deadline, the European Medicines Agency will accept electronic-only orphan drugs applications for designation. This also applies to any responses to validation issues. Applicants should submit their applications as a CD or DVD with a cover letter. As previously, the deadlines for submission available on the Agency's website refer to the last acceptable day of receipt of electronic documentation.

For any questions please e-mail orphandrugs@ema.europa.eu

To minimise the amount of paper received, the applicant is also invited to send to the European Medicines Agency any other documentation at any time during the procedure only by e-mail or using the secure e-mail system, Eudralink. Please contact the Eudralink Helpdesk at the Agency to open an account eudralink@ema.europa.eu

Documentation to be provided for the submission of an orphan drug application for designation by electronic means:

The applicant shall submit to the Agency in electronic form the complete application for orphan drug designation including full copies of literature references. In parallel, the applicant should also submit the complete application directly to the address of the appointed COMP co-ordinator(s) http://www.ema.europa.eu/htms/general/contacts/COMP/COMP_members.html

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Each of the submissions, to the Agency and to the COMP Co-ordinator(s) appointed, should include signed paper copy of the cover letter and a CD or a DVD, containing:

Documentation	**Format**
Cover letter	PDF
Application form. The application should be signed by no other than the sponsor. Useful links: European Medicines Agency application form http://www.ema.europa.eu/pdfs/human/comp/628300an.doc Common European Medicines Agency/FDA application form http://www.ema.europa.eu/pdfs/human/comp/EMEAFDA_Application_Form_for_Orphan_Medicinal_Product_Designation.doc	PDF
Sections A-E of the application. Useful links: Guideline http://www.ema.europa.eu/pdfs/human/comp/628300en.pdf	Word
Proof of establishment of the sponsor in the EU	PDF
If applicable, letter of authorisation from the sponsor for the person/company acting on their behalf during the procedure	PDF
Translations of the name of the product and the proposed orphan indication into the official languages of the European Union, plus Icelandic and Norwegian http://www.ema.europa.eu/pdfs/human/comp/translation_table.doc	Word
Bibliography saved as single publications and titled as first author and year, such as in 'Smith PH et al 2004.PDF'.	PDF

Important

If more than one indication is applied for the same product, separate applications should be submitted for each orphan indication. In this regard, 'treatment' and 'prevention' of the same condition are considered as two separate indications and should be the subject of two separate applications for orphan designation.