

From the Editor

On multilingualism and medical writing



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I arrived in Europe in September 1991 and was completely unprepared for the multilingualism of this continent. My first European home was the bilingual city of Brussels in the trilingual country of Belgium. Not quite the Tower of Babel but still overwhelming. Since then, I have lived in three more European countries and have observed how the EU grew and evolved. With growth came more diversity and yes – more languages.

27 member states and 24 official languages

The EU currently has 27 member states and 24 official (“*de jure*” = from the law)¹ languages. Why don't the numbers match?

Several national languages (Dutch, English, French, German, Greek, and Swedish) are shared by two or more countries in the EU. On the other hand, many member states have national and regional languages that are not included in the official EU 24.^{2,3} The rules on EU languages are laid down in Regulation 1.⁴

Of the 24, only 3 (English, German, and French) are considered working languages. German is especially widely spoken across the

union. It is an official *de jure* language in four countries (Austria, Belgium, Germany, and Luxembourg) and used as a *de facto* (“from the fact”)¹ language in Denmark, Italy, and Poland. It is spoken by approximately 20% of the EU population.³

French ranks second, used officially in Belgium, France, and Luxembourg, and is a first language to about 14% of EU citizens.³

Only 2 of the 27 EU members claim English as their official tongue – Ireland and Malta – accounting for only 1% of the EU population.³ Yet, the large majority of medical writing and communications activities in Europe are performed in English. Do you ever wonder why?

EMA policy on translations of medicines information

EMA Policy 0084 provides some insights on how the EMA deals with EU multilingualism with respect to dissemination of information on

human and veterinary medicines.

The policy document clearly states that English is the EMA's primary working language. All technical information on the EMA website is in English. This is due to the fact that English is “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.”⁵

EMA does not translate all technical information (i.e., those included in the Common Technical Document [CTD] modules). This “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.”⁵

In this aspect, EMA rightly puts the promotion and protection of human and animal health in the EU over pure multilingualism.

EMA does translate documents for the patients and lay audience and all external communications with the public and the media. Certain key information relating to medicines is made available in all EU languages (plus Norwegian and

Icelandic!*)⁵ including:

- Product information and package leaflets for centrally authorised products
- Overviews in lay language of what these medicines are and why they are approved
- Q&As in lay language about refusals and withdrawals of applications
- Information about major reviews of human medicines, with EMA recommendations on issues such as safety concerns

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Language requirements for medical and in vitro diagnostic devices

The European Commission released in January 2024 a guidance on languages corollary to the above EMA policy document to cover medical and in vitro diagnostic devices.⁶ As in pharma, technical documentations are provided in English; all patient and public facing documents (e.g., IFU, implant cards) are translated into the EU 24, plus Norwegian, Icelandic – and even Turkish.*

Languages the world over

There are supposedly several hundreds of recognised languages globally. Many countries have more than one official language. India supposedly has 16, and South Africa, 11.⁶

Between 50 to 60 countries consider English as one of their *de jure* official languages.

* Even though Iceland and Norway are not EU members, they are part of the European Economic Area (together with Lichtenstein) and follow the European medicines and medical devices regulatory framework. Turkey is fully recognised under the MDR and IVDR since 2022.

Interestingly, the US and Australia are not among them. In these countries, English is the *de facto* (not *de jure*) language.

Multilingualism is complex, yet beautiful. It comes with challenges and opportunities. This issue of *Medical Writing* spotlights multilingualism and the important role that medical translators play, not only in Europe but throughout the world.

Thank you to Claire Harmer and Ana Sofia Correia for putting this edition together. *Merci. Danke. Gracias. Grazie. Salamat.* I wish I could say it in many more ways!

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The graphic features a vibrant green plant on the left side. The text 'Valencia' is written in a large, stylized green font. Below it, '2024 European Green Capital' is written in a bold, black sans-serif font. A paragraph of text describes the award's focus on inclusive sustainability, sustainable tourism, food production, climate neutrality, and ecosystem restoration. At the bottom, there is a logo for the EMA Spring 2024 57th Conference, dated 7th-11th May 2024, and the phrase 'and the host city of...' in a handwritten style.