



European Union's EMEA finds translation issues tough to resolve

By Peter O'Donnell—Brussels, Belgium

The opening of the European Agency for the Evaluation of Medicines in London in early 1995 was hailed as a major step toward creating a single procedure for drug registration, eliminating the hodgepodge of country-by-country regulatory approaches that had existed previously in the European Union. Formed 40 years after the EU came into being, and nearly 20 years after it first agreed on a single procedure for drug registration, the EMEA's establishment appeared to be turning the much-vaunted European single market into a reality for the pharmaceutical sector.

But as pharmaceutical firms have discovered since then, the EMEA's formation does not mean the end of regulatory red tape, especially when it comes to translation requirements. The EMEA has been vexed since its inception with ensuring that regulatory applications are translated accurately into the 11 official languages of the EU's 15 member countries. As many companies already know, this is no easy task.

Translation snafus

From its earliest days, the EMEA realized that much of its work was going to consist of seeking consistency. Consistency in the scientific opinions reached by its key advisory committees on the merits of new drug applications is crucial, of course. But equally important is achieving consistency in the way those opinions are expressed across the 11 official EU languages: Danish, German, Greek, English, Spanish, Finnish, French, Italian, Dutch, Portuguese, and Swedish.

Translation snafus have resulted in a number of embarrassing glitches: A diagnostic agent's predictive value was rendered in one translation as "prophetic value." In another case, antibodies were described as being able to "bind with a lot of enthusiasm" instead of having high affinity. Faced with such occurrences, the EMEA decided it had to act fast to improve the quality of translations.

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The EMEA's task wasn't made any easier by the fact that the tightly budgeted agency wasn't going to be doing all of the translations itself. Under the EMEA's so-called centralized procedure, an applicant company has to supply 11 language versions of the summary of product characteristics, as well as the labeling and package insert. And the national representatives

of the EU's 15 member states have to play a role in developing the translations of the scientific opinions that the EMEA reaches. Worst of all, even the translation that fell directly under the EMEA's responsibility could not be done in-house. It had to be sent off to the EU's translation center in Luxembourg that had also just been created as a consequence of the byzantine politics of European integration.

Within weeks of starting work, the EMEA was reporting that translations were not always reflecting the text adopted by its scientific committees, and that the texts received did not always reach sufficient quality standards for different reasons, be they orthographical, grammatical, legibility or general formatting. The mistakes were not only inelegant; they were slowing down the authorization process. This was a serious problem, since one of the principal motives for setting up the EMEA in the first place was to speed up drug registrations in Europe.

Looking for a solution

In response to the translation problems, the EMEA in June 1996 set up a working group on Quality Review of Documents (QRD). The group brought together some of the key bodies involved: the member states, the Luxembourg translation center, and the European Commission, which has to formally endorse the EMEA's opinions to give them legal effect. The QRD's main task was to ensure consistency and accuracy of translations of product literature. It is proving to be a long battle.

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So far, the QRD has created a series of product literature templates that set out the standard headings and indicate the most commonly used standard phrases and terms in all official EU languages. The templates also define the format and layout for the summary of product characteristics and for labeling and package inserts. In addition, a convention has been created in order to ensure absolute consistency between all language versions. The guidance is continually updated, based on the growing accumulation of experience.

Another of the roles of these templates is to provide guidance on the information to be supplied, through explanatory notes, which provide applicants with practical advice on how to draw up product literature. But the EMEA has to be very careful about this exercise. The politics of European drug registration decisions are already delicate enough, so this guidance is hedged with a forest of disclaimers that it is "without prejudice to any

final position of the EMEA” or the European Union institutions, or to “the binding nature of the relevant legislation.”

Applicants are firmly steered towards the formidable list of EU legislation and guidelines, which, in summary form, consist of a six-volume compendium entitled Rules Governing Medicinal Products in the European Union. This includes pharmaceutical legislation, a formal Notice to Applicants, guidelines on testing medicinal products with respect to quality, safety, the environment, information, and efficacy, as well as good manufacturing practices for medicinal products for human and veterinary use. There are also more than a dozen separate notes for guidance on everything from references to excipients in the label and package insert, through to the declaration of storage conditions or the compilation of QRD decisions on stylistic matters in product literature.

Even so, “the responsibility for the checking of mock-ups and specimens of packaging and patient information leaflets became a heavy task in 1997,” says the current annual report of the EMEA. One response has been to set up a series of workshops, internally and with the European pharmaceutical industry, to refine procedures dealing with linguistic matters and translations. And underneath the diplomatic neutrality of the annual report’s wording, only the faintest hint can be perceived of the seething indignation within the EMEA over being obliged to farm out much of its own work to an agency in Luxembourg over which it has no direct control.

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The problems between the EMEA and the Luxembourg center are not going to end quickly. Before the end of 1998, the European Union will have started substantive negotiations with candidate countries that could become full EU members by 2002, and bring with them five more languages: Polish, Hungarian, Czech, Estonian, and Slovenian. And right behind them in the queue to become EU member states are Slovakia, Lithuania, Latvia, Bulgaria and Romania. A European Union with 21 official languages is already in the making. The EMEA will need to burnish its templates until they glow to avoid becoming bogged down in the translation problems that an expanded EU will pose for drug registration.

Medical device requirements

Meanwhile, the world of medical devices is moving at a slightly gentler pace. The principal regulatory instrument in the European Union, Directive 93/42/EEC, is less demanding in its language requirements. It merely permits EU member states to require the use of their national language in product information. As a result, firms have been making their language choices largely on commercial grounds, related to the product type and the market in which they are selling.

Robin Hall, head of regulatory affairs at Howmedica/Pfizer in Ireland, says that once labels and manufacturer information have been agreed upon, in line with the EU rules and standards

governing this product sector, “We do most of our translations in-house, and then get them verified by a native speaker in the country we’re selling into, such as the head of marketing.”

However, even in medical devices the pressures are growing. Howmedica/Pfizer already automatically labels nearly all its products for the European market in English, French, German, Italian and Spanish. And when a country such as Portugal decides to require its local language, that has to be added. In the case of Portugal, Brazilian labeling will not be accepted, any more than France will accept French Canadian information.

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And increasingly, it seems, other countries are taking advantage of the provisions of 93/42/EEC directive to require local language use. These include the Scandinavians, despite the fact that the directive’s language provisions were a last-minute addition originally intended to be used only in exceptional cases for individual product or safety reasons.

But paradoxically, while regulatory pressures are tending to increase the scope of local language requirements, end-users often prefer to stick with what they know. Many German clinicians, for instance, are so used to dealing with U.S.-supplied devices with English-language information that they have been heard to express horror at the idea of a switch to the German language! Nonetheless the push towards more translation continues, both in the pharmaceutical and medical device sectors.

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The editorial staff of the *Medical Device Translation News* works with foreign correspondents, physicians, health and regulatory industry groups, and medical specialists around the world to bring you up-to-date regulatory information affecting European, Asian, and Latin American markets.

Upcoming issues will feature the most current country-specific language requirements under the Medical Device Directive and In Vitro Diagnostics Directive, country profiles, including barriers to entry, U.S. case studies involving successful implementation of labeling requirements, and reimbursement and pricing for medical devices in the EU.

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