

Medical Device Regulation in the European Union

LINDA R. HORTON *

I. INTRODUCTION

The challenge to a government that is establishing a system of controls over medical devices is to protect patients without unduly impeding innovation or driving up product costs. Medical devices are health care products other than pharmaceuticals,¹ and 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 higher protection level, for those high risk products that need testing and third-party review before entering general use.

The European Union's (EU's) system of medical device regulation has involved the application of "new approach" directives to a category of products that, in a number of EU Member States as well as in the United States and other developed countries, have been handled in an "old approach" manner as part of traditional control systems, that is, by 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 harmonizing legislation in the EU, then called the European Economic Community. At the same time, Member States continued to issue disparate forms of national legislation even in areas being harmonized. In 1979, however, the European Court of Justice laid the groundwork for a more preemptive form of Community legislation for goods with the *Cassis de Dijon* decision.² Other cases interpreting articles 30³

* Ms. Horton is Director, International Policy Staff, Food and Drug Administration. The views expressed in this article are those of the author and not necessarily those of the U.S. Food and Drug Administration.

¹ 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.

Council Directive 93/42/EEC, art. I(2)(a), 1993 O.J. (L 169) 1.

This definition is quite similar to that in U.S. law. See 21 U.S.C. § 321(h) (1988).

² Case 120/78, *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein*, 1979-2 E.C.R. 649 (1979). *Rewe* wished to import from France into Germany, *Cassis de Dijon Liqueur*, with its normal alcohol content of 15% to 20%. The beverage met French standards. German law, however, 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:"

In the absence of common rules, obstacles 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

and 36⁴ of the Treaty of Rome followed, such as, a 1987 decision striking down the German beer law on grounds that consumer protection could be attained by less restrictive means.⁵ These and other decisions brought home to the ordinary citizen that Community laws actually had an effect on everyday life.⁶ 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 movement of goods,⁷ even in areas that were traditionally and pervasively regulated, such as cases involving alcoholic beverages.⁸ Once a product was legally marketed in one Member State, and met essential requirements, it would be able to circulate freely within the Community, even if it did not fulfill all applicable standards in another Member State. Community lawmaking, then, could focus on harmonizing the essential requirements to ensure they met the intended purposes, but did not create technical barriers to trade.⁹ In effect, these rulings compelled mutual recognition among European Member States when traded products met 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-1980s to complete the common market for movement of goods by 1992 — and aided by the Single European Act's¹¹ 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 standards that are both *detailed* and *voluntary*.¹²

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.

Id. at 662. The Court held that because the German requirements exceeded what was necessary to meet goals that were 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.

³ "Quantitative restrictions on imports and all measures having equivalent effect shall . . . be prohibited between Member States." TREATY ESTABLISHING THE EUROPEAN ECONOMIC COMMUNITY art. 30.

⁴ 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.

Id. art. 36.

⁵ Case 178/84, *Commission v. Germany*, 1987-3 E.C.R. 1227 (1987). The German law, dating from 1516, stated 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 (beer with only the four ingredients could be identified easily) and (2) banning unsafe additives.

⁶ Statement by Markus Puder, European Union Law I, Georgetown Univ. Law Center (Sept. 1994).

⁷ HEALTH INDUSTRY MANUFACTURERS ASSOCIATION, *THE ENFORCEMENT OF EUROPEAN COMMUNITY LAW* 18 (Jan. 1990).

⁸ See *supra* notes 2 & 5.

⁹ E. JONGEN, *THE CREATION OF AN INTERNAL MARKET FOR INDUSTRIAL GOODS IN EUROPE THROUGH TECHNICAL HARMONIZATION, STANDARDIZATION, CERTIFICATION AND MUTUAL RECOGNITION* (Jan. 1991).

¹⁰ Statement by Jacques MacMillan, European Comm'n, at U.S.-EU negotiations on Mutual Recognition Agreements (Apr. 1995).

¹¹ Single European Act, 1987 O.J. (L 169) 1.

