

**MEDICAL DEVICE REGULATION
IN THE EUROPEAN UNION**

**Linda R. Horton
Director, International Policy
U.S. Food and Drug Administration**

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by Linda R. Horton¹

The challenge to a government in establishing a system of controls over medical devices is to protect patients but without unduly impeding innovation or driving up product costs.

Medical devices are, essentially, health care products other than pharmaceuticals.² Medical devices comprise a diverse array of products ranging from simple items like bandages and bedpans to complex products like pacemakers and other implants. Accordingly, the level of control needed to protect patients can range from minimal, for low-risk products, to a more protective level, for those high risk products that need testing and third-party review before entering general use.

¹ The views expressed in this paper are those of the author and not necessarily those of the U.S. Food and Drug Administration, where the author serves as Director, International Policy.

² Article I(2.)(a) of the EU Medical Devices Directive defines "medical device" as "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 for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." This definition is quite similar to that in U.S. law (21 U.S.C. 321(h)).

The European Union's system of medical device regulation has involved the application of the "New Approach" directives to a category of products that, in a number of EU Member States as well as in the U.S. and other developed countries, have been handled in an "Old Approach" way as part of traditional control systems, i.e., emphasizing harmonization through detailed regulations and oversight carried out by Member States' ministries.

Under the Old Approach, exemplified by food control, the 1960s and 1970s saw a brisk pace of Community harmonizing legislation. At the same time, Member States continued to issue disparate forms of national legislation even in areas being harmonized. Then the 1979 Cassis de Dijon decision³ of the European Court of Justice laid the groundwork for a more preemptive form of Community

³ Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein, Case 120/78 [1979] ECR 649. Rewe wished to import from France, into Germany, Cassis de Dijon Liqueur, with its normal alcohol content of 15-20%. The beverage met French law. However, German law forbade marketing of spirits with an alcohol content of less than 32%. Rewe sued Germany in the German national court, which referred the case to the European Court of Justice. In considering the German government's claim that its rules were necessary in view of public health and consumer protection requirements, the Court interpreted the Treaty as including a "rule of reason" :

[O]bstacles to movement within the Community resulting from disparities between the national laws relating to the marketing of the products in question must be accepted in so far as those provisions may be recognized as being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defense of the consumer.

The Court held that because the German requirements exceeded what was necessary to meet goals that are, without question, legitimate, they infringed the principle of proportionality: a national measure may not restrict trade among member states more than what is necessary to achieve its legitimate objective.

legislation for goods. Other cases interpreting Articles 30⁴ and 36⁵ of the Treaty of Rome followed, e.g., a 1987 decision striking down the hallowed German beer law on grounds that consumer protection could be attained by less restrictive means.⁶ These and other decisions brought home to Otto, the ordinary citizen, that European Community laws actually have an effect on everyday life.⁷ Furthermore, they stimulated a new regulatory philosophy.

Community institutions concluded that it was no longer necessary to seek complete uniformity of regulatory standards in order to guarantee the free

⁴ "Quantitative restrictions on imports and all measures having equivalent effect shall ... be prohibited between Member States." European Economic Community (EEC) Treaty.

⁵ "The provisions of articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of ... public policy or public security; the protection of health and life of humans, animals or plants; ...or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however [be] a means of arbitrary discrimination or a disguised restriction on trade between Member States." EEC Treaty.

⁶ Commission v. Germany, Case 178/84 [1987] ECR 1227. The German law, dating from 1516, said that beverages sold in Germany could be called "beer" only if manufactured solely from malted barley, hops, yeast, and water. Additives were disallowed in beer even if approved for other beverages. In holding that Germany could not bar entry of beer legally manufactured and sold in other Member States, the Court suggested that legitimate consumer protection goals could be met by (1) an ingredient labeling requirement (so consumers wanting beer with only the four ingredients can identify it) and (2) banning unsafe additives.

⁷ Marcus Puder, *European Union Law I*, Georgetown University Law Center, September 1994.

movement of goods,⁸ even in areas that are traditionally and pervasively regulated, considering that several leading cases involved a highly regulated product, alcoholic beverages. Once a product is legally marketed in one Member State, and it meets essential requirements, it would be able to circulate freely within the Community, even if it does not entirely fulfill all applicable standards in another Member State. Community lawmaking could, then, focus on harmonizing the essential requirements to assure that they meet the intended purposes but do not create technical barriers to trade.⁹ In effect, these rulings compelled mutual recognition among European Member States when traded products meet community directives, and the directives became a type of mutual recognition agreement.¹⁰

Tying this new thinking to the Community's push in the mid-80s to complete by 1992 the common market for movement of goods-- and aided by the Single European Act's substitution of the qualified majority for unanimity in much European Council lawmaking on goods--the New Approach was conceived as a way to impose uniformity. Harmonization would be achieved through essential requirements that are both **general** and **mandatory**, complemented by European

⁸ The Enforcement of European Community Law: A Study Prepared for the Health Industry Manufacturers Association 18, January 1990.

⁹ E.Jongen, European Commission, The creation of an internal market for industrial goods in Europe through technical harmonization, standardization, certification and mutual recognition, January 1991.

¹⁰ Statement by Jacques MacMillan, European Commission, at U.S.-EU negotiations on Mutual Recognition Agreements, April 1995.

standards that are both **detailed** and **voluntary**.¹¹

Launched in 1985 by a European Council resolution and a European Commission White Paper on Completing the Internal Market,¹² the New Approach is noteworthy in its call for government/private sector partnerships to carry out functions that traditionally or elsewhere, e.g., in the U.S., had been thought of as government roles. First, European private sector standards bodies were called upon to develop product standards,¹³ with this activity partially subsidized by the European Commission and Member State governments with respect to topics identified as priorities. A company whose product meets such standards would be deemed to satisfy the essential requirements of the applicable directive. Second,

¹¹ European Commission, **GUIDE TO THE IMPLEMENTATION OF COMMUNITY HARMONIZATION DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH**, Brussels, Luxembourg, 1994.

