30 November 2017
EMA/41277/2007 Rev. 8[3]
Human Medicines Research & Development Support

Checklist for sponsors applying for the transfer of Orphan Medicinal Product (OMP) designation

Sponsors (holders of the OMP designations) are advised to provide the European Medicines Agency with the following documents:

1. A signed cover letter from a holder of the OMP designation named in the decision of the European Commission on the designation as orphan medicinal product *(in PDF format).*

2. A comprehensive document template 1 - orphan designation transfer form *(in Word and in PDF format)* signed by both the current sponsor and the new sponsor (legal or natural person), including:

   a. Identification of the sponsor of the designation to be transferred ("current sponsor") and the identification of the sponsor to whom the transfer is to be granted ("new sponsor"). Please include name and address (telephone, fax and email if available) for both sponsors, current and new; if either sponsor is not a physical person, please include the name of a relevant contact person. This is necessary for the delivery to the sponsors of the EC decision[1] on the transfer. Please note that the contact persons may be different from the signatories of the document, if so desired.

   b. A statement certifying that a copy of the complete and up-to-date designation application has been made available or has been transferred to the new sponsor.

   c. A statement on the date from which the new sponsor can actually take over the responsibility for and the rights of the designation for the medicinal product concerned from the current sponsor (i.e., the date of implementation of the transfer).

3. Proof that the new sponsor is established in the European Economic Area[2] (EEA), e.g. a certificate of registration in the register of legal entities, a certificate of incorporation, a copy of a passport or ID card in case of an individual, etc. *(in PDF format).*

4. When the person authorised to communicate with the European Medicines Agency on behalf of the current or new sponsor represents a third party (e.g. a consulting company or an individual), a letter of authorisation stating the contact point should be provided by the sponsor (*in PDF format).*

[1] The European Commission delivers decisions on transfers to the receiving sponsor via courier. Therefore, the details of a contact person in the company are required.
[2] 28 EU Member States plus Iceland, Liechtenstein and Norway.

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5. It is advised that the request for transfer contains the translations of the name of the active ingredient and of the indication in the official languages of the Member States. The sponsors are advised to send the translations using template 2 *(in Word format)* as follows:

- for orphan designations granted prior to May 2004, the translations in all languages listed in the template 2 are required;
- for orphan designations granted after May 2004, but prior to January 2007, only the translations in Bulgarian, Croatian and Romanian are required;
- for orphan designations granted after January 2007, but prior to July 2013 only the translations in Croatian are required.

For orphan designations granted after July 2013 no translations are requested.

Sponsors are requested to send all documents to: orphandrugs@ema.europa.eu

New:[3]

Administrative consequences of the United Kingdom's withdrawal from the EU

The EMA would like to refer to the EC-EMA Notice to marketing authorisation holders published in May 2017 on the European Commission and Agency websites. This notice reminds marketing authorisation holders to check whether they have to adapt processes and to consider changes to the terms of their marketing authorisations in advance of UK's withdrawal from the EU. These changes also apply to orphan designation holders. Required changes should be in place not later than 30 March 2019, in order to ensure processes and marketing authorisations continuous validity once the UK becomes a third country.

For any future applications including legal requirements and/or activities currently based in the UK, you are advised to consider the relevant changes in advance of the submission of a new application for orphan medicinal product designation.

Guidance (in the form of Q&As) can be found on the EMA website. For any questions that you may have further to the Q&As publication, you are advised to liaise with your EMA contact point.

[3] Administrative consequences of the United Kingdom's (UK) withdrawal from the EU