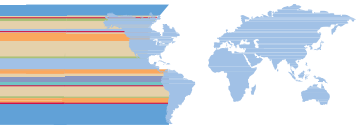


Pharmaceuticals and Devices in the EU: Their Languages & Their Regulations

Position Paper

Key Points

- **Expansion of the European Union means an extension of their diverse regulations to ten new markets.**
- **Many of the EU regulatory requirements include a language component that can often stall product acceptance and release.**
- **In-house coordination of these efforts can prove to be the bottleneck in product releases due to the lack of a coordinated, dedicated resource team.**
- **Working with a single global partner like L10N Technology can over- come this barrier and accelerate gains in market share.**

Overview:

On May 1, 2004, ten new countries joined the European Union bringing the total community to 25 nations. This momentous expansion, involving a population increase of 19%, means additional market opportunities for pharmaceutical firms, but reaching these new customers means communicating in more languages, through different channels, and tailoring your message and approach to the unique cultures and heritages of these countries and regions.

Compounding this is the fact that the expansion is occurring at a time when the EU is seeking to foster a more open and competitive drug market, fueling demand for increased advertising and direct-to-consumer (DTC) marketing. To offset the potential risks of this dynamic environment, the EU is simultaneously seeking to strengthen its control and influence over the content and communications practices employed by pharmaceutical manufacturers to reach and serve their customers.

So what exactly is covered by these regulations? What linguistic and cultural perspectives must you consider when creating and delivering your message? What, if anything, can be done to make this effort less taxing and speed your share gains in these markets?

Note:
This paper will provide you with an overview of the regulatory directives currently at work in the EU with an emphasis on the linguistic and cultural considerations that must be made when operating and selling in these markets. This document is not meant as a complete guide to these issues, and Bowne encourages you to contact and work with local counsels regarding regulatory applications, sales, and product distribution.

Overview of the Regulatory Environment:

In the EU, the laws and regulations are called Directives that are issued by the European Council. There are three Directives specifically relating to medical devices:

1. *Active Implantable Medical Devices Directive (AIMDD)*
   Council Directive 90/385/EEC covers energy sourced medical devices such as pacemakers, heart valves, etc

2. *Medical Devices Directive (MDD)*
   Council Directive 93/42/EEC covers all other medical devices that are not energy sourced implantable medical devices

3. *In-Vitro Diagnostic Directive (IVDD)*
   Council Directive 98/79/EC covers in vitro diagnostic products, such as blood test kits, glucose monitoring devices, diagnostic equipment, etc.

Each of the Directives mentioned above have similar regulatory requirements based on Essential Requirements. These requirements cover manufacture, quality control, test data, environmental conditions, sterilization, labeling, etc. that must be addressed and satisfied in order to comply with the specific Directive for a given product.

ISO Inspection - Each firm must be inspected by a Notified Body for compliance with ISO (International Standards Organization) quality systems standards.

Technical Files - The company must also prepare a Technical File for each product family containing specific technical information.

Device Classification - It is necessary to classify the company products to determine which conformity assessment process should be followed. The product will be Class I, Class II, Class IIb or Class III depending on the product claims and indications. Such classification is based on risk, with Class III as the highest risk classification category.

Conformity Assessment - Conformity Assessment is a self-determination by the firm of conformance of the product to a particular Directive. There are various conformity paths to satisfy a particular Directive. In most cases, the firm must certify that the product conforms to the Directive, usually signed by the RAQA head. There are various conformity paths for the Directives; refer to the appropriate Directive for the product.

CE Mark - After receiving a favorable inspection by a Notified Body, the product labeling may bear the CE mark. The use of the CE mark allows the product to be sold throughout the EU without obtaining approval from each Member State.

EU Authorized Representative - The firm must appoint an Authorized

Representative in the EU. This authorized representative is your company's agent in the EU and intercedes with your Notified Body and with each Competent Authority, when necessary. This appointed company also actively participates in reporting product complaints (Vigilance System) and any necessary products corrections or recalls.

In addition to these regulatory-oriented requirements, there are several consumer-oriented laws and directives, which is where we will focus the remainder of this paper as they are often the source of bottlenecks and frustration on the part of the manufacturer. These requirements are distinct from the others as their consumer orientation carries with it the additional need to be translated the content into the 20 "official" languages of the European Union.

