



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

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 medicines to patients, healthcare professionals and the general public.

While English is the Agency's working language¹ and the original language for most communications and 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 provides 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 accessing and publishing 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 potential 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 considering the user needs and the scope of communications.

This policy describes which information is available in official EU languages other than English. EMA is committed to further develop its multilingual approach in the future, where feasible, taking into

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.

account needs and feedback from stakeholders, including patients, consumers and healthcare professionals.

4.1. Information on the EMA website in official EU languages other than English⁵

Documents with medicinal product-related information

Human medicines

In view of the Agency's public health mission, it aims to ensure that the following core information on human 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

When documents are available in different languages, translated versions can be found in expandable panels.

Veterinary medicines

Information about centrally authorised veterinary medicines, including the product information and authorisation details in official EU languages, is 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.

Content available via machine translation tool

Since June 2026, the EMA corporate website includes a browser-based translation feature developed by the European Commission, in line with standards for EU institutions. This tool helps users better understand EMA's role and work by providing content in their preferred language.

While English remains the default language of the EMA website, users can apply the tool to view webpages in any official EU/EEA language.⁸ Translations are machine-generated and only available within the user's browser for the duration of their session. The quality and accuracy of machine translation can vary from one text to another and between different language pairs. Due to technical limitations, the feature does not translate pages with dynamic content, documents, images and videos.

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

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.

⁸ All official EU languages are integrated in the tool at launch, with Norwegian and Icelandic added in due course.

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 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 language⁹ within a reasonable time frame and no later than two months from the date of receipt.¹⁰

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 for documents

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.¹¹

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

⁹ 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.

¹⁰ *Ibidem*, section 13.

¹¹ In this respect, see: <https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/working-group-quality-review-documents>

4.6. 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.¹²

5. Related documents

[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](#)

[European Medicines Agency Code of Good Administrative Behaviour](#)

[Guidance document on the Irish language derogation](#)

6. Changes since the last revision

The policy is revised following the introduction of a browser-based machine translation tool on the EMA corporate website that enables users to view webpages in any official EU/EEA language.

Amsterdam,

[*Signature on file*]

Emer Cooke

Executive Director

¹² 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