EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2025
EMA/699123/2021/Rev. 3[1]
Human Medicines Division

Irish language derogation ending on 1 January 2022

The European Commission's report (EUR-Lex - 52021DC0315 - EN - EUR-Lex (europa.eu)), published in June 2021, on whether the Union institutions have sufficient available capacity for the Irish language, relative to the other official EU languages, concluded that Regulation No 1[2] can apply without a derogation as of 1 January 2022.

What does this mean for the European Medicines Agency opinions and the European Commission decisions?

European Commission decisions addressed to the Member States adopted after 1 January 2022, such as for certain referrals, PSUR single assessment (PSUSA) procedures or assessment of non-interventional post-authorisation safety studies (PASS), will be translated into Irish.

For Commission decisions on centrally authorised medicines addressed to individual companies, EMA will engage with the marketing authorisation and orphan designation holders established in the Republic of Ireland regarding whether they will require Commission decisions to be communicated to them in Irish or whether they would like to request a language waiver.

If a company or individual established in Ireland requests a language waiver, the Commission decisions addressed to them will not need to be translated into Irish.

The provisions regarding the translation of Commission decisions can be adapted in the future taking account of the particulars for the delivery of healthcare in Ireland.

For all new marketing authorisation applications, irrespective of where the applicant is established (i.e. in Ireland or elsewhere), applicants will be required to submit the International Non-Proprietary Name (INN) translation in all official EU languages including the Irish language following a positive CxMP opinion adopted after 1 January 2022.

In those cases where the Irish translation of the INN is not available, applicants can submit the English language INN.

In addition, for all centralised procedures following a positive CHMP opinion, which include the Annex related to the Article 127a[3], the applicant/MAH will be required to submit the Irish translation of the aforementioned Annex.

[1] Revision 3 includes the requirement for companies to submit the Irish language translation of the Annex related to the Article 127a, where applicable.
[2] EEC Council: Regulation No 1 of 15 April 1958 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385)
[3] Annex related to the Article 127a of the Directive 83/2001 refers to the conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the Member States

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

What does a marketing authorisation holder (MAH)/applicant have to do to request a language waiver?

Commission decisions are notified to the marketing authorisation holder or applicant in the authentic language of the decision (normally the language of the Member State where the marketing authorisation holder or applicant is located).

However, Irish will not be considered as the authentic language for companies or individuals (in case of orphan designations) established in Ireland, where the concerned companies or individuals submit to the EMA a language waiver by which they request to use English as authentic language; therefore there will be no need for translation into Irish. The language waiver will be valid for all Commission decisions concerning the medicinal product(s) or orphan designation held by the same companies or individuals referred to in the waiver and established in Ireland. Therefore, it will not be necessary to submit a waiver for each individual marketing authorisation or orphan designation.

The waiver will be valid for a period of 3 years from the date of notification and will be automatically renewed for further consecutive periods of 3 years, unless the companies or individuals decide to withdraw the waiver. The withdrawal of the waiver will take effect at the end of the three years period or three months after it has been notified, whatever is earlier. Marketing authorisation holders should regularly review the corresponding information and update the waiver, as needed.

Companies or individuals are requested to submit their waiver to IrishWaiver@ema.europa.eu.

What happens in the case of Commission decisions addressed to the Member States?

For Commission implementing decisions and their annexes addressed to the Member States, translations in Irish will have to be provided as of 1 January 2022. In those cases where translation in Irish will be required, EMA has made available the QRD product information annex templates, for both human and veterinary medicinal products, as well as the necessary QRD reference documents, translated in the Irish language.

It is important to highlight that the above represents the current approach regarding the implementation of Regulation No 1 concerning the use of the Irish language. This approach might change in the future and different guidance may be issued. Companies should be aware that at a certain point in the future a more extensive use of the Irish language may be required.

Questions and answers on translation requirements after the ending of the Irish language derogation on 1 January 2022

1. Who should apply for the language waiver, waiving the right to receive Commission decisions in the Irish language on individual medicinal products?

