QRD Form 1 - human

For applicant/MAH when submitting the draft translations to the European Medicines Agency

SECTION 1 (to be completed by the applicant/MAH)

**Product name:**

Click here to enter text.

**Full application number:**

Click here to enter text.

**Applicant/MAHs contact details for translations:**

Click here to enter text.

Click here to enter text.

Click here to enter text.

**Rapporteur/Co-Rapporteur:** Click here to enter text.

**EMA procedure manager:** Click here to enter text.

**QRD template version number:** Click here to enter text. **WORKSHARING:**   **GROUPING:**

PI differences (for extensions and generics only):

*<Provide here a short description of the differences between the already authorised presentations and the new extension (e.g. indicate sections amended)> < Where the existence of usage patent(s) leads to differences in SmPC/PL compared to the reference medicinal product, this should be indicated here>*

Comments to be sent to:

email address for applicant/MAH’s translation coordinator(s) with a copy to the Agencyemail address for the EMA product mailbox

**SECTION 2** (to be completed by the Member State)

**Language code:**

Click here to enter text.

**Details of the Member State contact person for the translation check:**

Click here to enter text.

Click here to enter text.

Click here to enter text.

**Overall quality of translation\*:**

Click here to enter text.

\* *(very good, acceptable, unacceptable)*

If the translation is of unacceptable quality, Member State to respond **within 3 days** to the applicant/MAH with a copy to the Agency and include an explanation in the box below:

**The translation was unacceptable because** Click here to enter text.