



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Irish language derogation

7th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines – 01/12/2021

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Background

The EC report ([EUR-Lex - 52021DC0315 - EN - EUR-Lex \(europa.eu\)](#)), published in June 2021, concluded there is sufficient available capacity in the EU institutions to lift the derogation for the Irish language as of 1 January 2022.

!! The provisions of the newly published guidance regarding the translation of EC decisions can be modified in the future to extend the use of the Irish language!!



Practical consequences

- ❖ EC decisions (+ annexes) addressed to MSs (after 1 January 2022), shall be translated in Irish (certain referrals, PSUSAs or PASSs).
- ❖ EC decisions (+ annexes) of CAPs addressed to companies/orphan designation holders established in the Republic of Ireland will be translated in Irish, **unless** they request a language waiver.



Language waiver (A)

- ❖ EC decisions are notified in the authentic language of the decision (normally the language of the MS where the MAH is located).
- ❖ Irish will not be considered as the authentic language for companies or individuals (in case of orphan designations) established in Ireland, if the concerned companies or individuals submit to the EMA a language waiver requesting to use English as authentic language.
- ❖ The language waiver will be valid for all EC decisions for medicinal product(s) or orphan designations held by the same companies/individuals. Not necessary to submit a waiver for each MA or orphan designation.



Language waiver (B)

- ❖ The waiver will be valid for 3 + 3 years, unless withdrawn. => MAHs to regularly review and update the waiver, as needed.
- ❖ Waivers to be submitted to IrishWaiver@ema.europa.eu by 31 January 2022.
- ❖ For regulatory procedures with a scheduled CHMP, CVMP or COMP opinion in December 2021 (i.e. EC decision to be adopted in early 2022) the waiver to be submitted no later than the adoption of the scientific opinion in December 2021 at CHMP, CVMP or COMP.



QRD product information templates in Irish & eCDT

- ❖ EMA will publish shortly 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.
- ❖ EMA will provide information on how to include translations in the submission package as currently eCTD specification does not have a placeholder for translations in Irish.

Q & A on Irish translation requirement



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1.	Can a waiver be requested for EC decisions (+annexes) addressed to Member States?	NO, a waiver cannot be requested for EC decisions addressed to Member States.
2.	Who will be responsible for providing the translations required for EC decisions (+annexes) addressed to MSs.	The companies will be asked to provide translations in Irish. In case no volunteer is found, the Translation Centre in Luxembourg will perform the translations.
3.	Is a waiver needed for companies that don't have any MAH's in Ireland, but only local representatives?	NO.
	If the company's representative in Ireland is not a MAH in Ireland or legal entity, but a local representative only, is the waiver required and if so who should request the waiver (the MAH located elsewhere or the local representative in Ireland)?	NO.
	Who is considered the concerned company, the MAH or any local representative in Ireland?	MHA
	It is stated in the Q&A that EMA will engage with concerned companies but below it states that the company need to request a waiver – who will be taking the first action?	A mass mailing is being prepared, however Industry associations should also make an effort to inform their members. The published guidance also serves as a call for concerned companies to submit the waiver.
4.	For regulatory procedures with a scheduled CHMP, CVMP or COMP opinion in December 2021 (i.e. EC decision to be adopted in early 2022) the waiver to be submitted no later than the adoption of the scientific opinion in December 2021 at CHMP, CVMP or COMP: does this mean we need to submit before 16 December 2021?	The companies need to submit in time so that PI annexes will be sent to EC together with the waiver, i.e. at the latest with the submission of the translations' package.
5.	The waiver form itself does not refer anywhere to this being linked to a waiver for Irish/Gaelic. At the moment it seems very vague and could in theory relate to any other language and indeed indicates that CD would only be received in English, whereas in fact a CD will be available in all other EU languages. We would like to know if the waiver can be more specific on the Irish language only.	No change needed. The crucial point is to identify EN as the authentic language. The legal concept of authentic language is referring to the official language(s) of the MS where the MAH is established. The waiver can be used with the current format and content.