¹² COM(85)310 final; Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (85/c/136/01).

¹³ European Commission Communication on the development of European Standardisation - Action for faster technological integration in Europe (90/C 20/01) (Green Paper on Standardisation); Commission Communication - Standardisation in the European Economy (Follow-up to the Commission Green Paper of 8 October 1990) (92/C96/02); Council Resolution of 18 June 1992 on the role of European standardisation in the European economy. Recommendations included more support from industry, direct funding, more experts for standards work, methods to speed up the standards process, immediate application of adopted standards, and a European Standardization System including a Council, a Board, and various bodies, to work with national standardization bodies such as the British Standards Institute, the German DIN, the French AFNOR, etc.

in the important area of conformity assessment,¹⁴ i.e., product testing and audits of firms' quality control systems, Member States were directed to devise systems for granting recognition to private sector testing laboratories (analogous to Underwriters Laboratory in the U.S.) and to private quality auditors, to enable these bodies to carry out certain testing or auditing functions under specified directives.¹⁵

This reliance on private sector entities for quasi-governmental functions was not itself driven by the Cassis de Dijon case but was a policy choice pressed by the Commission. Why was this the route taken, rather than one that relied more on conventional Community harmonization through Commission-led committees?

First, there was great frustration in the slow progress of past efforts to harmonize, efforts that never kept pace with actions by Member State parliaments and ministries to add new and disparate requirements.¹⁶

¹⁴ The essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers. Council Decision of 13 December 1993 (90/683/EEC).

¹⁵ Council Resolution of 21 December 1989; Council Decision of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives (90/683/EEC). The Commission has prepared what it calls a general vade mecum explaining common concepts of the New Approach directives in different sectors (covering, for example, harmonized standards, notified bodies, CE-marking, and the transitional period)

¹⁶ If the Commission announces a plan to propose a directive to eliminate barriers to trade, it can invoke a standstill period that bars introduction of national measures in the field in question while the European standard is being drawn up.

Second, public-sector resources both in Brussels and in national capitals were insufficient to meet the needs.

Third, many of the areas covered by the New Approach involve nonregulated areas that in the Member States were handled not by ministries but by national private sector standards, e.g., on electricity or building materials. Despite the nonlegislative character of these standards, many had acquired commercial status (by mention in contracts) or even juridical status (by mention in local ordinances) and thus had the potential of creating disharmony within the Community if a mechanism were not found to achieve harmonized, EU-wide, voluntary technical standards.

Fourth, rapid changes in industrial technology, worldwide emphasis on quality, and the development of the general international quality systems standards of the ISO-9000 series had a profound impact on the private sector. Among other things, an array of techniques and procedures had been developed for the assessment of conformity, leading to a widespread belief that proof of conformity can be provided by more than one means -- hence, the Council's 1985 New Approach.

Finally, the technological pace and private-sector embrace of quality systems had influenced relationships between public authorities and

E. Jongen, The creation of an internal market for industrial goods in Europe through technical harmonization, standardization, certification and mutual recognition, January 1991. Much of the information in the paragraph in the accompanying text is derived from Mr. Jongen's paper.

manufacturers, at the very time that many European countries were privatizing national services and institutes.

The outcome of all of these trends was a re-orientation to a policy of flexibility and deregulation. One feature of this policy was to circumscribe the ability of public authorities to impede marketing of products from other Member States by permitting the execution of third party tasks by private bodies. Thus, the New Approach offered a way for Community institutions to remove standard-writing and market access decisions from national ministries (some of which were viewed by business or Community officials as parochial, nationalistic, and nontransparent) and to place these decisions with private-sector bodies that were felt to be more objective, transparent, and accountable to Community-wide commercial interests. While national governments could retain accreditation schemes for notified bodies, the criteria would be transparent and consistent, and products certified by other Member States' bodies would not be barred entry.¹⁷

The selection of medical devices as a candidate for New Approach Directives¹⁸

¹⁷ European Commission, Notified Bodies, DOC.CERTIF. 91/7 rev 3.

¹⁸ Others include simple pressure vessels (87/404/EEC, 90/488/EEC), toys (88/378/EEC), construction products (89/106/EEC), electromagnetic compatibility (83/336/EEC, 92/31/EEC), machinery (89/392/EEC, 91/368/EEC, 93/44/EEC), personal protective equipment (89/686/EEC, 93/95/EEC), non-automatic weighing instruments (90/384/EEC), appliances burning gaseous fuels (90/396/EEC), telecommunications terminal equipment (91/263/EEC), certain hot water boilers (92/42/EEC), certain electrical equipment (73/23/EEC), explosives (93/15/EEC), and protective systems for explosive atmospheres (94/9/ECC). See Council Directive of 22 July 1993 (93/68/EEC).

is surprising, for several reasons. First, why was not the approach chosen more like that for the other health product category, pharmaceuticals? After all, the dominant regulatory approach for pharmaceuticals has traditionally, in the U.S., Europe, and all developed countries, been governmental approval and inspection.¹⁹ At least for certain high-risk medical devices, this traditional approach was already being carried over into device law, in both the U.S.²⁰ and, at the outset of European medical device regulation, by the UK and other Member States.