Applicants, marketing authorisation holders or orphan designation holders established in Ireland, who do not wish to receive European Commission decisions in Irish.

2. Is it possible or necessary for a MAH's local representative based in Ireland to apply for a language waiver?

No, a local representative based in Ireland of a MAH established elsewhere (i.e. not in Ireland) cannot and does not need to apply for a language waiver.

3. Is it possible to request a single language waiver on behalf of several companies which are considered to be the same "applicant" or "MAH" within the meaning of the "global marketing authorisation" notion?

No, the language waiver should be requested for each legal entity established in Ireland. Therefore, it is not possible to apply the extensive interpretation of 'same applicant or MAH' used for the purpose of explaining the notion of a "global marketing authorisation", i.e. applicants and MAHs belonging to the same company group or that are controlled by the same physical or legal entity, or which have concluded tacit or explicit agreements concerning the marketing of the same medicinal product. Applicants and MAHs should take into account that in the cases when the European Commission decision is addressed to the Member States, it is not possible to request a language waiver, irrespectively of whether the concerned company is established in Ireland or not.

4. For how long is a language waiver valid?

The language waiver is valid for three years.

5. What happens at the end of the validity period of the Irish language waiver?

Unless the waiver is actively withdrawn by the requesting company or individual, the validity will be automatically extended for further consecutive periods of three years.

6. Will the request for a language waiver or a list of companies or individuals who requested language waivers be published on the EMA or the European Commission website?

No, neither the requests for language waivers nor the list of companies or individuals who have requested language waivers will be published on the EMA or the European Commission website.

7. Can a language waiver be requested for European Commission decisions addressed to Member States?

No, a language waiver cannot be requested for European Commission decisions addressed to Member States. These must be translated into the Irish language, together with their annexes. Where such annexes include the full product information or amendments to the product information of the nationally authorised medicinal product(s), these will also need to be translated into Irish.

8. Who will be responsible for providing the translation of the annexes required for European Commission decisions addressed to Member States?

For European Commission decisions addressed to Member States, such as for certain referrals, PSUSA procedures or assessment of PASS results, as well as for all procedures which include the Annex related to the Article 127a, the companies included in the concerned procedure will be asked to provide translations into the Irish language. Where more than one company is involved

and no volunteer is found, the Translation Centre in Luxembourg will perform the translations. Please see below under question 11 which procedures can result in an European Commission decision addressed to Member States.

9. The guidance refers only to "European Commission decisions addressed to Member States" and "European Commission decisions addressed to MAH or orphan designation holders established in Ireland", but there is no specification regarding the product information. Is it necessary that the product information is translated into the Irish language?

The product information annexes form legal part of the European Commission decisions. For Commission decisions addressed to individual companies established in Ireland, the product information and the other annexes to the European Commission decision need to be translated into the Irish language, unless a language waiver is requested. For European Commission decisions addressed to Member States, the product information or the amendments to the product information, as well as the other annexes to the European Commission decision always need to be translated into the Irish language.

10. If an Irish language product information is created for a referral, PSUSA or PASS procedure including a NAP and resulting in a Commission decision addressed to Member States, will the Irish product information be published on the EPAR webpage? Will it become outdated at the next label update or are companies expected to maintain it?

In the context of European Commission decisions addressed to Member States (for nationally authorised medicinal products) and accompanied by product information annexes including Irish, the Irish translation is only linked to the particular procedure [one-off]. The Irish language version of the product information annexes to the Commission decision addressed to Member States will not be published on the EPAR webpage, as EPAR concerns only centrally authorised products, and the companies will not be expected to maintain the Irish version of the product information.