¹² EUROPEAN COMMISSION, *GUIDE TO THE IMPLEMENTATION OF COMMUNITY HARMONIZATION DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH* (1994).

Launched in 1985 by a European Council resolution¹³ and a European Commission White Paper on completing the internal market,¹⁴ the new approach is noteworthy in its call for government/private sector partnerships to carry out functions that traditionally or elsewhere had been thought of as government roles. First, European private sector standards bodies were called on to develop product standards,¹⁵ with this activity partially subsidized by the European Commission and Member State governments for topics identified as priorities. A company whose product meets such standards would be deemed to have satisfied the essential requirements of the applicable directive. Second, in the important area of conformity assessment,¹⁶ that is, 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 the U.S. Underwriters Laboratory) and to private quality auditors, to enable these bodies to carry out certain testing or auditing functions under specified directives.¹⁷

This reliance on private sector entities for quasi-governmental functions was not driven by the *Cassis de Dijon* decision, 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 frustration at the slow progress of past efforts to harmonize, efforts that never kept pace with the actions by Member State parliaments and ministries to add new and disparate requirements.¹⁸

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 by national private sector standards and not by ministries, such as 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

¹³ Council Resolution on a new approach to technical harmonization and standards, 1985 O.J. (C 136) 1.

¹⁴ COM(85)310 final (1985).

¹⁵ Commission Communication on the development of European Standardization – Action for faster technological integration in Europe, 1991 O.J. (C 20) 1 (Green Paper on Standardization); Commission Communication – Standardization in the European Economy, 1992 O.J. (C 96) 2 (follow-up to the Green Paper); Council Resolution on the role of European standardization in the European economy, 1992 O.J. (C 173) 1. 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 *Deutsche Institut fuer Normung* (DIN), and the French *Association Francaise de Normalisation* (AFNOR).

¹⁶ “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 90/683 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, Annex I, 1990 O.J. (L 380) 13, 14.

¹⁷ Council Resolution on a global approach to conformity assessment, 1990 O.J. (C 10) 1; Council Decision 90/683, *supra* note 16. 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).

¹⁸ 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. E. JONGEN, *supra* note 9. Much of the information in the paragraph in the accompanying text is derived from Mr. Jongen's paper.

harmonized, Community-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 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 manufacturers, at a time when many European countries were privatizing national services and institutes.

The outcome of these trends was 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 nationalistic and nontransparent) and to place these decisions with private-sector bodies that were believed 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.¹⁹

II. IMPLEMENTATION OF THE MEDICAL DEVICE DIRECTIVES

The selection of medical devices as a candidate for New Approach Directives²⁰ is surprising for several reasons. First, why was the approach chosen not more like that for the other health product category, pharmaceuticals? The dominant regulatory approach for pharmaceuticals traditionally has been governmental approval and inspection in the United States, Europe, and all developed countries.²¹ For certain high-risk medical devices, this traditional approach was being carried over into device law in the United

¹⁹ European Commission, Notified Bodies, DOC.CERTIF. 91/7 rev 3.

²⁰ Other directives include simple pressure vessels (Council Directive 87/404/EEC, 1987 O.J. (L 220) 48; Council Directive 90/488/EEC, 1990 O.J. (L 270) 25), toys (Council Directive 88/378/EEC, 1988 O.J. (L 187) 1), construction products (Council Directive 89/106/EEC, 1989 O.J. (L 40) 12), electromagnetic compatibility (Council Directive 89/336/EEC, 1989 O.J. (L 220); Council Directive 92/31/EEC, 1992 O.J. (L 126) 11), machinery (Council Directive 89/392/EEC, 1989 O.J. (L 183) 9; Council Directive 91/368/EEC, 1991 O.J. (L 198) 16; Council Directive 93/44/EEC, 1993 O.J. (L 175) 12), personal protective equipment (Council Directive 89/686/EEC, 1989 O.J. (L 399) 18; Council Directive 93/95/EEC, 1993 O.J. (L 276) 11), non-automatic weighing instruments (Council Directive 90/384/EEC, 1990 O.J. (L 189) 1), appliances burning gaseous fuels (Council Directive 90/396/EEC, 1990 O.J. (L 196) 15), telecommunications terminal equipment (Council Directive 91/263/EEC, 1991 O.J. (L 128) 1), certain hot water boilers (Council Directive 92/42/EEC, 1992 O.J. (L 167) 17), certain electrical equipment (Council Directive 73/23/EEC, 1972 O.J. (L 77) 29), explosives (Council Directive 93/15/EEC, 1993 O.J. (L 121) 20), and protective systems for explosive atmospheres (Council Directive 94/9/EEC, 1994 O.J. (L 100) 1). See Council Directive 93/68/EEC, 1993 O.J. (L 220) 1.

