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EU directive has special ramifications for manufacturers of medical devices / Part one

The Medica conference in Düsseldorf, Germany, is the largest gathering of medical companies in Europe. The 2002 conference hosted some 3,000 exhibitors covering a floor space of 233,000 square meters. The exhibitors came from as far away as Australia, United States, Canada, South America and South Africa to rub shoulders with their European counterparts. It was a colossal affair and one that required any salesperson who visited to have had on his or her best walking shoes. It also behoved the salespeople to be ready for the unexpected question.

I was doing the rounds at the 2002 Medica conference imparting information about my company, Celer Pawlowsky, and explaining to anyone who would listen (or even wouldn't) how we specialized in translation for the medical-device industry. I was quite pleased with the way things were going. Most listened politely. Quite a few showed a lot of enthusiasm. Feeling buoyed, I approached one stand belonging to a large non-European-owned medical-device company. After introducing myself, I launched into my well-practiced spiel about what services my company offered, how we specialized in this area, what companies we were already working for and so on. I imparted a 30-second overview of Celer Pawlowsky in my best Business Development patter.

"And so," said I, finishing off, "we can translate your product into other languages, helping you to increase your market share."

I felt I had given a good presentation, and I stood back waiting for the usual questions about price and so forth — or to be told "go away." The representative on this stand, however, hit me with the question I least expected to hear.

"What," said he, looking puzzled, "do you mean by other languages?"

I waited vainly for the punch line, convinced his question was a lead-in to a joke. After a few

seconds — it seemed much longer — I realized it was a genuine question.

"Languages other than English," I replied sheepishly.

"Oh, those," replied the rep. "No, we don't need those."

I promptly withdrew from the fray, feeling as deflated as a balloon from last Christmas' office party.

Accepting that this was one dead horse beyond the use of flogging, I took myself off for a coffee and a chance to lick my wounds. It was only during this recuperative break that I realized I had missed the opportunity to educate this one representative on the looming deadline of the European Union (EU) IVD Directive (98/79/EC). This directive and deadline will oblige his company to recognize that there are languages out there other than English.

When going to Medica, I had assumed that everyone knew about the directive and its December 2003 deadline. In retrospect, it is clear that not every company is aware of it. I would suggest that this would be truer of non-European owned companies. In light of this experience, I have written this article to outline the implications of the IVD Directive (98/79/EC) — and two previously issued directives — and the impact they will have for anyone who wishes to sell medical devices into the European Economic area from December 7, 2003, and onward.

The IVD Directive (98/79/EC)

This 37-page long IVD Directive (IVDD) was promulgated on October 27, 1998, by the European Parliament. It came into effect at the beginning of 2000. It was the last of three directives covering medical industry regulations in Europe. The first was enacted in 1990 (90/385/EEC) and the second in 1993 (93/42/EEC). IVD stands for In Vitro Diagnostic medical device, the specific product area covered by this

directive. For the purpose of the directive the definition of an in vitro diagnostic medical device is a wide-sweeping and comprehensive one.

A short definition is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings (Article 1, 2a).

For full details on what is covered, refer to the Official Journal of the European Community 7.12.98.

While the IVDD was promulgated in 1998, companies were given five years to adapt the proposals. That five years runs out on December 7, 2003. So, what does that mean from a translation point of view?

One of the things the directive requires — in conjunction with the two previous directives — is the adoption by companies of a defined multilingual documentation process. This includes requiring a company to make provision for translating a company's product packaging, end-user instructions, labels and any other essential collateral documentation accompanying the product.

The European Commission issued translation guidelines in February 1998 (MEDDEV 2.5/5 Rev. 3) which state that as part of the quality system or of the documents defining the manufacturing process, the manufacturer should have procedures for ensuring accurate translation of [for example] labeling, instructions for use and product claims in marketing material. These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation.

In addition, the IVD Directive (98/79/EC) states: Member States may require the information to be supplied pursuant to Annex I, part B, section 8 to be in their official language(s) when a device reaches the final user. . . . Member States may authorize the information referred to in the first subparagraph to be in one or more other official Community language(s).

It also states: Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential user. . . . This information comprises the data on the label and the instructions for use.

Noted that while previous directives state that national languages may be required for this kind of information, most EU member states have now made it clear that this is now an absolute requirement. This fact, plus the need to meet the requirement to take in to account "the knowledge" of the potential user, would seem to make "accurate translation" an imperative.

The EU is not relying on the good will of medical-device companies to adopt the regulations by the 2003 deadline. The EU has a much more potent weapon in its armory to ensure compliance: the CE mark.

What Is the CE Mark?

The CE mark is a symbol that appears on all products in compliance with EU regulations. It is currently required for many products sold in the European Economic (EE) area (the 15 member states plus Iceland, Liechtenstein and Norway). If an EU product directive applies to a company's product, then CE marking is mandatory before that product can be sold in the EE area. The CE mark is analogous to a "passport" that allows manufacturers to freely distribute their products in the EE area. An estimated 50% of all goods shipped into Europe are impacted by the need to have a CE mark.

Manufacturers should also remember that the EU is in negotiation with 13 other countries that are seeking to become full members of the EU (Bulgaria, Hungary, Poland, Turkey, Cyprus, Latvia, Romania, Czech Republic, Lithuania, Slovak Republic, Estonia, Malta and Slovenia). Ten of these countries will be full members by June 2004, two others by 2007. Turkey may be two years later. The EE area will then cover an area occupied by 31 countries. It will pose a stern translation challenge for those seeking to distribute their products throughout this huge market.

For companies that manufacture medical devices — that is, those devices that fall under the wide ambit of the IVD Directive (98/79/EC) — adherence to the directive is mandatory for obtaining the CE mark. One of the things companies will have to do is to make their products available in the languages of the markets of the EE area. No compliance, no CE mark. *No CE mark, no European market!*