EMEA Language Requirements - Pharmaceutical Labeling & Product Information

Package inserts, leaflets and labels present a particular challenge to the pharmaceutical industry, not only because they must be modified for each dosage and form of medication, but also because they must be provided in the native language of the ultimate consumer.

Product information must be created for each medication in each of its presentations, for each of its brand names, and in the native language of every country in which it is marketed. In Europe, where product information is typically translated into 20 languages, pharmaceutical companies may have to create and manage 900 different documents in support of a single medication. The costs associated with creating product information climb over the marketing life of the drug as new discoveries force multiple rounds of reviews and approvals. Just one change to the product or an amendment to the information regarding a drug can require the entire set of documentation to be updated and resubmitted for review.

The 25 current EU members use a total of 20 different languages. While the majority of these countries require translation into their national languages, the requirements often differ from country to country, depending on whether a self-test or professional-use device is involved (see Table I).

Country	Language Requirement	Notes
Austria	German	Requires use of national language.
Belgium	Dutch, French, or German	Any one of the above as required by the professional user and all three for patient use.
Cyprus	Greek, Turkish	Requires use of national language.
Czech Republic	Czech	Requires use of national language.
Denmark	Danish	Requires use of national language.
Estonia	Estonian	Requires use of national language.
Finland	Finnish, Swedish, or English	Information accompanying the device must be in Finnish, Swedish, or English, unless the information takes the form of generally known directions or warning symbols. Information intended for users or patients to ensure the safe use of the device must be in Finnish or Swedish.
France	French	Requires use of national language.
Germany	German	Other EU languages may be used for nonsafety data.
Greece	Greek	Requires use of national language for "instructions for use" documents. English is acceptable for labeling of professionally used devices and software.
Hungary	Hungarian	Requires use of national language.
Ireland	English	Requires use of national language.
Italy	Italian	Requires use of national language.
Latvia	Latvian	Requires use of national language.
Lithuanian	Lithuanian	Requires use of national language.
Luxembourg	French	English accepted for professional use; patient information in French and German.
Malta	Maltese	Requires use of national language.
Netherlands	Dutch	Patient information must be in Dutch. English may be negotiated for professional use.
Poland	Polish	Requires use of national language.
Portugal	Portuguese	Requires use of national language.
Slovakia	Slovak	Requires use of national language.
Slovenia	Slovenian	Requires use of national language.
Spain	Spanish	Requires use of national language.
Sweden	Swedish	Generally requires use of national language. English may be negotiated for professional use.
United Kingdom	English	Requires use of national language.