Since 2001, the EU commission, with the G10-Medicines group, has focused on defining a number of European standards relative to the regulatory and competitive environment of the pharmaceutical industry. A central concern of this initiative is the question of availability, accuracy and legibility of drug information and the potential for such information to increase the active participation of patients in their own health and treatment options.

To that end, legibility of, and accessibility of patients to, drug information is considered a seminal requirement. Already, new rules on the presentation and order of information on in-box leaflets has been decided upon, and legibility tests are considered as a compulsory measure for drug information. The EU Commission has also clearly taken into consideration the increasingly important role played by the Internet as a medium for disseminating and accessing drug-related content, and has noted that significant issues exist with the quality, accuracy and reliability of some of this information currently available online. It has decided to provide an online public health portal framework that will provide the European public with health information, in partnership with the healthcare industry. It is also considering a label system for health information sites that would be validated for the reliability and relevance of the information provided.

Labeling - Revisions in product labeling will be necessary for your firm to market in the EU. Graphical symbols (EN980) are required on all product labels. Many firms have introduced multi-lingual labels based on priority markets. The CE mark must appear on the label along with the code number for the Notified Body in juxtaposition.

Directions for Use - The Consumers Protection law enacted by the EU Council requires that full directions (package insert) for use be provided to the user in local language. Most firms have therefore gone to a multi-lingual Directions for Use, including all country languages for all Member States. This practice not only satisfies the regulatory requirements but also supports specific liability concerns. The CE mark must appear on the Directions for Use with the notified body number and the name and address of the EU Authorized Representative.

Advertising - Directive 92/28/EEC, on advertising, distinguishes between medicines that are available over the counter, most of which may be advertised to the general public, and prescription-only ones, which may be advertised only to health professionals such as doctors and pharmacists. They may also prohibit such advertising where the product is eligible for reimbursement. The directive also lists a set of therapeutic indications that must not be mentioned in advertising to the general public. The monitoring of this advertising is modeled on that of the cross-industry directive concerning misleading advertising. Hence, self-regulation plays a major part.

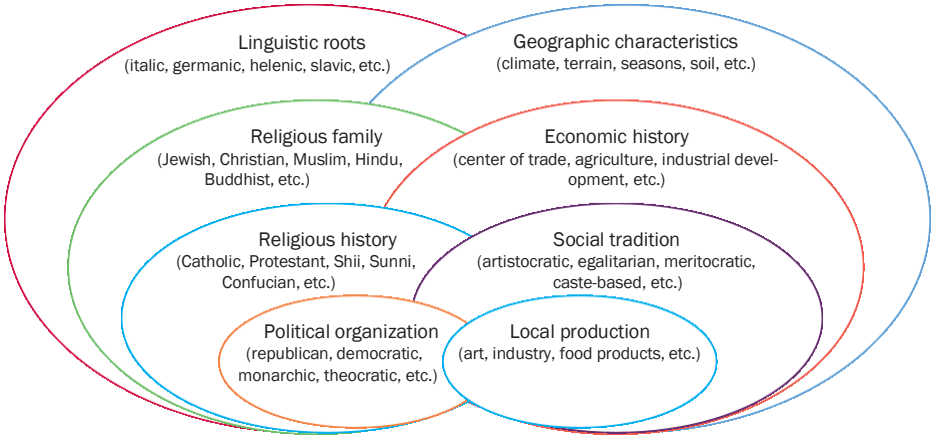
The Language and Cultural Considerations:

Whether mandated by regulatory requirements or expected by consumers, the success of your product in these markets will depend on the social acceptance of your brand and message by the consumers. Their ability to access and react to your message will depend on the language used and their response will be shaped by the culture with which they are affiliated.

There are, of course, cultural characteristics that can be identified, shared and leveraged in various regions of the world. Today the Western World shares many cultural characteristics across world regions and incorporates many that are considered valid differentiators between regions. Where there is a bonding, it is usually facilitated by a common history of political, economic and cultural development.

