EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Multilingualism on the EMA website and in external communications

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1. Introduction and purpose

At the heart of the public health mission of the European Medicines Agency (hereinafter EMA or the Agency) is a commitment to provide information about the medicines to patients, healthcare professionals and the general public.

While English is the Agency's working language[1] and the original language for most documents, EMA publishes translations of information of interest to broad audiences (including patients and healthcare professionals) in other official European Union (EU) languages as well as in Icelandic and Norwegian.

The purpose of this policy is to explain in a clear and transparent manner the use of official EU languages by the Agency. In developing this policy, the Agency has taken into account the recommendations from the European Ombudsman on the use of official EU languages when communicating with the public.[2] The policy explains in which languages EMA publishes information on its website and in which types of situations.

2. Scope

This policy applies to all staff members in the Agency involved in producing or publishing information for EMA's website or interacting with the media and stakeholders. The policy addresses the use of EU languages for the purpose of publication of information relating to medicines, the work of the Agency, public consultations, social media activities and responses to enquiries from the public and the media.

3. Definitions

The reference to the "official EU languages" shall mean the official languages and working languages of EU institutions as laid down in Article 1 of Regulation No 1.[3]

4. Policy statement

The decision on whether to translate content from the original language into other official EU languages is based on the possible impact and relevance of the information for stakeholder groups and the public. Priority for translation is given to information on medicines specifically targeted at patients, healthcare professionals and the wider public as well as corporate information that is relevant for a broad audience.

EMA aims to provide equal treatment for all EU languages other than English.[4]

This policy lists the items which are published in official EU languages other than English. The list will be updated as necessary, taking into account feedback from stakeholders, including patients, consumers and healthcare professionals.

[1] Article 1 of the Decision of the Executive Director on the linguistic regime of the European Medicines Agency of 1 June 2015 (EMA/347181/2015): "*The working language of the European Medicines Agency is English. This shall not prevent the Agency from using other European Union official languages as it might be considered appropriate*".
[2] The use of official EU languages when communicating with the public - Practical recommendations for the EU administration | Correspondence | European Ombudsman (europa.eu)
[3] As explained by Article 1 of Regulation No 1 determining the languages to be used by the European Economic Community, "*[t]he 24 official languages of the EU are Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish*".
[4] With the exception of Irish in some cases. See footnote 5 below.[5] Some information is not available in Irish. See EMA's publication on some exceptions for the Irish language.

4.1. Documents produced and published in official EU languages other than English[5]

Medicinal product-related information

Human

In view of the Agency's public health mission, it aims to ensure that the following core information on medicines which it evaluates and supervises are available in official EU languages other than English:

- The product information for centrally authorised human medicines, including the package leaflets.[6]
- Overviews for centrally authorised human medicines, explaining in lay language what the medicines are and why they are approved.
- Q&As in lay language about refusals and withdrawals of applications for marketing authorisation and extensions of indication for human medicines.
- Information about major reviews of human medicines (known as referrals), explaining EMA's recommendations about issues such as a safety concern.[7]

Veterinary

Information about centrally authorised veterinary medicines, including the product information and authorisation details in official EU languages, are now published on a separate website for both centrally and nationally authorised medicines for animals: Veterinary Medicine Information website. This website is owned and maintained on behalf of the European Union medicines regulatory network by EMA.

Core corporate information

To ensure that interested parties have access to key information concerning the work of the Agency, the following information is made available in official EU languages other than English:

- Frequently asked questions (FAQs).
- 'About us' section, providing an overview of the main responsibilities of the Agency.
- General information, such as brochures about the work of EMA and informative content about public health emergencies.

4.2. The availability of technical information in English

A large proportion of the content on EMA's website concerns the EU pharmaceutical legislative framework which is technical in nature. In general, this information is intended for EU-based marketing authorisation applicants and holders of marketing authorisations which effectively operate in English for their regulatory submissions within the EU and internationally.

The availability of this technical information in English (in effect, the language in which the pharmaceutical industry operates globally; as well as the only language in which a large part of the pharmaceutical-related terminology of the World Health Organization and the European Directorate for the Quality of Medicines of the Council of Europe is made available) reduces the genuine risks for misunderstandings and mistakes that could arise if highly technical information (and information

[5] Some information is not available in Irish. See EMA's publication on some exceptions for the Irish language.
[6] Including in Icelandic and Norwegian.
[7] Including in Irish, Icelandic and Norwegian for referral procedures involving nationally authorised medicines.

subject to regular changes and revisions) were to be made available in all official EU languages. The avoidance of such risks ultimately better serves the interest of promoting and protecting human and animal health in the EU.

Therefore, although key information relating to medicines is made available in all EU languages, EMA does not translate all technical information that is made available on its website in English.

4.3. Use of EU languages in external communications with the public and the media

In its interactions with the public, EMA accepts enquiries in all EU languages and responds in the same language[8] within a reasonable time frame and no later than two months from date of receipt.[9]

Regarding media relations, in cases where journalists request an urgent response, EMA will provide a response in English.

4.4. Other uses of EU languages

Social media activities

Depending on the relevance of the content to the public, EMA may publish audio-visual materials with subtitles or voice-overs in other official EU languages, mainly on EMA social media platforms.

Public consultations

To facilitate the participation of interested parties in its public consultations, EMA makes, when possible, consultation documents available for the wider public in other official EU languages at the beginning of the consultation process.

Contributions from the public are accepted in any official EU language.

4.5. Sources of translations

Marketing authorisation applicants or holders prepare all the translations of the approved English product information for medicines, which EMA reviews with the assistance of experts from national competent authorities (NCAs) before publishing.[10]

The Translation Centre for the Bodies of the European Union (Cdt) carries out most of the other translations for EMA. In some cases, documents are translated in-house by EMA staff.

4.6. Accessing translated information on the EMA website

The main interface and navigation of EMA's website are currently not multilingual due to the size and complexity of the website. However, where information is available in different languages, drop-down menus are used to enable users to access the various translations.

EMA is committed to further develop and improve its multilingual approach in the future to ensure that the information of most interest to the public is made available in languages other than English, as appropriate.

[8] In this respect, see: section 11 of the European Medicines Agency Code of Good Administrative Behaviour (EMA/264257/2013); available at: https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-good-administrative-behaviour_en.pdf.
[9] *Ibidem*, section 13.
[10] In this respect, see: https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/working-group-quality-review-documents

5. Personal Data Protection

The processing of personal data as applicable to or resulting from the implementation of this policy on multilingualism on the EMA website and in external communications will be performed in accordance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.[11]

6. Changes since the last revision

New policy.

Amsterdam, January 2023

[Signature on file]

Emer Cooke

Executive Director

[11] In this respect, see: Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC