



PROBING THE EUROPEAN IN VITRO DIAGNOSTICS RULES

By Peter O'Donnell—Brussels, Belgium

There are just over twelve months to go before another major change hits the European devices market. As of June 2000, it will be possible to place in vitro diagnostic products anywhere on the 18 markets of the European Economic Area (EEA) provided they bear a recognized distinguishing mark of conformity. The new European Union (EU) directive on in vitro diagnostic medical devices, adopted at the end of 1998, will break down national market barriers across the 15 EU member states, and in the three countries that have joined it in the EEA (Norway, Iceland, and Liechtenstein).

Viewed in a positive light, the new EU rules will replace costly individual national regulations with consistent Europe-wide regulation. And the expectation in Brussels, where the measure has been discussed over the last four years, is that competitive forces and demand from hospitals will drive manufacturers to use the new approach at the earliest opportunity.

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This new approach to harmonization goes some way to ensuring easier market access for IVD devices. But its operation—which presumes that any product manufactured in accordance with harmonized standards conforms to certain essential requirements, and can therefore be marketed throughout the EU—is likely to raise almost as many questions as it answers.

The June 2000 date “is concentrating the minds of IVD product manufacturers, or at least it should be,” says John Place, Director of the European Diagnostic Manufacturers Association (EDMA). But the concentration is not just born of impatient enthusiasm. Preparations are not yet complete, and there is a tight timeline that regulatory authorities and manufacturers must meet if the new opportunity is to fulfill expectations. By December 7 this year, national laws must incorporate the provisions of the directive. But so far, few of the 15 member states have made progress with draft legislation, much less with completed statutes.

The directive's special provisions for high-risk products demand development of common technical specifications—specific requirements that have to be agreed upon by all national authorities. At present, it is still an optimistic assumption that they will be agreed upon by the end of 1999.

Even that will leave manufacturers only six months to comply—“a bare minimum,” says EDMA.

A database accessible to the national authorities will have to be up and running by the time the directive comes into force. Unless data on registration of IVD manufacturers and products, certification, and vigilance procedures are in place by June 2000, manufacturers will be obliged to send a notification to each member state authority on each product marketed. But discussions are still continuing over the form of this future European Regulatory Database, known as EUDAMED, and what sort of classification it will use—and once that decision is finally made, national authorities will still have to make working registration software available for device manufacturers.

Arguments continue with some national authorities over the risk inherent in the IVD products regulated by the Directive, with some of the so-called “Notified Bodies” created by the directive believing that certain IVD products can be dangerous per se, and that only strict control of them can avoid serious outcomes. Manufacturers have been insisting that their products are safe and reliable, and that the major mistakes of the past, such as HIV scandals, were a result of poor decisions on the use of existing products. But the battle has still to be won.

Not for the first time, France is at the center of some of these discussions, and its propensity to impose blocking regulations on IVD imports have already run into criticism from the EU authorities even before the IVD directive comes into effect. In June 1998 the EU's executive body, the European Commission, issued a formal warning to France about what it called “unjustified restrictions on imports into France of ‘in vitro’

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diagnostic medical devices legally manufactured and/or sold in other member states.” French legislation requires all such medical devices to be registered with the French medicines agency before they can be marketed in France. Moreover, the legislation imposes a series of labeling requirements, including an obligation to indicate the registration number obtained in France on each package. While the Commission was prepared to accept that such a registration procedure could be justified for certain types of diagnostic medical devices such as those used to

test for the AIDS and hepatitis viruses, it said there was no justification for applying it to all diagnostic medical devices. The Commission added that the specific labeling requirements for the French market, which are costly for companies, could not be justified on consumer protection grounds. The case is still unresolved, and European device executives are watching it closely, both because of the importance of the French market and because it is a touchstone of wider EU regulatory issues.

Some of the biggest unanswered questions over the implementation of the impending directive concern language requirements. The directive imposes obligations on the labeling of products for professional use, largely—believe manufacturers—because of national prestige political considerations that influence EU rules just as much as do technical considerations. What concerns manufacturers is that the text of the IVD directive allows EU member states to require information supplied with a product to be in local languages when the product reaches the final user. It fears that as member states transpose the directive into national law, they will be all too ready to impose mandatory use of local languages—which will mean that companies will be required to put up packs in the eleven different official languages of the EU if they want to take advantage of the market access potential of the new law.

Manufacturers are determined to do everything they can to resist any imposition of national language requirements—particularly mandatory use of local languages. They believe changes are unnecessary, because the costs of preparation, translation and separate packaging will make products more expensive, without any real benefit to health care. And on legal grounds, there are likely to be challenges about how far the EU is justified in imposing—and member states are justified in enforcing—national language requirements in a single market designed to promote cross-border trading.

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The industry argument on language use is essentially that there is no evidence that the current language regime for labeling and giving instructions for IVD products creates a problem for professional users of these products, or that it is a threat to the health of patients. Already it is common practice for manufacturers to produce one form of product for sale throughout the EEA, and to label it in the major European languages (English, French, German and possibly Spanish and Italian); instructions for use are usually also in a similar limited number of languages, with occasional further languages included in special cases.

European manufacturers say there is no need to tighten this regime, as the new directive threatens to do. Manufacturers accept that all products designed for non-professional uses should be labeled and include instructions for use in the official language(s) of the country of sale. However, they believe that this requirement is excessive, pointing out that professional

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users in Europe are accustomed to English. Indeed most professional and technical literature is available only in English.

Since member states have not yet produced their national legislation—and have not decided how far to avail themselves of the option they enjoy under the directive to impose local language use—it is still too early to say what the outcome will be. But within the European device market, the working assumption at present is that a form of compromise is possible: member states will require national language(s) in principle, but manufacturers will be able to seek exemptions for certain products, particularly sophisticated high-technology products used by limited numbers of specialized laboratories; or small volumes of reagents supplied in small vials (as the primary container) and in small boxes (as the secondary container), so that the lack of space on the labels makes it physically impossible for manufacturers to give text in multiple languages.

In practice this would mean that companies wishing to market products in smaller countries would have to ask for exemption from local language requirements. Where exemption was not granted, the company might choose not to sell directly in the local country market and rely instead on imports by specific professional users. In such cases, manufacturers run the risk that clinical laboratories will not be allowed to import products that do not fulfill local language requirements.

Six months after the directive was formally adopted, and just over a year before it comes into effect, company planning is difficult, because most of the elements in the new rules that are likely to impede marketing are still in the hands of the national authorities. Individual company preparation is largely precluded by external events: manufacturer's energies are currently being employed more in industry-wide lobbying of national authorities to avert over-restrictive exploitation of the scope offered by the directive.

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