Like EU device regulation, EU drug regulation includes harmonized directives, committees of experts to coordinate work, "mixed competency," and "subsidiarity," i.e., Member State enforcement. However, in contrast to EU devices, EU drugs need government approvals by either Member State ministries or (increasingly) by a new EU institution--the European Medicines Evaluation Agency--that came into being in London on January 1, 1995. The EMEA will approve certain drugs centrally and will coordinate Member States' approvals, to facilitate mutual recognition of national approvals and thus eliminate duplicative approval requirements. A Community program for harmonizing Member State health ministries' drug testing guidelines led in 1989 to an activity of the EU, U.S.,

¹⁹ The U.S. system requires each drug manufacturer to submit an application for FDA approval that contains full reports of safety and effectiveness. 21 U.S.C. 355. This system dates back to 1938, and vaccines and other biological products require an FDA license under an even older (1902) law. 42 U.S.C.262. Similar systems prevailed in the UK, Germany, France, and other European countries at the time the EU embarked on harmonization efforts for pharmaceuticals.

²⁰ 21 U.S.C. 360e.

and Japan known as "ICH." (ICH is the International Conference for the Harmonisation of the Technical Requirements for the Registration of Pharmaceuticals for Human Use.)

Furthermore, it is unclear that medical devices truly meet the criteria laid out in the Council's resolution creating the New Approach, in that devices meet neither the criterion that the product category be sufficiently homogeneous to allow common "essential requirements" to be defined²¹ nor the criterion that it be genuinely possible to distinguish between essential requirements and manufacturing specifications so as to keep to a minimum the number of essential requirements.²² The very complexity of the directives on medical devices, as discussed below, shows the challenge that the EU has faced in applying the New Approach to devices.

Apparently, the European Commission viewed medical devices as more like an "industrial product" than a pharmaceutical. While both devices and pharmaceuticals were assigned to the Directorate General for Industry (DG III), devices were administratively assigned to the program that also was responsible

²¹ "One of the main purposes of the new approach is to make it possible to settle at a stroke, with the adoption of a single Directive, all the problems concerning regulations for a very large number of products, without the need for frequent amendments or adaptations to that Directive. Consequently in the selected areas there should be a wide range of products sufficiently homogeneous to allow common 'essential requirements' to be defined. ..." Council Resolution of 7 May 1985 (85/C 136/01).

²² *Id.*

for pressure boilers and industrial machinery. Thus, the Community's first directive in the medical device area²³ related to general industrial policy.

The announced purpose of the European medical device program was "to put an end to the fragmentation of the existing [European] market, to the inconsistency of national regulations, to the duplication or multiplication of certification."²⁴ The syringe is an example of the legal inconsistencies in the EU at the time work began on the medical device directives. In some Member States syringes were regulated as drugs, in another a medical device law governed them if sold as sterile, and in others they were subject to no regulations at all. With respect to conformity assessment, in certain Member States (e.g., Germany, Spain, and France) a form of product certification known as type testing was a prerequisite for placing on the market certain devices, particularly ones with electrical aspects, while quality systems were certified for supply to the UK public health services, although this was not a legal requirement.²⁵ One country had laws for contact lenses but not for the implantable intraocular lenses used to

²³ Council Directive 84/529, effective September 1986, adopting CENELEC HD 395-1.

²⁴ *Id.* at 4. The Anselmann speech is the source of the information on Member State device laws. Norbert Anselmann, European Commission, THE FORTHCOMING EC LEGISLATION ON MEDICAL DEVICES: PROVISIONAL RESULTS AND OUTLOOK, 5-6, presented to the Regulatory Affairs Professionals Society conference on International Harmonization of Medical Device Regulation, June 22-23, 1992.

²⁵ Robert G. Britain, National Electrical Manufacturers Association, Coping With International Issues: An Industry Approach, December 1990.

replace natural lenses after cataract removal. Another regulated wheelchairs but not anaesthesia equipment.

The three European Union medical device directives that will bring harmony to these differences are now at various stages:

- o **Directive 90/385/EEC on Active Implantable Medical Devices²⁶**
 - Published 20 July 1990;
 - Date of first application, 1 January 1993;
 - End of transitional period, 31 December 1994.

- o **Directive 93/42/EEC on Medical Devices**
 - Published 12 July 1993;
 - Date of first application, 1 January 1995;
 - End of transitional period, June 1998.²⁷

- o **Proposal for a European Parliament and Council Directive on in vitro diagnostic medical devices²⁸**
 - Published 7 July 1995.

²⁶ Examples of active implantable medical devices are an implantable pulse generator for a pacemaker and an implantable drug administration device. European Commission Working Document, Guidelines Relating to the Application of [the two Council Directives on Medical Devices], 4 November 1994.

²⁷ During the transitional period, national regulations continue except that optional application of the EU directive is permitted. After the expiration of the transitional period, application of the harmonized regime becomes mandatory, and member states may not continue disparate regulatory systems.

²⁸ 95/C 172/02, 7 July, 1995, Official Journal of the European Communities No. C 172/21. An in vitro diagnostic is a medical device which is a reagent, reagent product, kit, instrument, apparatus, or system, intended by the manufacturer to be used in vitro solely or principally for the examination of substances derived from the human body for the purpose of providing information relevant to the detection, diagnosis, or treatment of a patient's physical state.

Except where otherwise stated, this paper focuses on the Medical Devices Directive,²⁹ as it is the most comprehensive of the three.

The philosophy of the New Approach as it relates to medical devices has been described as based on three pillars:

- [1.] The Community legislator will confine himself to the "essential requirements"...which must be met...
- [2.] The European standards bodies ... will ensure that further technical expression of the legal requirements is given via harmonized European standards. These standards may be respected by manufacturers on a voluntary basis. Conformity with [them] has an advantage: competent authorities shall presume compliance with the pertinent legal requirements themselves.
- [3.] The Directives finally define...the conformity assessment procedures [by which] the manufacturer, if necessary together with a certification body, establishes whether the design and manufacture of his devices meet the legal requirements.³⁰

²⁹ The legal procedure for its adoption was the cooperation procedure in Article 100a of the EEC Treaty.

³⁰ Norbert Anselmann, Principal Administrator, European Commission, THE FORTHCOMING EC LEGISLATION ON MEDICAL DEVICES: PROVISIONAL RESULTS AND OUTLOOK, 5-6, presented to the Regulatory Affairs Professionals Society conference on International Harmonization of Medical Device Regulation, June 22-23, 1992. In 1991, before embarking on its harmonization program, the Commission described the situation as follows:

...there are considerable differences between the Member States as regards both the technical design and production requirements and the administrative procedures for the examination, testing, inspection and authorization for marketing, and the putting into service and after-sales surveillance of medical devices. ...A large number of specific laws cover certain groups of products such as electro-medical equipment, disposable products, equipment for the disabled, sterile products, and even specific products. ...

European Commission Proposal for a Council Directive concerning medical devices, 23 August 1991.

The central obligations of the Medical Device Directive are found in Articles 2 and 3.³¹ Article 2 requires that,

Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.

Article 3 requires devices to "meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned." Annex I elaborates on both general requirements and requirements as to design and construction (e.g., chemical, physical, and biological properties; infection and microbial contamination; construction and environmental properties; measuring functions; protection against radiation; and energy sources).³²

When a Member States' "competent authority" has so recognized a testing or auditing body, that authority must then "notify" the Commission and other Member States of this recognition--hence, the term "notified bodies."

Once the conformity of a medical device has been established in accordance with the applicable directives, whether by a manufacturer's self-declaration of conformity when that is all that is required, or by means of a third party approval by a private-sector certification body when that is required,³³ then that conformity

³¹ Council Directive 93/42/EEC of 14 June 1993 (93/169).

³² *Id.*

³³ In a Decision dated 13 December 1990, the Council laid out eight typical conformity assessment procedures for use in New Approach directives (90/380 EEC). A 22 July 1993 Council Decision provided details on the modules for the

is valid throughout the entire Community. The proof of eligibility for this free movement is the affixation to the product of a CE mark to the product. The CE mark serves as a technical passport for the product through the Community.³⁴

Administration. As may be seen from the above discussion, the EU regulatory scheme for medical devices does not contemplate a single regulatory body with nationwide scope along the lines of the U.S. Food and Drug Administration (FDA), but rather a multifaceted system with roles for the European Commission, private standards organizations, the 15 Member States' competent authorities, and the notified bodies (private or public) those authorities designate to carry out conformity assessment functions. Thus, approval decisions are highly decentralized, as they are made by notified bodies, and enforcement is likewise highly decentralized as it is to be done by the Member States (with or without help by notified bodies).³⁵

The Commission's tasks are to:

- o watch over correct transposition,
- o take measures in cases of non-transposition or incorrect transposition,
- o monitor and follow the transposition process,
- o elaborate on directives through explanatory documents,

various phases of the conformity assessment procedures and the rules for affixing the CE mark (93/220 EEC). See also European Commission, Guide to the Implementation of Community Harmonization Directives Based on the New Approach and the Global Approach, first edition, Luxembourg, 1994.

³⁴ Council Decision of 22 July 1993.

³⁵ Norbert Anselmann, Principal Administrator, European Commission, The Forthcoming EC Directives on Medical Devices, 14 November 1991.

- o facilitate communication within the Community by a system of committees with Member State representatives,
- o oversee a system of medical device vigilance, and
- o provide infrastructure for notified bodies.

The Commission portrays the breakdown of tasks between notified bodies and national authorities as follows:

	Notified Bodies³⁶	National(Competent) Authorities³⁷
Intervention Relates to	Premarket Stage	-Implementation -Enforcement -Postmarket Stage
Tasks	Conformity Assessment: -Quality Assurance Systems -EC Type Examination -Statistical Verification	-Surveillance of the Market -Vigilance -Decisions on classification -Clinical Investigations
Decision is Valid Within:	-European Union -European Economic Area	Territory of the Member State

Manufacturers have a free choice to select a notified body within the European Economic Area so long as it has been deemed technically competent, by a national authority, for the required tasks. In the contractual arrangements between the manufacturer and the notified body, the parties agree on the time

³⁶ Articles 11, 12 Medical Devices Directive.

³⁷ Articles 2,8,9,10,11,12,13,14,16, Medical Devices Directive.

limits for completion of verification operations and of the assessment.³⁸

It is noteworthy that a notified body has responsibilities of a "public" nature, such as the granting, denial, or withdrawal of certificates, the ability to request more information if needed, the authority to make unannounced visits to view quality assurance if needed, and the supplying of information directly to competent authorities despite contractual relationships with manufacturers.

Classification. Fundamental to the regulation of medical devices in the EU, as in the U.S. and other developed countries, is the use of a classification scheme to determine the level of control over a device. It would be unrealistic and uneconomical to apply the highest level of control possible to all devices. The EU classification system considers the extent of human vulnerability to a device, with criteria concerning the time of uninterrupted contact of the device with the body as well as the degree of invasiveness. Special considerations govern contraceptives and devices that are combined with drugs.

The classification system is meant as a practical tool for assigning the device to the correct conformity assessment procedure reflecting the device's risk:

- o Class I devices, the most innocuous, enter the marketplace with only a manufacturer's self-declaration of conformity.³⁹
- o Class IIa devices are subject to production quality system control registration by a third-party body.

³⁸ Article 16(4), Medical Devices Directive.

³⁹ Special provisions govern Class I devices that have additional attributes, such as sterility or a measurement function.

- o Class IIb and III devices are subject to quality system control for both production and design.
- o Furthermore, Class III devices which are critical devices, as a general rule, undergo a clinical evaluation under the responsibility of the manufacturer, and the conformity of the device's design must be separately considered by a notified body before the device is placed on the market.⁴⁰

All devices need clinical data, not just class III device.⁴¹ Thus, while the EU device classification system nominally has three classes of devices as in the U.S.

system,⁴² the EU's Class II is divided into IIa and IIb with different requirements for

⁴⁰ European Commission, Proposal for a Council Directive concerning medical devices, 4, COM(91) 287 final SYN 353, 23 August 1991. A manufacturer of a Class III device avoids repetition of the same clinical investigations in more than one member state. *Id.* at 14.

⁴¹ John Hartley, British Standards Institute, personal communication to author, June 23, 1995.

⁴² In the U.S., **Class I** consists of devices for which general controls, applicable to devices generally, are deemed to be adequate. 21 U.S.C. 360c(a)(1)(A). General controls include authority to act against adulterated or misbranded devices, banning, registration and device listing, premarket notification (unless exempted), reporting, and compliance with good manufacturing practices. (General controls apply to devices in all three classes.) **Class II** devices are those needing some form of special controls such as performance standards, postmarket surveillance, patient registries, guidelines (including guidelines on clinical data to be submitted in premarket notifications), recommendations and other appropriate actions as FDA deems necessary (e.g., adherence to voluntary standards). 21 U.S.C. 360c (a)(1)(B). **Class III** devices are those for which premarket approval is required due to both the inadequacy of general and special controls for that device and the need for the device's safety and effectiveness to be demonstrated through testing; there is a presumption that a device belongs in class III if it is purported to be for a use in supporting or sustaining life or presents a potential unreasonable risk, 21 U.S.C. 360c(a)(1)(C), or if it is new technology not substantially equivalent to previously marketed devices, 21 U.S.C. 351(f). Due to a grace period for pre-1976 class III devices (and post-1976 substantially equivalent devices) that ends only when FDA by rule calls for Premarket Approval Applications (PMAs) for such

each, so that the EU in essence has four classes.

The EU classification system calls upon the manufacturer to preliminarily classify its devices prior to embarking on a conformity assessment procedure.⁴³ If the notified body disagrees with the classification and the matter cannot be resolved, it must be referred to the competent authority of the Member State in whose territory the issue arises, and the Commission may become involved to ensure consistency.⁴⁴

The Commission has issued a guideline to assist manufacturers, competent authorities and notified bodies in ascertaining the appropriate classification of devices.⁴⁵

Registration. Registration is required only for EU manufacturers of class I devices and, custom-made devices, and for imported devices;⁴⁶ registration is with the competent authority in the Member State where the manufacturer or importer

devices, 21 U.S.C. 360e(b), the U.S. marketplace includes devices that FDA has previously identified as needing comprehensive approval but that have never undergone such approval. The agency still needs to either call for PMAs for these devices or reclassify them, a process that Congress through deadlines in the 1990 Safe Medical Devices Act (21 U.S.C. 360e(i)) has pressed FDA to complete.

⁴³ Mika Reinikainen, ABSTRACT, CLASSIFICATION OF MEDICAL DEVICES, presented at Regulatory Affairs Professional Society conference on International Harmonization of Medical Device Regulation, 22-23 June 1992, Washington, D.C.

⁴⁴ Article 13, Medical Devices Directive.

⁴⁵ Commission of the European Communities, Guidelines to the Classification of Medical Devices, 3rd Draft (Status: 1994-01-21).

⁴⁶ Article 14, Medical Devices Directive.

has its registered office. The European Commission is establishing parameters for a common data base to collect information on manufacturer registrations.⁴⁷

Standards. The Medical Device Directive recognizes two European standards organizations, CEN⁴⁸ and CENELEC,⁴⁹ as the competent bodies for the creation of harmonized standards in accordance with a 1983 Directive⁵⁰ and a 1984 agreement between these bodies and the Commission.⁵¹ The standards are voluntary, and all parties concerned (manufacturers, users, certification bodies, public authorities, and health care professionals) participate in their elaboration. Notwithstanding their voluntary character, the EU Medical Devices Directive offers a powerful incentive for manufacturers to comply with these standards. It provides that Member States shall presume compliance with the essential

⁴⁷ The database will also include information on decisions (by notified bodies) that allow devices on the market and (by competent authorities) that take devices off the market. Norbert Anselmann, Principal Administrator, EC Commission, The Forthcoming EC Directives on Medical Devices, November 14, 1991.

⁴⁸ CEN is the European Committee for Standardization, the world's largest regional standards group. It promotes the harmonization of European regional technical standards for non-electrical industrial products. Its membership comprises the national standards bodies of the EU (e.g., Germany's DIN, UK's British Standards Institute, and France's AFNOR).

⁴⁹ CENELEC is the European Committee for Electrotechnical Standardization, which promotes harmonization of European regional standards in the electrotechnical field.

⁵⁰ Council Directive 83/189/EEC of 28 March 1983 lays down a procedure for the provision of information in the field of technical standards and regulations.