²¹ The U.S. system requires each drug manufacturer to submit an application for Food and Drug Administration (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 United Kingdom, Germany, France, and other European countries at the time the EU embarked on harmonization efforts for pharmaceuticals.

States²² and, at the outset of European medical device regulation, by the United Kingdom and other Member States.

Like EU device regulation, EU drug regulation includes harmonized directives, committees of experts to coordinate work, “mixed competency,” and “subsidiarity,” that is, Member State enforcement. However, in contrast to EU devices, EU drugs need government approval by either Member State ministries or (increasingly) by a new EU institution — the European Medicines Evaluation Agency (EMA) — that came into being on January 1, 1995. The EMA 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, the United States, and Japan known as the International Conference for the Harmonization of the Technical Requirements for the Registration of Pharmaceuticals for Human Use.

Furthermore, it is unclear that medical devices meet the criteria laid out in the Council’s resolution creating the new approach, in that devices do not meet the criterion that the product category be sufficiently homogeneous to allow common “essential requirements” to be defined,²³ or that it be genuinely possible to distinguish between essential requirements and manufacturing specifications so that a minimum number of essential requirements are kept.²⁴ The complexity of the directives on medical devices, as discussed below, shows the challenge the EU has faced in applying the new approach to devices.

The European Commission viewed medical devices more like “industrial products” than pharmaceuticals. While both devices and pharmaceuticals were assigned to the Directorate General for Industry, devices were administratively assigned to the program that also was responsible for pressure boilers and industrial machinery. Thus, the Community’s first directive in the medical device area²⁵ 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.”²⁶ With respect to conformity assessment, some Member States (such as Germany, Spain, and France) required a form of product certification known as type testing as a prerequisite for placing certain devices, particularly ones with electrical aspects, on the market, while quality systems were certified for supply to the United Kingdom’s public health

²² 21 U.S.C. § 360e.

²³One 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 on a new approach to technical harmonization and standards, 1985 O.J. (C 136) 1, 9.

²⁴ *Id.*

²⁵ Council Directive 84/529 on the approximation of the laws of the Member States relating to electrically operated lifts, 1984 O.J. (L 300) 86. (effective Sept. 1986, adopting CENELEC HD 395-1).

²⁶ *Id.* at 4. The syringe is an example of the EU legal inconsistencies 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. Remarks by Norbert Anselmann, European Comm’n, The Forthcoming EC Legislation on Medical Devices: Provisional Results and Outlook 5-6, at the Reg. Aff. Professionals Soc’y Conference on International Harmonization of Medical Device Regulation (June 22-23, 1992) [hereinafter Anselmann, EC Legislation].

services (although this was not a legal requirement).²⁷ One country had laws for contact lenses, but not for the implantable intraocular lenses used to replace natural lenses after cataract removal. Another regulated wheelchairs, but not anesthesia equipment.²⁸

The three EU medical device directives that will bring harmony to these different regulations are now at various stages in development:

- Directive 90/385/EEC on Active Implantable Medical Devices²⁹
 - Published July 20, 1990
 - Date of first application January 1, 1993
 - End of transitional period December 31, 1994
- Directive 93/42/EEC on Medical Devices³⁰
 - Published July 12, 1993
 - Date of first application January 1, 1995
 - End of transitional period June 1998
- Proposal for a European Parliament and Council Directive on *in vitro* diagnostic medical devices³¹
 - Published July 7, 1995

Except where otherwise stated, this article focuses on the Medical Devices Directive,³² 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.

²⁷ ROBERT G. BRITAIN, COPING WITH INTERNATIONAL ISSUES: AN INDUSTRY APPROACH (Nat'l Electrical Mfrs. Ass'n 1990).

²⁸ Anselmann, EC Legislation, *supra* note 26.

²⁹ Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, 1990 O.J. (L 189) 17. 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] (Nov. 4, 1994).

³⁰ Council Directive 93/42/EEC, *supra* note 1. 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.

³¹ Proposal for a European Parliament and Council Directive 95/C 172/02 on *in vitro* diagnostic medical devices, 1995 O.J. (C 172) 21. An *in vitro* diagnostic is a medical device that 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.

³² The legal procedure for its adoption was the cooperation procedure in article 100a of the EEC Treaty.

[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.³³

The central obligations of the Medical Device Directive are found in articles 2 and 3.³⁴ 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.³⁵

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 (for example, chemical, physical, and biological properties; infection and microbial contamination; construction and environmental properties; measuring functions; protection against radiation; and energy sources).³⁶

When a Member State’s “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,³⁷ then that conformity is valid throughout the EU. Proof of eligibility for this free movement is the affixation to the product of a CE mark. The CE mark serves as a technical passport for the product through the EU.³⁸

A. Administration

As has been discussed, the EU regulatory scheme for medical devices does not

³³ Anselmann, EC Legislation, *supra* note 26, at 5-6. In 1991, before embarking on its harmonization program, the Commission described the situation as follows:

[T]here 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.

Commission Proposal for a Council Directive concerning medical devices (Aug. 23, 1991).

³⁴ Council Directive 93/42/EEC, *supra* note 1, arts. 2, 3.

³⁵ *Id.*, art. 2.

³⁶ *Id.* annex I.

³⁷ In a decision dated December 13, 1990, the Council laid out eight typical conformity assessment procedures for use in new approach directives. Council Decision 90/683, *supra* note 16. A July 22, 1993 Council Directive provided details on the modules for the various phases of the conformity assessment procedures and the rules for affixing the CE mark. Council Directive 93/68/EEC, *supra* note 20. *See also* EUROPEAN COMMISSION, GUIDE TO THE IMPLEMENTATION OF COMMUNITY HARMONIZATION DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH (1994).

³⁸ European Council Decision 93/68/EEC, *supra* note 20.

contemplate a single regulatory body with nationwide scope similar to the U.S. Food and Drug Administration (FDA), but rather a multifaceted system with roles for the European Commission, the private standards organizations, the fifteen Member States' competent authorities, and the notified bodies (private or public) those authorities designate to carry out conformity assessment functions. Thus, approval decisions (made by notified bodies) and enforcement (implemented by Member States with or without assistance from the notified bodies) are highly decentralized.³⁹

The Commission's tasks are to:

- watch over correct transposition,
- take measures in cases of incorrect transposition or non-transposition,
- monitor and follow the transposition process,
- elaborate on directives through explanatory documents,
- facilitate communication within the Community by a system of committees with Member State representatives,
- oversee a system of medical device vigilance, and
- provide infrastructure for notified bodies.

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

	Notified Bodies ⁴⁰	National(Competent)Authorities ⁴¹
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 as long as it has been deemed technically competent by a national authority for the required tasks. In the contractual arrangements between a manufacturer and the notified body, the parties agree on the time limits for completion of verification operations and the assessment.⁴²

It is noteworthy that a notified body has responsibilities of a "public" nature, such as the granting, denying, or withdrawing certificates; requesting more information if needed; making unannounced visits to view quality assurance if needed; and supplying information directly to competent authorities despite contractual relationships with manufacturers.

³⁹ Norbert Anselmann, European Comm'n, The Forthcoming EC Directives on Medical Devices (Nov. 14, 1991) [hereinafter Anselmann, EC Directives]

⁴⁰ Council Directive 93/42/EEC, *supra* note 1, arts. 11, 12.