Q & A on Irish translation requirement



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6.	It is confusing as the guidance seems to relate to „EC decisions addressed to member states“ and „EC decisions addressed to MAH and orphan designation holders established in Ireland“ only, but not to any kind of clarification on the need of PI translations into Irish language.	PI annexes form legally part of the EC decision. Further clarifications are not considered necessary.
7.	If an Irish PI is created for the following procedure types, will it be published on the EPAR and will it then become outdated at the next label update or are we expected to maintain it? -Referrals -Periodic safety update reports (PSURs) -Post-authorisation safety studies (PASS)	In the context of these types of procedures the Irish translation is only linked to the particular procedure [one-off] (so no consolidation in the EPAR webpage)
8.	Please explain the exact timing of implementation, e.g. PSUR procedure ongoing with linguistic review, is it only at the time of CHMP Opinion in January 2022 that Irish translation of the PI needs to be included, or already for those CHMP Opinions in December for which the EC Decision is expected in 2022? I guess it would be only for CHMP Opinion as of January, otherwise Irish would miss the linguistic review timetable, but just wanted to have confirmation.	It is for all concerned procedures with opinion in December for which the EC decision will be issued in 2022.
	Do we have to submit a waiver for PSUSA for purely national authorised products with CHMP opinion and thus linguistic review in December 2021 (day 14 = 30.12.2021), and EC decision beginning 2022.	No waiver can be submitted for PSUSAs with EC decision addressed to Member States
9.	Who has to apply for the waiver	If the EC decisions are addressed to a company based in IE, then the waiver needs to be applied by concerned MAH/applicant. However, as stated above, for EC decisions addressed to Member States, a waiver cannot be requested.
	only MAH or also Irish affiliate?	MAH only
10.	For the waiver: can we use for the MAH the wording reflecting the concept of global marketing authorisation holder like the explanation we used in the letter of intent for worksharing (CMDh document - 'The same mother company or group of companies or which are licensees or exercise concerted practices concerning the placing on the market of the relevant medicinal product in different Member States') to reflect that not only Company XX AG and Company XX Ireland but because of referrals /PSUSA procedure also other Company XX affiliates or subsidiaries may be affected as well?	NO, it should be done per legal entity, so not the extensive interpretation for the purpose of the GMA. In any case, in the scenario where the EC decision is addressed to the Member States, whether the company is based or not in Ireland does not play any role; no waiver is applicable.



11.	Will the waiver always be prolonged for further 3 years until we actively withdraw it? As stated in the guidance, it is 3 + 3y = total of 6y	Yes, it will be prolonged automatically for periods of 3 years, non stop, unless the MAH withdraws it
	if not and we have to renewed it, what would be the appropriate time before it would end?	Recently published guidance is incorrect and will be amended soon. As stated above, the waiver will be prolonged automatically for periods of 3 years, unless withdrawn by the MAH. Marketing authorisation holders should regularly review the corresponding information and update the waiver, as needed.
12.	Will the waiver or list of companies with waivers be published on EMA or EC website?	No
	On the first page third paragraph mentions 'certain referrals, PSUSAs or assessment of PASS' – what does 'certain' mean?	Referrals: The wording in the Notice to Applicants (volume 2a, chapter 3 - Union Referral procedures, p. 24), states that for nationally authorised medicinal products (NAPs) the CD is addressed to Member States and for centrally authorised medicinal products (CAPs), the CD is addressed to applicants/MAHs. The referral procedures that include NAPs and, therefore, could finalise with a CD addressed to the Member States, are referrals triggered in accordance with Art 107i, Art 31, Art 29(4) or Art 30 of Directive 2001/83/EC, Art 13 of Regulation (EC) No 1234/2008 or Art 29 of Regulation (EC) No 1901/2006 on medicinal products for paediatric use. Further information regarding the different types of refferrals, their assessment and possible outcomes can be found on the EMA web-page concerning referral procedures (https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures) PSUSAs: in the cases when the PRAC recommendation after PSUSA results in a variation, suspension or revocation of the marketing authorization (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 a EC decision addressed to Member States. Further information regarding the assessment of PSURs and the possible outcomes can be found on the EMA web-page 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"



13.		PASSs: similarly to the cases highlighted for PSUR/SA, for procedures of non-interventional imposed PASS results (therefore no protocol review or amendment to the protocol), when the PRAC recommends a variation, suspension or revocation of the marketing authorization 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 a EC decision addressed to Member States. Further information regarding the assessment of PASS results and possible outcomes can be found on the EMA web-page 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
	Are only safety procedures in scope?	No
	Are also MRP/DCP that runs into a CHMP referral and ending with EC decision in scope	YES
14.	On the second page the last sentence mentions ‘... more extensive use of the Irish language may be required...’ – please propose, that we would like to have a reasonable / lead-in time before this comes into effect.	If and when the policy changes, industry will be notified in advance. No change needed now.
15.	At what time will the eCTD specification be updated?	We have already opened 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. We will discuss this further in the Harmonisation Group and will work on a Q&A document including a workaround and hopefully will be able to include a timeline in that document.



Any questions?

Further information

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