



MEDICAL DEVICE TRANSLATION NEWS

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Enlarged European Union Poses New Linguistic Challenges for Device Companies

By Jeanette Marchant—London, UK

On May 1, 2004, the accession of 10 new countries to the European Union will swell the EU's population by 75 million and add 9 new languages to the current 11 national languages used by today's 15 member states. Half of central Europe's national languages are Slavic in origin, whereas Latvian and Lithuanian have Baltic common roots. Hungarian has some similarities to Estonian, which is closely related to Finnish.

For medical device manufacturers that are just coming to grips with the language requirements of the existing European Union members, the potential trade opportunities in the enlarged European market could be limited by the need to add new languages to labels and instructions for use.

The region's major trading partners for medical devices are Germany (in terms of both imports and exports) and the US (for imports). Approximately 25% of medical devices imported into Poland are sourced from Germany, while the United States accounts for around 23%, followed by Japan (around 7%). Poland exports over 40% of medical device output to Germany, with Denmark accounting for the second largest share of almost 9%. Germany is Hungary's major trading partner for imports, accounting for around 25%, followed by the United States with a 16% share, while over 30% of Hungary's medical device exports go to the US, followed by Brazil which takes over 15%. The Czech Republic's major importers are Germany (over 27%) and the United States (20%), while over 40% of its exports go to Germany.

The three largest acceding countries – the Czech Republic, Hungary and Poland – consume around 63% of combined medical device sales in the 10 new European Union members.

Medical Technology Trade in New EU Markets (€millions)			
Country	Imports	Exports	Domestic Market
Cyprus	21	6	28
Czech Republic	284	153	363
Estonia	39	19	60
Hungary	190	100	270
Latvia	44	5	56
Lithuania	56	3	81
Malta	n/a	n/a	n/a
Poland	454	129	175
Slovakia	96	34	112
Slovenia	86	33	134
TOTAL	1270	482	1279

Source: Eucomed Industry Profile 2003

Per capita expenditure on medical devices is highest for the Czech Republic at €32.7 (2001 figures), compared with €26.6 for Hungary (2001) and €18.4 for Poland (2000).

The current language requirements of the 10 acceding countries are not expected to change from May 1, 2004, with the possible exception of Estonia which might accept other official European Union languages for professional users of medical devices. The following review provides a snapshot of the language requirements and other pertinent issues for medical technology in the new markets.

Cyprus:

All three medical device directives (MDDs) have been transposed into Cyprus law. Any official European Union language is acceptable to the Competent Authority except for self-diagnostic devices for which Greek must be used. Imports of CE-marked products have been encouraged and although there will be some devices which are not CE-marked on the market in May 2004, there is no deadline for their removal, according to Stelios Christofides of Cyprus' Competent Authority. Non CE-marked devices already imported to Cyprus will be permitted to be put into service after May 2004. Notification of IVDs will continue to be required after May.

Czech Republic:

The MDDs have been transposed and Czech will continue to be required from May 2004. Local authorised representatives have not been required since 2002. Notification will continued to be required for placing medical devices on the market.

Estonia:

Current legislation, which requires Estonian for lay users of devices but does not specify whether other official European Union's languages are accepted for professional users, will be replaced when the new Medical Device Act (transposing all the MDDs) enters into force in May 2004. At this stage it is unclear what will be the language requirements of the final legislation, which is still going through Parliament. According to the Competent Authority, provision of clear and understandable information to users is essential to avoid errors arising from misuse of devices. This may entail translation of manuals into Estonian.

Hungary:

Hungarian will continue to be required for instructions for use. Packaging labels may be in English. All products must be labeled by their smallest packaging unit of distribution, stating the producer. Manufacturers have been able to place CE-marked devices from the European Union on the Hungarian market without local certification since June 2001 and from non-European Union countries since November 2003, according to

Hungary's Notified Body, the Institute for Medical and Hospital Engineering, ORKI. Since April 2000, non-CE-marked devices have not been permitted to be distributed in Hungary.

Additional costs incurred by Hungarian companies in preparation for the legislative changes on European Union accession, including attendance at workshops and training sessions and language lessons, are said by the Hungarian medical device industry association, AMDM, to be between €800 and €1000 a month, and this will rapidly increase from May 2004.

Latvia:

While Latvian is generally required, English or German are accepted for professional use only. The language for software is optional. Local representation will be mandatory only for third-country manufacturers. Only third country and national manufacturers will be required to notify the Competent Authority when placing medical devices on the market after May 2004.

Lithuania:

All the relevant medical device directives have been transposed into Lithuanian law. Lithuanian will continue to be required, although software could be in English. No local authorised representative is required, although registration will be necessary to place devices on the market, for which the current fee is €15. During a transitional period from January 2004 until accession, medical devices which are not CE-marked will not be permitted to be placed on the market.

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Malta:

The three regulations transposing the MDDs have already entered into force. Either Maltese or English may be used. No local representative is required. Notification is required to place devices on the market although there is no fee. All products will need to be CE-marked from May 2004.

Poland:

Polish will remain the required language for medical devices and IVDs. All documents have to be in Polish and there is no exception for professional users. Poland has been granted an extension to December 2004 before having to fully comply with the medical device directives. Poland's new Office for Registration has been tackling the backlog of medical devices which were on the market before October 1, 2002, and which had to be re-registered. The deadline of October 2003 for re-registration was not met and the process has not yet been completed, according to local industry association, Polmed.

Current registration certificates will remain valid after May 2004. In the meantime, CE-marked devices can be exported to Poland although notification is required. Local authorised representatives will not be mandatory from May 2004.

The Medical Devices Act is scheduled for adoption in May 2004 which will help to simplify the notification process for manufacturers. The industry is lobbying for an improved fee structure to replace the current fee per individual product with charges only for each application form.

Country	Population (million)
Cyprus	0.8
Czech Republic	10.3
Estonia	1.4
Hungary	10.1
Latvia	2.4
Lithuania	3.5
Malta	0.4
Poland	38.2
Slovakia	5.4
Slovenia	2.0

Slovakia:

The MDDs have been transposed and general requirements for all products request Slovak, although Czech is accepted in practice. Some non-CE-marked devices are expected to remain on the market after May 2004.

Slovenia:

All the MDDs have been transposed. Slovenian is required for all medical devices (stickers are accepted) with the exception of instructions for use for professional use where English may be used. English is also accepted as an alternative to Slovenian for software. Only CE-marked devices can be placed on the market or put into service from May 2004.

The process of transposing the medical device directives into the local legislative framework can be difficult, according to Antonio Lacerda de Queiroz, head of the medical devices sector at the European Commission's Enterprise Directorate General. Speaking at Eucomed's Technical Forum in Brussels on October 30, 2003, he noted that the existing MDDs are relatively small but the guidelines are extensive. The Commission cannot interfere with the development of legislation unless individual countries request its help. He encouraged countries to enter into collaborations such as that forged between Poland and Spain, and between the Baltic republics and Nordic countries, in developing their regulatory infrastructure.

Several of the acceding countries have based their laws on the English version of the official MDDs, including Malta, Slovenia and Slovakia. It was noted at the Eucomed meeting that the translation of the directives was less important than their correct implementation.

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