⁴¹ *Id.* art. 2, 8, 9, 10, 11, 12, 13, 14, 16.

⁴² *Id.* art. 16(4).

B. Classification

Fundamental to the regulation of medical devices in the EU is the use of a classification scheme to determine the level of control over a device. Similar schemes are utilized in the United States and other developed countries. 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, as well as criteria concerning the time of uninterrupted contact of the device with the body and the degree of invasiveness. Special considerations govern contraceptives and devices that are combined with drugs.

The classification system is designed to be a practical tool for assigning the device to the correct conformity assessment procedure that reflects the device's risk:

- Class I devices enter the marketplace with only a manufacturer's self-declaration of conformity.⁴³
- Class IIa devices are subject to production quality system control registration by a third-party body.
- Class IIb and III devices are subject to quality system control for both production and design.
- Furthermore, Class III devices that are critical devices undergo a clinical evaluation under the responsibility of the manufacturer, and the conformity of the device's design must be considered separately by a notified body before the device is placed on the market.⁴⁴

Thus, while the EU device classification system nominally has three classes of devices as does the U.S. system,⁴⁵ the EU's Class II is divided into IIa and IIb with different requirements for each, so that in essence the EU has four classes.

The EU classification system calls on a manufacturer to preliminarily classify its

⁴³ Special provisions govern Class I devices that have additional attributes, such as sterility or a measurement function.

⁴⁴ European Commission Proposal for a Council Directive concerning medical devices (COM(91) 287 final-SYN 353) 4. A manufacturer of a Class III device avoids repetition of the same clinical investigations in more than one member state. *Id.* at 14. Note that all devices, not just Class III devices, need clinical evidence.

⁴⁵ In the United States, 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 the FDA deems necessary (e.g., adherence to voluntary standards). *Id.* § 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, *id.* § 360c(a)(1)(C), or if it is new technology not substantially equivalent to previously marketed devices, *id.* § 351(f). Due to a grace period for pre-1976 Class III devices (and post-1976 substantially equivalent devices) that ends only when the FDA by rule calls for premarket approval applications (PMAs) for such devices, *id.* § 360e(b), the U.S. marketplace includes devices that the FDA previously has identified as needing comprehensive approval, but that never have 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 has pressed the FDA to complete. Pub. L. No. 101-629, § 4(b), 104 Stat. 4511, 4515 (codified at 21 U.S.C. § 360e(i)).

devices prior to embarking on a conformity assessment procedure.⁴⁶ 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.⁴⁷ The Commission has issued a guideline to assist manufacturers, competent authorities, and notified bodies in ascertaining the appropriate classification of devices.⁴⁸

C. Registration

Registration is required only for EU manufacturers of Class I, custom-made, and for imported devices;⁴⁹ registration is made with the competent authority in the Member State where the manufacturer or importer has its registered office. The European Commission is establishing the parameters for a common data base to collect information on manufacturer registrations.⁵⁰

D. Standards

The Medical Device Directive recognizes two European standards organizations, the European Committee for Standardization (CEN)⁵¹ and the European Committee for Electrotechnical Standardization (CENELEC),⁵² as the competent bodies for the creation of harmonized standards in accordance with a 1983 Directive,⁵³ and a 1984 agreement between these bodies and the Commission.⁵⁴ The standards are voluntary, and 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 by providing that Member States shall presume compliance with the essential 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*.⁵⁵ If an EU standard does not exist, the manufacturer (or the notified body) can apply another suitable standard or guideline.⁵⁶ If a Member State or the Commission considers that the harmonized standards do

⁴⁶ Mika Reinikainen, Classification of Medical Devices, remarks at Reg. Aff. Professional Soc'y Conference on International Harmonization of Medical Device Regulation, Washington, D.C. (June 22-23, 1992).

⁴⁷ Council Directive 93/42/EEC, *supra* note 1, art. 13.

⁴⁸ Commission of the European Communities, Guidelines to the Classification of Medical Devices (Status: 1994-01-21) (3rd draft).

⁴⁹ Council Directive 93/42/EEC, *supra* note 1, art. 14.