⁵¹ Vienna guidelines on cooperation, 13 November 1984. For specific devices, e.g. sutures, European Pharmacopeia monographs may be considered equal to harmonized standards. See preamble to Medical Devices Directive, 169/2.

requirements where a device meets a relevant national standard adopted pursuant to the harmonized standards the references to which have been published in the Official Journal of the European Communities.⁵² If an EU standard does not exist, the manufacturer (or the notified body) can apply another suitable standard or guideline.⁵³ If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements, there is a procedure⁵⁴ for that Member State to bring the matter to the attention of the Commission for reference to a standing Committee on Standards and Technical Regulations for advice on what steps to take, e.g., to work in CEN or CENELEC to strengthen the standard, to substitute a Directive, or to allow Member States to act.

Clinical investigations. The Medical Devices Directive includes requirements for clinical investigations of medical devices in human subjects.⁵⁵ It also forbids Member States from creating any obstacle to devices intended for clinical investigation being made available for that purpose if they meet the required conditions.⁵⁶

After the declaration of the opinion of an Ethics Committee has been given,

⁵² Article 5, Medical Devices Directive.

⁵³ Id.

⁵⁴ Articles 5(3), 6(2) Medical Devices Directive.

⁵⁵ Article 15 and Annex VIII, Medical Devices Directive. Special requirements for custom-made devices are also prescribed in the Directive.

⁵⁶ Article 4(4), Medical Devices Directive.

and at least 60 days before an investigation begins, the sponsor is required to notify it to the competent authorities⁵⁷ in those Member States where the clinical investigation will be performed. In the case of a Class III device or an implantable and long-term invasive Class IIa or Class IIb device, the manufacturer must await passage of the 60 days before beginning the investigation. Clinical investigations must be performed according to EN 540, the European Standard for Clinical Investigations (sometimes called Good Clinical Practices, or GCPs).⁵⁸ Also, the International Standards Organization (ISO) is developing a clinical practice standard for clinical investigation of medical and dental materials and devices. There is a high degree of similarity between the European requirements, draft ISO standards, and the U.S. Investigational Device Exemption (IDE) regulations.⁵⁹ Underlying all of these documents on good clinical research practice is the Declaration of Helsinki and its subsequent amendments,⁶⁰ which are the accepted basis for the ethics of

⁵⁷ In France a similar requirement (the 1990 Huriet law) was implemented in 1990. As of February 1995, only the UK had issued guidelines implementing clinical trials requirements pursuant to the EU Medical Devices Directive. Alan Kent, GUEST INTERVIEW, THE CURRENT AND FUTURE ROLE OF THE UK MDA, 2, and Malcolm Carlisle, CLINICAL INVESTIGATION DEVICES IN THE EC, 6-11, both in The Regulatory Affairs Journal (Devices), February 1995.

⁵⁸ Peter Duijst and Odile Gaffori, Implications of the European Harmonization for Clinical Investigation With Medical Devices, 3-4, presented to the Regulatory Affairs Professional Society conference on International Harmonization of Medical Device Regulation, June 22-23, 1992, Washington, D.C.

⁵⁹ 21 U.S.C. 360j(g); CFR Part 812.

⁶⁰ The Helsinki Declaration was adopted by the 18th World Medical Assembly in Helsinki, Finland. in 1964 and was last amended by the 41st World Medical Assembly in Hong Kong in 1989. Annex X(2.2) to the Medical Devices Directive

clinical investigations, i.e.,

- o Strict confidentiality by all parties,
- o All agreements recorded in writing and signed by relevant parties,
- o Qualified professionals to carry out their tasks,
- o Suspension or termination of the investigation in cases of real or potential risks to subject,
- o The data collected verify that the device is suitable for the population for which intended.

Quality systems. As noted above, many medical devices (class IIa, IIb, and III) must be manufactured in accordance with quality systems requirements and these systems must be certified by an independent third party, i.e., a notified body. The standards governing these requirements are EN 46000, which adopts the ISO-9000 series of the International Organization for Standardisation. The ISO-9000 standards for quality system state very general standards for quality systems. EN 46000 is written specifically for the medical device industry.

Audits of quality systems; inspections. It is the responsibility of the quality system certification body to perform audits of manufacturers' quality systems as part of the initial certification process and as proof of continuing conformity. Notified bodies' audits will largely supplant the traditional regulatory inspections that have been carried out by the health ministries in the Member States.

However, the oversight roles of these competent authorities for the notified bodies will likely entail an investigative or adjudicative role between notified bodies and

states that, "It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki declaration [including] every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results."

manufacturers.⁶¹

Vigilance system. With such a decentralized system, and one in which crucial premarket product entry decisions are made by private bodies, an effective system is essential to collect, analyze, and share information on incidents from the day-to-day use of medical devices, so that all players in the EU medical device system, particularly the Member State competent authorities, can take actions as needed to protect the public. Hence, Article 10 of the Medical Devices Directive mandates creation of a Medical Devices Vigilance System. Incidents requiring reporting are those leading to death; serious deterioration in the health of the patient, user or other person; life-threatening illness or injury; permanent damage; or a condition necessitating medical or surgical intervention. Each Member State must transpose legislation that orders manufacturers to report certain adverse incidents to the competent authority in the country of occurrence.⁶² As is discussed below, some Member States require users (hospitals or physicians) to report, as well. Article 10 of the Directive requires a Member State to share information on an incident with the Commission and other Member States only

⁶¹ Alan Kent, Chief Executive of the UK Medical Devices Agency (MDA), GUEST INTERVIEW, THE CURRENT AND FUTURE ROLE OF THE UK MDA, 1, Regulatory Affairs Journal (Devices), February 1995. Concern was expressed about the potential loss of expertise gained by MDA due to discontinuance of its inspections of manufacturers, once part of the manufacturer registration scheme for National Health Service-eligible devices.