For example, the past several centuries of history, entertainment, consumer goods and other economic and cultural elements have created a cultural bond between Western Europe and Northern America. This common ground creates a layer of identity between these regions. But these affinities, however real, can hide other differences. Cultural identification is not monolithic, nor is it subject to clear-cut borders. Cultural affinity is defined on a sliding scale, from the general to the particular.

There are many factors that will influence the development of a culture in terms of customs, world view, values and so on. The sphere of influence of each individual



factor will not be superimposed over that of other factors. Each point on the globe is in a web of multiple influences, creating an infinite number of local dilutions of any cultural set, on any scale considered.

As a result, it is not possible to identify absolute and clear-cut borders of cultural areas that would lend themselves to complete description on a scale consistent with the requirement of a market. We must look for some workable compromise on which to base a segmentation of cultural areas for the purposes of doing business. Fortunately, the past few centuries have seen the emergence of the concept of nation-states, which eventually evolved into what we now refer to as countries.

Countries are very useful to global business, as they are based on some form of consensual understanding of the rules of society. This cultural consensus is embedded in the laws and regulations of the country. In countries that have been in existence for a long time, this framework has itself become part of the culture. So although a country does not exactly outline a monolithic cultural area, the cultural, linguistic and legal framework provided by such an entity makes it possible to target it as an area in which certain cultural rules can be relied upon as a common ground.

Language, in particular, is acknowledged as a key determinant of culture, and in some cases is quite closely identified with the area outlined by the borders of the country. However, it is important to bear in mind that this is by no means a general rule, and many countries have several living languages spoken by millions of people. For example, in Belgium there are two distinct communities, one French-based and the other Dutch-based, with very strong ties to France and the Netherlands respectively. A similar situation exists in Switzerland, where three distinct languages (German, French and Italian) and, therefore, communities coexist. Such countries require slightly more challenging approaches to cultural adaptation, and need to be considered in conjunction with the other countries that are host to some of the languages spoken.

So, as the essential medium through which ideas and culture are carried, language remains the first level of cultural affinity, but this rule is strongly balanced by the political, historical and economic context that has organized cultural groups along lines that are often distinct from the language influence.

Depending on the nature and subject matter of your content and the scope of your global project, there can be several situations: in some cases each country will need a distinct version of the content; in other cases one version of the content could cover several countries (appropriately translated, of course). There may also be a situation where a given language may appear in two or more distinct content versions. In this case, French (France, Belgium, Quebec, Switzerland, etc.), Spanish (Spain and multiple Central and South American countries), English (US, UK, Australia, New Zealand, Canada, etc.) are often the languages involved, even beyond the specific linguistic differences that exist between their various instances.

An Approach:

Cultures and languages are fluid concepts--they grow and evolve with their populations. So too do the EU regulations surrounding pharmaceuticals and medical devices. Ensuring your products and messaging remain current amid these shifts can often overwhelm your product teams, who may have traditionally relied on your in-country employees as a proxy for dedicated translation support.

L10N Technology, the world's leading medical translation company with more than 2,000 employees in 24 countries and 10,000 certified linguists operating worldwide (including all EU member states), offers comprehensive language service support. Whether it is through a central point of control or a distributed model working with your own in-country teams, Bowne can craft a custom approach to delivering high quality translations of your Directions for Use, Labels, Advertising and Promotional materials that conform to all EU regulatory guidelines pertaining to language.

LT would welcome the opportunity to explore the value our enterprise-class solutions can bring to your organization and would invite you to contact us for an initial discussion about your global objectives and how we might be able to help you achieve them.

To learn more, contact us at info@bowneglobal.com or find us on the web at www.bowneglobal.com.

About LT

L10N Technology (LT) is the leading provider of translation, localization, technical writing and interpretation services that enable businesses to deliver locally relevant and culturally connected products, services and communications anywhere in the world. Companies throughout the world use our solutions to help grow their businesses in the Americas, Europe, Asia and Latin America.

Our scalable end-to-end solutions can help accelerate a company's time to market while improving the quality and consistency of the company's products and services. Our wide range of clients include leading businesses in information technology, automotive, e-learning, life sciences, entertainment, telecommunications, aerospace and power and utilities industries.

To learn more, contact us at mcgcompany@naver.com or find us on the web at www.liontech.co.kr.