⁵⁰ The database also will include information on decisions by notified bodies that allow devices on the market and by competent authorities that take devices off the market. Anselmann, EC Directives, *supra* note 39.

⁵¹ CEN is 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, the United Kingdom's British Standards Institute, and France's AFNOR).

⁵² CENELEC promotes harmonization of European regional standards in the electrotechnical field.

⁵³ Council Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations, 1983 O.J. (L 109) 80.

⁵⁴ Vienna guidelines on cooperation (November 13, 1984). For specific devices, e.g., sutures, European Pharmacopoeia monographs may be considered equal to harmonized standards. See Council Directive 93/42/EEC, preamble, *supra* note 1, at 2.

⁵⁵ Council Directive 93/42/EEC, *supra* note 1, art. 5.

⁵⁶ *Id.*

not entirely meet the essential requirements, there is a procedure⁵⁷ 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 (for example, to work in CEN or CENELEC to strengthen the standard, to substitute a Directive, or to allow Member States to act).

E. Clinical Investigations

The Medical Devices Directive includes requirements for clinical investigations of medical devices in human subjects.⁵⁸ It also restricts Member States from creating any obstacle to devices intended for clinical investigation from being made available for that purpose if they meet the required conditions.⁵⁹

After declaration of the opinion of an Ethics Committee has been given, and at least sixty days before an investigation begins, a sponsor is required to notify the competent authorities⁶⁰ 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, a manufacturer must wait sixty 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 (GCPs)).⁶¹ 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.⁶² Underlying all of these documents on good clinical research practice is the Declaration of Helsinki and its subsequent amendments,⁶³ which are the accepted standards for ethical conduct of clinical investigations:

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

⁵⁷ *Id.* art. 5(3), 6(2).

⁵⁸ *Id.* art. 15, annex VIII. Special requirements for custom-made devices are also prescribed in the Directive.

⁵⁹ *Id.* art. 4(4).

⁶⁰ In France a similar requirement (the 1990 Huriet law) was implemented in 1990. As of February 1995, only the United Kingdom 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*, REG. AFF. J. (DEVICES), Feb. 1995, at 2; Malcolm Carlisle, *Clinical Investigation Devices in the EC*, REG. AFF. J. (DEVICES), Feb. 1995, at 6-11.

⁶¹ Peter Duijst & Odile Gaffori, Implications of the European Harmonization for Clinical Investigation With Medical Devices, remarks at the Reg. Aff. Professional Soc'y Conference on International Harmonization of Medical Device Regulation 3-4, Washington, D.C. (June 22-23, 1992).

⁶² 21 U.S.C. § 360j(g); C.F.R. pt. 812 (1995).

⁶³ The Helsinki Declaration was adopted by the 18th World Medical Association in Helsinki, Finland in 1964, and was last amended by the 41st World Medical Association in Hong Kong in 1989. See 21 C.F.R. § 312.120. Annex X(2.2) to the Medical Devices Directive states that "[i]t 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." Council Directive 93/42/EEC, *supra* note 1, annex X(2.2).

intended.

F. *Quality Systems*

Class IIa, IIb, and III devices must be manufactured in accordance with quality systems requirements; 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. The ISO-9000 standards for quality system state general standards for quality systems. EN 46000 was written specifically for the medical device industry.

G. *Audits of Quality Systems and 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 proof of continuing conformity. Notified bodies' audits will largely supplant the traditional regulatory inspections that have been carried out by the health ministries of the Member States. The oversight roles of these competent authorities for the notified bodies, however, likely will entail an investigative or adjudicative role between notified bodies and manufacturers.⁶⁴

H. *Vigilance System*

With such a decentralized system in which crucial premarket product entry decisions are made by private bodies, it is essential to have an effective system to collect, analyze, and share information on incidents from day-to-day use of medical devices. By doing so all participants in the EU medical device system, particularly the Member State competent authorities, can take action as needed to protect the public.