⁶² This country may be different than the country in which the notified body initially authorized the device--or the device may be from a "third country" such as the U.S.

after its competent authority, in conjunction with the manufacturer, has completed its investigation to ascertain whether the device was a cause of the incident.

Many EU nations (including Austria, Belgium, Denmark, Finland, France, and Sweden) require user reporting, in addition to manufacturer reporting, of adverse events. In the UK, user reporting is voluntary but encouraged, as the Medical Devices Agency conducts thorough follow-up on all incidents reported.

Manufacturers face mandatory reporting of serious incidents, which are reported to the Commission. Similarly, in Ireland reporting is mandatory for manufacturers but voluntary for users. Greece and Portugal plan similar systems. Use in Spain of a decentralized approach to device vigilance has been questioned by the Commission, and similar questions could be raised about Germany's reliance on 16 lander authorities.⁶³

Although the EU vigilance system is similar to the U.S. Medical Device Experience reporting system⁶⁴ with respect to the types of incidents to be reported, it is quite different with respect to confidentiality. The U.S. Freedom of Information Act (FOIA) requires FDA to disclose the MDR reports on marketed medical devices, purged of identifying information on the patient and physician.⁶⁵

⁶³ 5 Europe Drug & Device Report No. 9 at 3-4, May 1, 1995.

⁶⁴ 21 CFR Part 803.

⁶⁵ Counterpart reports on experience with investigational medical devices in the U.S. are less likely to be discloseable, even after deletion of patient and physician identifiers, because of the confidential-commercial-information status that U.S. law confers on the existence and content of applications on investigational products. 21 CFR Parts 20, 812.

In the EU, even purged reports are treated as confidential. Furthermore, in the EU, but not in the U.S., the risk of economic harm to a manufacturer as a consequence of a disclosure of adverse information about its product is seen as grounds to withhold such reports from the public--and perhaps even from counterpart regulatory authorities such as the U.S. FDA.⁶⁶ Although there is a public health element to this concern in that both Member States and industry believe that reporting compliance will be higher if the adverse incident report itself, not just personal identifiers, are assured confidential treatment,⁶⁷ efforts at international cooperation are impeded when governmental regulatory authorities cannot collaborate to identify joint safety concerns due to corporate secrecy interests. A recent FDA proposed rule⁶⁸ assures other countries that information provided to FDA in confidence will remain confidential as the information will remain the other country's document not a "record" under FOIA. The availability

⁶⁶ [A]ccess to [medical device vigilance] data has to be defined in accordance with the directives and certainly in full respect of the confidentiality clause. ... in the Community there is no legislation like the Freedom of Information Act. The availability of regulatory data will, therefore, be much more restrictive in comparison with the situation in the United States.

Norbert Anselmann, European Commission, The Forthcoming EC Directives on Medical Devices, 14 November 1991.

⁶⁷ Confidentiality Vital to Device Regulatory Base, 4 Europe Drug & Device Report No. 18, pp. 6-7, 19 September 1994. "Device makers fear the economic consequences of having delicate data fall into the wrong hands and point out that a company's share prices could drop if adverse incidents were publicized prematurely [even to the Commission and other member states]." *Id.*

⁶⁸ Public Information; Information Sharing With State and Foreign Officials, 60 FR 5530, 27 January 1995.

of this assurance in the realm of medical device reporting may help more the EU toward sharing with FDA information it collects under the vigilance system.

Labeling. The Medical Devices Directives establishes general rules as to the elements of labeling and information that must be provided to a professional or lay person.⁶⁹ The responsibility rests on the manufacturer to determine the intended users of the product and the appropriate information to be provided. EU Member States are allowed to require that such information be made available to the user and the patient in their national language or another Community language.⁷⁰ It is expected that most Member States will apply this linguistic requirement to all elements of labeling and information, including package labeling, product marking (such as display screens), instructions for use, warning statements, and all information whether for lay or professional use as determined by the manufacturer. Some flexibility may be offered, particularly by the Nordic countries. For example, in Denmark, information intended for a patient must be in Danish, while information intended for professional users can be in English.⁷¹ More flexibility may be demonstrated for display screens, with some Member States being prepared to accept a different language (e.g., English) from the national language if screen messages are clearly explained in the accompanying

⁶⁹ Annex I, point 13, Medical Devices Directive.

⁷⁰ Article 4(4), Medical Devices Directive.

⁷¹ Caroline Freeman, Consultant, A SINGLE MARKET BUT NOT A SINGLE LANGUAGE, 5, The Regulatory Affairs Journal (Devices), February 1995.

literature.⁷²

Safeguard clause. Where a Member State ascertains that devices otherwise eligible for free marketing may compromise the health or safety of patients, users, or other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market.⁷³ Such a decision must be notified to the Commission and other Member States, whereupon the Commission reviews whether the interim measures are justified. If they are, the Commission initiates a process intended to result in steps by each Member State to take uniform action concerning the product. If the Commission finds the measures unjustified, it informs the Member State and manufacturer (and presumably can bring an infringement action against a Member State that retains the interim measures).

Issues in Implementation.

