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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 to the European Medicines Agency the following supporting information with their application for the transfer of the sponsor, submitted online via the **IRIS system**[2]:

1. Proof that the new sponsor is established in the European Economic Area[3] (EEA), e.g. a copy of a certificate of registration in the register of legal entities or a certificate of incorporation for organisations; a copy of identification document (e.g. a passport or ID card) in case of a natural person. **It should be noted that:**

- **when the new sponsor is an organisation**, the relevant documents should be uploaded in the portal folder of the submission;
- **when the new sponsor applying is a 'natural person'**, in order to respect data protection rights and freedoms, the relevant documents should not be included in the portal folder of the submission. Once EMA receives the application, the Orphan Medicines Office will e-mail the portal contact for the application outside the submission portal to verify the citizenship of the new individual sponsor of a country of the EEA. At the end of the validation process all personal data are deleted from EMA's systems. Please refer to Privacy Statement for proof of establishment of natural persons in orphan designation.

2. Translations of the name of the active ingredient and of the indication in the official languages of the Member States, using the specific form. The sponsors are advised to complete the relevant translations required as part of the online application form 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.

[1] Update of broken link.
[2] EMA's secure online system to submit applications for orphan designation and to manage pre- and post-designation activities.
[3] 27 EU Member States plus Iceland, Liechtenstein and Norway.

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In addition, the current and new sponsor, as applicable, will have to complete the following steps before the submission of the application for the transfer:

1. Sponsors that are organisations will have to check that the current and new sponsor are both registered in the Organisations Management Service (OMS) with up to date information. In the case that any of the sponsors details are outdated, users should update the data within the 'change request' functionality in the OMS interface.
2. Sponsors that are individuals will just need to have an account in the EMA's Account Management portal and provide telephone number corresponding to the address as mentioned in the application.
3. All the contact persons authorised to communicate on behalf of the current and new sponsor should have an EMA account or obtain one on the EMA's Account Management portal, and the appropriate affiliation to their organisation(s).
4. All contact persons at the sponsor's premises, if different from the contact person authorised to communicate, should have an EMA account or obtain one on the EMA's Account Management portal. These contacts will be the recipients of the EC Decision on the transfer delivered by the European Commission to the sponsors premises in the EEA. The telephone numbers for these contacts should be of the sponsors premises in the EEA and not elsewhere.
5. All contacts should have their profile updated in the IRIS portal and include relevant contact telephone numbers to avoid any delays with the EMA validation of the application.
6. If a Research Product Identifier (RPI) is not available for the product, this should be requested simultaneously (with a separate submission in IRIS) by the existing sponsor.
7. If the active substance is not yet available as a current and authorised term in EUTCT, this will require a separate process to register the substance before the RPI can be requested. Click here to complete the form for registering a new active substance in EUTCT.

Detailed information on how complete the processes above prior to the submission of the application on the transfer can be found in the 'Iris quick guide to registration'.