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 implement legislation that requires manufacturers to report certain adverse incidents to the competent authority in the country of occurrence.⁶⁵ Some Member States require hospitals and/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 after its competent authority, in conjunction with the manufacturer, has completed its investigation to ascertain whether the device was the cause of the incident.

Many EU nations require user reporting, in addition to manufacturer reporting, of adverse events. In the United Kingdom, user reporting is voluntary, but is strongly encouraged because the Medical Devices Agency (MDA) 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

⁶⁴ Kent, *supra* note 60, at 1. Concern was expressed about the potential loss of expertise gained by the United Kingdom's MDA due to discontinuance of its inspections of manufacturers, once part of the manufacturer registration scheme for National Health Service-eligible devices.

⁶⁵ 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 United States.

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 sixteen lander authorities.⁶⁶

Although the EU vigilance system is similar to the U.S. medical device experience reporting system⁶⁷ 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)⁶⁸ requires the FDA to disclose the reports on marketed medical devices, purged of identifying information on the patient and physician.⁶⁹ In the EU, even purged reports are treated as confidential. Furthermore, 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 United States' FDA.⁷⁰ 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, not just personal identifiers, are given confidential treatment,⁷¹ efforts at international cooperation are impeded when governmental regulatory authorities cannot collaborate to identify joint safety concerns due to corporate secrecy interests. A recent proposed rule⁷² assures other countries that information provided to the FDA in confidence will remain confidential because it will remain the other country's document not a "record" under FOIA. The availability of this assurance in medical device reporting may encourage the EU to share with the FDA information it collects under the vigilance system.

I. 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.⁷³ The responsibility rests on the manufacturer to determine the product's intended users 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.⁷⁴ Most Member States probably will apply this linguistic requirement to all elements of labeling and information, including pack-

⁶⁶ 5 EUROPE DRUG & DEVICE REP. May 1, 1995 at 3-4.

⁶⁷ 21 C.F.R. pt. 803.

⁶⁸ Pub. L. No. 89-487, 80 Stat. 250 (1966), as amended 5 U.S.C. § 552 (1988).

⁶⁹ Counterpart reports on experience with investigational medical devices 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 C.F.R. pts. 20, 812.

⁷⁰ [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.

Anselmann, EC Directives, *supra* note 40.

⁷¹ Confidentiality Vital to Device Regulatory Base, 4 EUROPE DRUG & DEVICE REP. Sept. 19, 1994, at 6-7. "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.*

⁷² Public Information; Information Sharing With State and Foreign Officials, 60 Fed. Reg. 5,530 (Jan. 27, 1995).

⁷³ Council Directive 93/42/EEC, *supra* note 1, annex I(13).

⁷⁴ *Id.* art. 4(4).

age labeling, product marking (such as display screens), instructions for use, warning statements, and all other 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.⁷⁵ More flexibility may be demonstrated for display screens, with some Member States accepting a different language from the national language if screen messages are clearly explained in the accompanying literature.⁷⁶

J. *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.⁷⁷ The Commission and other Member States must be notified of the decision, whereupon the Commission will review it to determine if the interim measures are justified. If they are, the Commission will initiate a process intended to result in each Member State taking uniform action concerning the product. If the Commission finds the measures unjustified, it informs the Member State and manufacturer, and could bring an infringement action against a Member State that retains the interim measures.

III. ISSUES IN IMPLEMENTATION.

A. *Delays in Transposition and Incomplete Transposition.*

In the thirty-month transitional period for the Active Implantable Medical Device Directive, no country was able to fully implement this legislation by its first application date of January 1, 1993. The United Kingdom almost implemented the legislation, and Germany avoided transposition and applied the Directive directly. It was the only country to make timely designations of notified bodies. France prepared a decree to establish a notified body within its health ministry to perform conformity assessment procedures.⁷⁸

Similarly, not all Member States have transposed the newer and more comprehensive Medical Devices Directive into their national law. For example, the Italian government's failure to transpose the directives has Italian manufacturers subject to a nonharmonized approval system that the industry has characterized as a bureaucratic maze of forty-five steps.⁷⁹ Delays are compounded by a requirement to submit sample products, accompanied by packaging and labeling exactly as intended for marketing. These requirements have forced manufacturers to complete manufacturing systems for a few control products. More important, the lack of a national law transposing the directive has resulted in Italian manufacturers having difficulty shipping their devices elsewhere in the EU, because Italian law bars export of an unapproved device unless it

⁷⁵ Caroline Freeman, *A Single Market But Not a Single Language*, REG. AFF. J. (DEVICES), Feb. 1995, at 5.