Delays in Transposition and Incomplete Transposition. In the 30-month transitional period for the Active Implantable Medical Device Directive, no country was able to fully implement this legislation by its first application on January 1, 1993. The UK came close, while Germany found a way to sidestep transposition and apply the Directive directly. Germany was the only country to make timely

⁷² *Id.*

⁷³ Article 8, Medical Devices Directive.

designations of notified bodies. France got as far as preparing a decree to establish a notified body within its health ministry to perform conformity assessment procedures.⁷⁴

Similarly, not all Member States have transposed the newer and more comprehensive Medical Devices Directive into their national law. For example, the failure of the Italian government to transpose the directives has left Italian manufacturers subject to a non-harmonized approval system that the industry characterizes as a bureaucratic maze of 45 steps.⁷⁵ Delays are compounded by a requirement for a manufacturer to submit sample products, accompanied by packaging and labeling exactly as intended for marketing. These requirements force a manufacturer to complete a manufacturing system for just a few control products. More importantly, the lack of a national law transposing the directive means that Italian manufacturers have difficulty shipping their devices elsewhere in the Community because Italian law bars export of an unapproved device unless it meets Community law, and there is no transposed EU law in Italy with which to comply.

It is important to note that, following general rules of Community law, a Member State cannot prevent the free circulation of medical devices in compliance with the relevant directive, whether the Member State has transposed the directive

⁷⁴ PJB Publications, Clinica 533, p. 7, 6 January 1993.

⁷⁵ *Id.* at 3.

or not.⁷⁶

Additional Regulatory Requirements. Member States continue to add requirements that go beyond European directives, such as a recent French demand for premarket approval of heart valves⁷⁷ and a Spanish registration requirement that Commission officials argue violates Article 30 of the Treaty of Rome and represents a barrier to trade.

The lack of a comprehensive registration requirement in the Medical Devices Directive is an incentive to disharmony. Although Member States are allowed to require manufacturers to provide a single notification that their products are on the market, presumably after notified body approval, Member States may not use such a requirement as a way to interpose an approval⁷⁸ requirement. Registration is allowed only for class I devices, custom-made devices, and imports. The UK, Finland, the Netherlands, and Sweden want all who assemble or sterilize devices to register. Spain plans a registry of manufacturers of high-risk devices, while Italy wants to require some form of registration that includes an authenticated copy of the compliance certificate. Furthermore, Italy plans to ask firms to submit technical dossiers "off the record," claiming it is for manufacturers' own protection that they do so notwithstanding the Directives' assignment of dossier

⁷⁶ Norbert Anselmann, European Commission, Directive implementation heads European agenda, in PJB Publications, *Clinica Review* 585, at 6, 10 January 1994.

⁷⁷ PJB Publications, Ltd., *Clinica*, April 10, 1995.

⁷⁸ 5 Europe Drug & Device Report No. 3, at 6, February 6, 1995.

review to notified bodies.⁷⁹

France recently shelved its controversial plan for a device notification scheme that would have included submission of technical documentation to the health ministry. However, France, supported by Belgium, Italy and Luxembourg, is not backing down on its ban on the sale in France of CE-marked condoms that do not meet French standards. There is as yet no harmonized European standard for condoms due to dissension among CEN members on a draft European condom standard as to the necessity for batch testing.⁸⁰ The Commission, Austria, Germany, Spain, and the UK believe the draft European standard to be adequate, and the Commission is bringing an infringement action against France in the European Court of Justice to press for acceptance of CE-marked condoms.

Health Care Requirements. There is the potential for conflict between the goals of the internal market in goods--a competency of the EU institutions--the prerogatives of Member States under their health care systems, an area not within the competency of the EU.⁸¹ This issue has caused the Commission to warn the UK Medical Devices Agency (MDA) that it is skating on thin ice with its

⁷⁹ 5 Europe Drug & Device Report No. 8, at 2, April 17, 1995.

⁸⁰ 5 Europe Drug & Device Report No.8, at 3, April 17, 1995.

⁸¹ The preamble to the Medical Device Directive states that "the harmonized provisions [of the Directive] must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the abovementioned measures provided Community law is complied with ...[emphasis added]. 12 July 1993 (93/L169/1).

Manufacturers Registration Scheme (MRS) for devices purchased by UK health care entities.⁸² The issue is whether, during the transitional period for the Medical Devices Directive, a Member State may require or encourage an evaluation of a device by the health care procurement or reimbursement agency, over and above what was done to secure a CE mark and the right to market in the EU.⁸³

To defuse the issue, MDA has told hospital purchasers to treat equally devices from firms signed up under MRS and devices that are CE-marked to show compliance with the EU Directive. At the same time, MDA says it remains committed to MRS until the Directive becomes compulsory in June 1998. MDA also is being selective about the notified bodies in other countries to which it will grant mutual recognition, a likely bone of contention with the Commission. Certainly, after the effective date of the Directive, the UK will have no choice but to accept CE-marked products.

⁸² 5 Europe Drug & Device Report No. 8, at 3-4, April 17, 1995; and No.9, at 6, May 1, 1995.

⁸³ Alan Kent, the Chief Executive of the UK Medical Devices Agency (MDA), had stated that the British National Health Service will continue to perform a user evaluation of CE-Marked products for purchasing. GUEST INTERVIEW, THE CURRENT AND FUTURE ROLE OF THE UK MDA, 1, The Regulatory Affairs Journal (Devices), February 1995:

That is a quite independent service meant to provide independent information on the performance of the product in laboratory and user settings to the purchaser, and to some extent the state of compliance. Just because it is CE marked, it doesn't mean that people aren't still going to want to make choices between CE Marked products, and between CE Marked and non-CE Marked products. The MDA therefore believes there is still a role for those reports.

Conclusion. The EU's decision to apply a New Approach to medical device regulation involves many challenges.

Experience alone will tell if the choices made were the right ones. Other countries, including the U.S., will have a strong interest in the results of this intriguing experiment.