



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 March 2019
EMA/41277/2007 Rev. 10
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](#)¹:

1. Proof that the new sponsor is established in the European Economic Area² (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 a passport or ID card in case of an individual sponsor. The relevant documents should be uploaded with the application. For sponsor applying as 'individual' the passport/ID card documents will be deleted from the EMA systems immediately after validation of the application.
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.

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 In the case that any of the sponsors details are outdated, users should update the data within the 'change request' functionality in the OMS interface.

¹ EMA's secure online system to submit applications for orphan designation and to manage pre- and post-designation activities

² 28 EU Member States plus Iceland, Liechtenstein and Norway.



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'](#).