

Regulatory affairs, clinical trials and the language of science

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The importance of English for the pharmaceutical industry stems from the structure of drug regulation as much as from corporate culture. A new medicine must be approved by the authorities of each market in which it is sold. The largest markets are the United States, the European Union, Japan and China. The United States Food and Drug Administration receives applications in English. The European Medicines Agency in Amsterdam conducts its scientific assessments in English, although the product information for patients must be available in all official languages of the Union. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, known as ICH, has developed guidelines and a Common Technical Document that structure applications in the same way across its members. ICH works in English.¹

The Swiss Agency for Therapeutic Products, Swissmedic, located in Bern, has adapted to this international practice. It accepts large parts of the documentation for marketing authorisations in English, while the information for healthcare professionals and the patient information leaflets must be provided in German, French and Italian. Swissmedic participates in international cooperation, including the Access Consortium with the authorities of Australia, Canada, Singapore and the United Kingdom and the Project Orbis of the FDA for oncology products, all of which runs in English. A Basel company that submits an application to Swissmedic can therefore use the same English dossier that it submits to the FDA and the EMA, which reduces cost and speeds up the review.²

Clinical trials, which take place at hospitals and research centres around the world, generate documentation that is also largely in English. Protocols, investigator brochures, case report forms and clinical study reports are prepared in English because they are used across many countries and submitted to several authorities. The Good Clinical Practice guideline of

ICH, revised in recent years, sets standards that apply worldwide. The patient-facing documents, however, must be in the language of the participants. In Switzerland, informed consent forms are prepared in German, French or Italian according to the region. The cantonal ethics committees, including the Ethics Committee Northwest and Central Switzerland, review the documents in the local language. Clinical research therefore combines an English core with a multilingual periphery, which requires careful management of translations.³

Scientific publishing completes the picture. Since the second half of the twentieth century, English has become the dominant language of the natural sciences, displacing German, which had been the leading language of chemistry and medicine before the First World War. The chemists of Basel who founded the dye industry in the nineteenth century published in German and read the German and French literature of their field. Their successors publish in English in international journals, present their work at conferences in English and evaluate each other's papers through peer review in English. The decline of German as a language of science, which historians of science have traced in detail, mirrors the shift that took place inside the companies.⁴

The industry's dependence on English has a further consequence for intellectual property. Patent applications in the life sciences are typically filed first in the United States or at the European Patent Office, which accepts English as one of its three official languages together with French and German. European patents can then be validated in Switzerland, which as a party to the London Agreement on translation requirements no longer requires a full translation of a European patent granted in English. The patent language of Basel's pharmaceutical groups is thus English. The Federal Patent Court, which is discussed later in this chapter, has had to accommodate this practice in its proceedings.⁵

1 Notes

1. On the Common Technical Document (ICH M4) and the role of ICH, which was reorganised as an association under Swiss law with its seat in Geneva in 2015, see the ICH website. On the language regime of the European Medicines Agency, see Regulation (EC) No 726/2004 and Directive 2001/83/EC as amended. To be verified. ↩
2. Therapeutic Products Act (HMG, SR 812.21), Therapeutic Products Ordinance (VAM, SR 812.212.1) and Swissmedic guidance on formal requirements for applications, including the language of

documentation. On the Access Consortium and Project Orbis, see the Swissmedic website. Status to be verified. ↩

3. ICH guideline E6 on Good Clinical Practice, revised as E6(R3) with adoption in about 2025, and the Swiss Human Research Act (HFG, SR 810.30) and Clinical Trials Ordinance (KlinV, SR 810.305). On the Ethics Committee Northwest and Central Switzerland (EKNZ), see its website. Status to be verified. ↩
4. On the decline of German as a language of science, see Ulrich Ammon, *Die Stellung der deutschen Sprache in der Welt*, Berlin 2015, and Michael D. Gordin, *Scientific Babel: How Science Was Done Before and After Global English*, Chicago 2015. To be verified. ↩
5. Art. 14 of the European Patent Convention on the languages of the European Patent Office. Agreement on the application of Article 65 of the Convention on the Grant of European Patents of 17 October 2000 (London Agreement), in force for Switzerland since 1 May 2008. To be verified. ↩

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