



National differences undermine effort to unify European regulations

France singled out as most defiant Member State

By Peter O'Donnell—Brussels, Belgium

How far has Europe gone in becoming a single market for medical devices? “Half the way, with three quarters still to go,” as an Irish industry executive remarked the other day. No one who follows European markets pretends that it is as bad as it was ten years ago. But by the same token, no one believes it is close to offering the completely homogeneous market that European Union officials in Brussels like to claim it is becoming.

“There has been a major step [forward] with the directive harmonizing requirements,” says Jean-Marie Vlassembrouk, head of industry affairs in the Brussels office of Baxter World Trade. “But the problem now is implementation.” His caution catches a mood that is easily detectable among medical device manufacturers across Europe. The European Union has imposed legislation to level out the playing field, but there are still plenty of obstacles impeding the players.

For many companies trying to get their products onto the European market, there is a sense of frustration. After arguing for years over the form that the EU's Medical Devices Directive (MDD) should take, and making some difficult concessions and accepting a number of tough compromises along the way, the grim reality that industry executives now face is that each of the 15 member states is choosing to apply the so-called single market legislation in its own way. This consequently undermines the concept that the hard-fought legislation was intended to bring into life.

“It's not exactly cherry-picking,” a German industry leader who didn't want to be named told *Medical Device Translation News*. “But each member state is choosing to apply the new rules in the way that suits them.” More courteous European industry executives attribute the idiosyncrasies to misunderstandings and insufficient knowledge of the MDD. But for the less reserved, the aberrations amount to crude protectionism.

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In fact, Europe is as split on authorization of medical devices as it once was on drugs. Regulatory standards in northern European countries — preeminently the U.K., Scandinavia, the Netherlands, and Germany — are respected for their rigor, while

the southern states of Spain, Portugal, Italy, Greece, and even France, are perceived as warmly welcoming to their own national products, but capriciously conservative about foreign imports. As a result, the third-party certification system established by EU rules to boost the chances of free circulation for medical devices has all but fallen apart. “Countries simply do not have enough confidence in one another's assessment skills,” says Baxter's Vlassembrouk.

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The finger of blame is pointed most consistently at France, which has developed a reputation for devoting so much attention to consumer protection that the fundamental European Union concept of free circulation of products is not embraced. It is an open secret that France is flouting EU law by systematically demanding a review by French regulatory authorities for every new non-French product on the market. Of course, France claims its reticence about new foreign products is based on health protection. But companies trying to launch products in France see it more as a question of protectionism than a question of health.

The hostility so widely perceived within the European medical devices industry towards recalcitrant governments, especially France, is fueled not only by questionable scientific decisions, but also by what manufacturers believe to be flagrant breaches of the equitable treatment that a single market is supposed to offer all products. “Reimbursement practice also differs widely,” says Vlassembrouk. Yet again France serves as the primary example. In the summer of 1998, while senior French industry figures were on their traditional four-week August break, the French government took the industry by surprise, with the announcement of a 5% cut for all active implantable devices, including such equipment as heart valves.

Formulating a response

No one in the European medical devices industry knows quite how to respond to these apparent breaches of the single market ideal. The informal consensus is that it is largely a matter of waiting for regulatory authorities to unlearn entrenched habits. In the meantime industry pressure has been brought to bear on the most flagrant abuses. One of the first concrete results of this

new level of determination is the recent decision by the European Commission — the European Union's administrative body that ensures compliance with legislation — to take France to the European Court of Justice.

Pushed by European companies, and by some sympathetic governments who find their own exports to France blocked, the Commission has sent a formal warning to the French government. It cites "unjustified restrictions on imports into France of 'in vitro' diagnostic medical devices legally manufactured and/or sold in other Member States" — i.e., the French law that requires all medical devices to be registered with the French pharmaceutical agency before they can be marketed in France. The Commission also objects to the French requirement for package labeling to carry a French registration number, and to the French failure to provide mutual recognition for conformity tests carried out in other EU countries.

The Commission says the French registration procedures may be justified for diagnostic medical devices to test for the AIDS and hepatitis viruses, but certainly not for all diagnostic medical devices. And specific labeling requirements for the French market are costly for economic operators and cannot be justified on consumer protection grounds. The Commission will withdraw the court action if France backs down on these issues.

France, however, remains hotly defensive of its position. According to Charles Descours, the French senator responsible for a new Senate report on controls for healthcare products: "Manufacturers can cut the risk to the minimum. But the state itself must carry out the risk-benefit assessment." And he insists that the French rules on medical devices need to be applied "even more rigorously." The HIV-contaminated blood saga in France continues to present the spectacle of former French health ministers fighting off criminal convictions in French courts of law, ten years after the scandal broke. It has bred a form of paranoia in French government circles, and French secretary of state for health Bernard Kouchner presented new measures to fight hospital infections just last September with a set of guidelines on how to disinfect medical devices.

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France not the only offender

But it is not just France that creates problems. For Jim Wormout, who handles international marketing at Mallinckrodt, the latest complication to what he describes as a "mixed situation" in Europe is recent action by Spanish health authorities. Spain has decided to go its own way on the high-risk products classified as Class III under the new EU rules. The Spanish health ministry is insisting that all such products obtain special registration in Spain before they are put on the market. But, as Wormout points out, his firm's products are already fully compliant with the EU rules that are supposed to allow market access across all 15 EU member states without any further formalities.

The German Association of Medical Device Industry (BVMed) has sharply criticized some member states for insisting on national marking for medical devices in addition to the certification provided for by the directive — the CE Mark. "The CE Mark signifies comprehensive safety, efficiency, and thus quality of the products. Therefore, additional marks on medical devices bearing CE marking are unnecessary," says BVMed General Director Joachim M. Schmitt.

Countries simply do not have enough confidence in one another's assessment skills

There is also a major problem for medical device companies with the transitional arrangements now that the MDD is in force. Conservative estimates are that \$250 million worth of medical products already in the distribution chain do not bear the certification mark, but satisfy the new rules in every other respect. The European Commission has issued guidelines urging member states to allow this inventory onto the market during a grace period up to 2003. But as Eucomed, the European industry association says, the value of Commission guidance "will still depend upon the willingness of national authorities to follow its spirit." And there is evidence of member state resistance: Italy, for instance, is refusing to apply the guidelines for Mallinckrodt products, notes Wormout.

As long as this kind of opposition continues, firms are still obliged to keep close contacts with the diverse markets in the EU if they want to get their products onto the market. Rob Schipper, executive director of the Netherlands foreign investment agency, recently advised U.S. biomedical and medical device companies to establish a European presence: "Companies can accelerate product commercialization, shorten clinical trials and gain rapid product approvals," he said. His advice is a clear indication of the fact that a single European market is still a long way away for medical devices.

January Issue: Focus on Brazil

The January issue of *Medical Device Translation News* will focus on recent developments in the Brazilian medical device marketplace.

Recent reports suggest that Brazil, the eighth largest economy in the world, is experiencing a dramatic decrease in medical device imports from the United States, due largely to increased import tariffs. Nonetheless, the Brazilian market remains strategic for U.S. medical device manufacturers, as evidenced by an 11% increase in U.S. device exports to Brazil in 1997.

Our January issue will focus on the most recent developments, including the tariff increase, to help U.S. manufacturers export their products successfully to Brazil.

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