⁷⁶ *Id.*

⁷⁷ Council Directive 93/42/EEC, *supra* note 1, art. 8.

⁷⁸ 533 CLINICA, Jan. 6, 1993, at 7.

⁷⁹ *Id.* at 3.

meets EU law. Following the general EU law, however, 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 or not.⁸⁰

B. *Additional Regulatory Requirements*

Member States continue to add requirements that extend beyond the EU directives. For example, recently there was a French demand for premarket approval of heart valves⁸¹ and a Spanish registration requirement that Commission officials have argued 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 the requirement as a way to interpose an approval⁸² requirement. Registration is allowed only for Class I devices, custom-made devices, and imports. The United Kingdom, Finland, the Netherlands, and Sweden want all manufacturers that assemble or sterilize devices to register. Spain is planning a registry of high-risk device manufacturers, while Italy wants to require a registration that includes an authenticated copy of the compliance certificate. Furthermore, Italy intends to ask firms to submit technical dossiers “off the record” stating it is for the manufacturers’ protection that they do so, notwithstanding the Directives’ assignment of dossier review to notified bodies.⁸³

France recently halted its controversial 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 relinquishing its ban on the sale of CE-marked condoms that do not meet French standards. As yet there is not a harmonized European standard for condoms because of a disagreement among CEN members as to the necessity for batch testing required in a draft European condom standard.⁸⁴ The Commission, Austria, Germany, Spain, and the United Kingdom have held that the draft European standard is 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.

C. *Health Care Requirements*

There is the potential for conflict between the goals of the internal market in goods – a competency of the EU institutions – and the prerogatives of Member States under their health care systems – an area not within the competency of the EU.⁸⁵ This issue has

⁸⁰ Norbert Anselmann, *Directive Implementation Heads European Agenda*, 585 CLINICA, Jan. 10, 1994, at 6.

⁸¹ 650 CLINICA, Apr. 10, 1995, at 5.

⁸² 5 EUROPE DRUG & DEVICE REP., Feb. 6, 1995, at 6.

⁸³ 5 EUROPE DRUG & DEVICE REP., Apr. 17, 1995, at 2.

⁸⁴ *Id.* at 3.

⁸⁵ 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 above mentioned measures *provided Community law is complied with*. . .

Council Directive 93/42/EEC, *supra* note 1, at 1 (emphasis added).

resulted in the Commission warning the United Kingdom's MDA that its Manufacturers Registration Scheme (MRS) for devices purchased by U.K. health care entities may not be in compliance.⁸⁶ The issue of concern 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, in addition to the evaluation conducted to secure a CE mark and the right to market in the EU.⁸⁷

To defuse the issue, the MDA has told hospital purchasers to treat devices from firms signed up under MRS and devices that are CE-marked equally to show compliance with the EU Directive. At the same time, the MDA says it remains committed to MRS until the Directive becomes compulsory in June 1998. The MDA also is being selective about the notified bodies in other countries to which it will grant mutual recognition, a likely source of contention with the Commission. Certainly, after the effective date of the Directive, the United Kingdom will have to accept CE-marked products.

IV. 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 United States, have a strong interest in the results of this intriguing experiment.

⁸⁶ 5 EUROPE DRUG & DEVICE REP., Apr. 17, 1995, at 3-4; 5 EUROPE DRUG & DEVICE REP., May 1, 1995, at 6.

⁸⁷ Alan Kent, Chief Executive, United Kingdom MDA, has stated that the British National Health Service will continue to perform a user evaluation of CE-Marked products for purchasing:

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.

Kent, *supra* note 60, at 1.