11. The guidance refers to "certain referrals, PSUSAs or assessment of PASS" – what does "certain" mean?

Referrals: for nationally authorised medicinal products (NAPs) the Commission decision is addressed to Member States and for centrally authorised medicinal products (CAPs) the Commission decision is addressed to applicants/MAHs. Referral procedures that include NAPs and, therefore, could result in a Commission decision addressed to the Member States, are referrals triggered in accordance with Articles 29(4), 30, 31 or 107i of Directive 2001/83/EC, Article 13 of Regulation (EC) No 1234/2008 or Article 29 of Regulation (EC) No 1901/2006, and Articles 54(8), 70(11) or 82 of Regulation (EU) 2019/6.
Further information regarding the different types of referrals, their assessment and possible outcomes can be found on the EMA webpages concerning referral procedures (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures and https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/veterinary-referral-procedures)

PSUSAs (human medicinal products only): in the cases when the PRAC recommendation after PSUSA results in a variation, suspension or revocation of the marketing authorisation (therefore other than maintenance) and the said PSUSA includes CAPs/NAPs or the said PSUSA includes only NAPs but there is only majority (no consensus) at CMDh level about the implementation of the PRAC recommendation, there will be an European Commission decision addressed to Member States.
Further information regarding the assessment of PSURs and the possible outcomes can be found on the EMA webpage concerning Periodic safety update reports (PSURs) (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/periodic-safety-update-reports-psurs), specifically in the section "Post-authorisation procedural advice: questions and answers"

PASSs (human medicinal products only): for procedures assessing a non-interventional imposed PASS final study report (therefore not for protocol review or amendment to the protocol), when the PRAC recommends a variation, suspension or revocation of the marketing authorisation and the said procedure includes CAPs/NAPs or the said procedure includes only NAPs but there is

only majority (no consensus) at CMDh level about the implementation of the PRAC recommendation, there will be an European Commission decision addressed to Member States.

Further information regarding the assessment of PASS results and possible outcomes can be found on the EMA webpage concerning Post-authorisation safety studies (PASS) (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/post-authorisation-safety-studies-pass-0), specifically in the section Non-interventional imposed PASS: questions and answers

12. Are only safety-related referrals in the scope of this guidance?

No, all referrals are concerned by the provisions of this guidance. The types of referrals that can result in an European Commission decision addressed to Member States are detailed under question 11 above.

13. Some types of referrals on human medicinal products are triggered for medicines evaluated in a mutual-recognition or decentralised procedure, when there is a disagreement between Member States regarding a marketing authorisation application or a variation being evaluated, or in cases when Member States have adopted different decisions over the years for some medicines and there is a need to harmonise across the EU. Are these types of referrals in the scope of this guidance?

Yes, these referrals are triggered in accordance with Article 29(4) or 30 of Directive 2001/83/EC, or Article 13 of Reg (EC) No 1234/2008 and are in the scope of this guidance. These referrals result in an European Commission decision addressed to Member States.

14. Some types of referrals and related procedures on veterinary medicinal products are triggered for medicines evaluated in a mutual-recognition or decentralised procedure, when there is a disagreement between Member States regarding a marketing authorisation application or a variation being evaluated, and the European Commission requires a clarification on the draft Decision to be prepared on this matter; or in cases when Member States disagree on the proposed harmonised SPC in the SPC harmonisation procedure. Are these types of referrals in the scope of this guidance?

Yes, these are the procedures triggered under Article 54(8) and the referrals triggered under Article 70(11) of Regulation (EU) 2019/6 and they are in the scope of this guidance. These referrals result in an European Commission decision addressed to Member States.

15. When will the eCTD specification be updated?

EMA has already initiated the discussion on the need for an update of the eCTD specification and the validation criteria, however, no firm timeline has been yet agreed for the update as it also contains other changes.

While the eCTD specification is being updated to enable the provision of the Irish translations alongside the eCTD package, Irish translations should be provided within the 'workingdocuments' folder, submitted together with the eCTD package.

The applicants should indicate in the submission cover letter that the Irish translations are included and that they can be found in the 'workingdocuments'. In this case, the Irish translations should be supplied as PDF files in the 'workingdocuments' folder sent together with the eCTD. In addition, MS Word files (with or without tracked changes as relevant) should be provided in the same folder 'XXXX-workingdocuments' within the same submission.

16. When will VNeeS specifications be updated?

Discussion will happen in collaboration with EMA and the Vet Harmonisation Group and relevant documentation will be updated. No timeline has been defined yet.