



Mutual Recognition Agreement follows murky path

The Mutual Recognition Agreement (MRA) signed last year by the U.S. and the European Union signaled progress in the effort to harmonize medical product safety standards between the world's two biggest markets.

Before this lofty goal is reached, however, representatives on both sides of the Atlantic first must deal with substantial confusion surrounding regulatory requirements. In the short term, manufacturers will not reap many benefits during this stage of goodwill building, and it remains unclear exactly how each country's regulations will change as a result of the MRA.

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One Approval Body for all markets

The practical benefit of the MRA is enormous. It would harmonize U.S. and EU regulations in five designated industries, including medical devices, worth more than \$40 billion annually.

Sir Leon Brittan, Vice President of the European Commission notes that the agreement will "cut red tape, reduce costs and bring products for healthcare patients, information technology users and other consumers to market faster without compromising quality."

If adopted, the MRA would enable a U.S. medical device manufacturer to use a single organization to obtain regulatory product approval in the U.S. and the EU. This will dramatically impact the way manufacturers work with third-party Conformity Assessment Bodies (CABs) in the U.S. and Notified Bodies in the EU.

According to the medical device section of the MRA, a Notified Body can apply to be a CAB or third-party reviewer. A device manufacturer would work with the CAB to obtain regulatory approval in the U.S. and the EU.

Before such a simplified regulatory approval process becomes reality, however, many details must be hammered out. First and foremost, the FDA has to define the procedure for a Notified Body to become a CAB. At present, a Notified Body can apply for CAB status only after completing the FDA accreditation program for third-party reviewers. The FDA reports that it will publish CAB guidelines on its web site (www.fda.gov) in early July.

Competing regulatory environments

Contrary to popular opinion, the MRA does not align U.S. and EU regulations; rather it aims to harmonize standards between the two markets. In fact, the medical device MRA only addresses conformity assessment. This limitation means that U.S. and EU regulatory agencies can change requirements independently of each other, which could propagate more confusion.

France is a good case in point. French authorities are intent on requiring medical device manufacturers to inform the government of their intention to introduce high-risk medical devices three months in advance of a planned product launch. If enacted, this stipulation could be devastating to manufacturers.

In a letter encouraging the U.S. Senate to support Notified Body legislation, Donna Slingsluff of the Health Industry Manufacturers Association (HIMA) writes, "Unlike pharmaceuticals, medical devices have relatively short product lifetimes, therefore a three-month introduction is a significant reduction in a product's market life... The oppor-

tunity for a medical device manufacturer to recapture research and development costs is significantly reduced by a three-month delay."

Such examples point to the extreme difficulty in harmonizing regulatory environments to a level where a CAB is qualified to approve products for markets in all member countries.

Language requirements undefined

Another area affected by the lack of a uniform set of requirements is regulation of language translation requirements for medical device documentation, including manuals, inserts, packaging, and IFUs. Like the Medical Devices Directive (MDD), which spells out CE Mark requirements (*Medical Device Translation News*, May 1998), the MRA does not specifically address language requirements.

A source at the FDA commented on foreign language requirements not yet directly addressed in MRA guideline, "EU Notified Bodies will be required to submit 510(k) and pre-market evaluation reports in English."

The same holds for U.S. CABs. A U.S. manufacturer who wishes to sell in Germany, for example, can work with a local CAB with an office in Germany. The assumption is that the CAB affiliate office will translate pertinent information into German for submission to local regulatory authorities.

According to Eric Water, manager of Technology International's European Medical Devices Compliance Division, U.S. manufacturers should ask the following questions regarding translation decisions:

- Does the member country require its own language on product documentation?
- Who will use the product, e.g., a nurse with little knowledge of medical English or an English speaking physician?
- Who is responsible for maintaining the product?

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The most basic consideration is safety and health. If a user is injured or inflicts harm on a patient as a result of misunderstanding the English instructions, the manufacturer may be held liable.

The issue of language translation has yet to be addressed by the FDA. Historically, language has not been a topic of relevance. Today it demands attention, both as a result of market convergence, highlighted by the MRA, and, to a certain extent, due to the growing number of non-English-speaking consumers in the U.S.

The fact that the FDA must address language concerns is but one sign that the road to mutual recognition, though difficult, is firmly embarked upon, despite the myriad of details which must be spelled out and the threat of additional member country regulations. The FDA and EU member country governing authorities remain committed to standards harmonization.

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