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MUTUAL RECOGNITION AGREEMENT:
IMPLICATIONS FOR THE U.S. MEDICAL DEVICE INDUSTRY**

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THE UNITED STATES-EUROPEAN UNION MUTUAL RECOGNITION AGREEMENT: IMPLICATIONS FOR THE U.S. MEDICAL DEVICE INDUSTRY

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ABSTRACT: A mutual recognition agreement (MRA) was signed by the United States and the European Union (EU) on May 18, 1998. The MRA contains six sectoral annexes covering different products and issue areas. This paper examines one of the annexes, the medical device annex, and its implications for the U.S. medical device industry. U.S. industry representatives and government officials are generally supportive of the MRA. Proponents state that the MRA has the potential to improve patient access to safe and effective technologies, reduce regulatory redundancies, enhance the access of U.S. and EU companies to each other's markets, provide significant savings to both companies and regulators, and set the stage for future regulatory cooperation and harmonization. However, despite general support for the MRA, some U.S. industry representatives and government officials maintain reservations about certain aspects of this agreement and the utilization of MRAs in general.

I. Introduction

This paper examines the mutual recognition agreement (MRA) signed by the United States and the European Union (EU) on May 18, 1998, and its implications for U.S. medical device manufacturers. The MRA contains a framework agreement and six sectoral² annexes covering different products and issue areas, including medical devices. This paper will limit its assessment to the MRA and the medical device annex (hereinafter referred to as the medical device MRA) and their relevance for the U.S. medical device industry.

Section II of this paper compares and contrasts the medical device regulatory approval systems of the United States and EU and highlights the problems that differences in the systems cause for medical device exporters. Section III describes the U.S.-EU MRA and medical device annex. Section IV presents the views of U.S. industry representatives and government officials concerning the MRA's

¹This paper represents solely the views of the author and is not meant to represent the views of the U.S. International Trade Commission or any of its commissioners. The invaluable assistance of Monica Reed and Wanda Tolson is gratefully acknowledged. Please direct all correspondence to Christopher Johnson, Office of Industries, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone: 202-205-3488, fax:202-205-2018, [email:cjohnson@usitc.gov](mailto:cjohnson@usitc.gov).

²The six sectoral areas covered by the U.S.-EU mutual recognition agreement (MRA) are electromagnetic compatibility, medical devices, telecommunications equipment, electrical safety, recreational craft, and pharmaceuticals.

effectiveness in overcoming problems for exporters caused by diverse regulatory systems. Finally, section V presents the findings of the paper and discusses implications for the U.S. medical device industry.

II. Medical Device Regulation in the United States and European Union

This section briefly highlights the regulatory systems of the United States and the EU, especially focusing on how both entities currently handle product evaluations and quality system inspections of medical device manufacturers. This will provide a context for the next section on the U.S.- EU MRA, which shows how the MRA streamlines product evaluations and quality system inspections for both countries.

U.S. Conformity Assessment³

The U.S. Food and Drug Administration (FDA), part of the U.S. Department of Health and Human Services, is the federal regulatory body in the U.S. government responsible for ensuring the safety and effectiveness of medical devices sold in the U.S. market. The FDA requires that manufacturers and importers follow various regulatory procedures before a new product is allowed to be placed on the market. These procedures are determined by the potential for harm to consumers and whether similar products are already in the U.S. market.

The FDA classifies medical devices into three categories depending on the potential degree of risk of the device.⁴ Class 1 devices are perceived as least risky and include such products as tongue

³A conformity assessment body (CAB) is responsible for determining and certifying that a firm has met minimum technical requirements established by the firm's customers or other interested parties, including government regulatory bodies. As such, a CAB is involved in conducting inspections, completing tests, and quality management systems and certifying whether firms meet the minimum requirements of the interested bodies. CABs can be either private sector or government organizations. Examples of private sector CABs are Underwriters Laboratories in the United States and the British Standards Institute in the United Kingdom. The FDA is an example of a government CAB.

⁴U.S. Food and Drug Administration (FDA), *Premarket Approval [510 (k)]*, June 30, 1998, pp. 1-5, found at Internet address <http://www.fda.gov>, retrieved Apr. 6, 2000; and Lee H. Monstein, "Primer on Medical Device Regulations," *Regulatory Articles* (Chicago: Radiological Society of North America),

depressors and crutches. Class II devices in general pose an intermediate degree of risk. Class III devices are devices believed to have the most potential risk. A device implanted in the body for life-supporting purposes, such as implantable cardiac pacemakers or defibrillators, are examples of Class III devices. Because the amount of regulatory control over a product is based on the degree of risk, only a few regulatory requirements may apply to many class I devices while class III devices are more strictly controlled by the FDA.

Anyone wishing to market Class II devices and certain Class I and Class III devices intended for human use in the United States must submit a 510(k) notification to the FDA at least 90 days before marketing unless the device is exempt from 510(k) requirements. Most Class I devices are exempt from 510(k) requirements.⁵ A 510(k) notification is a premarketing submission to the FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed⁶ device that is not subject to the premarket approval (PMA) process.⁷ Applicants must compare their 510(k) device to one or more similar devices currently in the U.S. market and support their substantial equivalency claims.⁸ Applicants under this process must submit descriptive data and, sometimes, performance data to the FDA to establish that their device is substantially equivalent to a predicate device.⁹ Once a device is determined to be substantially equivalent, it can then be marketed in the United States. This applies to both domestic- and foreign-made devices.

pp. 1-8, found at Internet address <http://www.rsna.org>, retrieved on Feb. 1, 2000.

⁵FDA, "Premarket Notification (510 (k))," p. 1, found at Internet address <http://www.fda.gov>, retrieved Jan. 9, 2001.

⁶A legally marketed device is a device which has been reclassified from Class III to Class II or I or a device which has been found to be substantially equivalent to such a device through the 510(k) process.

⁷"Premarket Notification," p. 1.

⁸"Primer on Medical Device Regulations," pp. 1-8.

⁹Ibid.

PMA is among the most stringent types of approval required by the FDA.¹⁰ In this process, a PMA application must be submitted to the FDA to request approval to market many Class III medical devices. Although some Class III medical devices are eligible to receive clearance for marketing through the 510(k) process, most class III devices require PMA. Unlike premarket notification, PMA is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence, including data developed in clinical trials, that provides reasonable assurance that the device is safe and effective for its intended use or uses. The medical device MRA does not cover any class III devices.

All medical device manufacturers are subject to good manufacturing practices (GMPs) promulgated as regulations pursuant to section 520 (f) of the Food, Drug and Cosmetic Act.¹¹ However, some Class I devices are subject only to the GMP requirements concerning record keeping at 21 CFR 820.180 and complaint handling at 21 CFR 820.198. The provision requires that domestic or foreign manufacturers have quality systems (QS)¹² in place for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States.¹³ The regulation has the following requirements:¹⁴

- (1) A quality system including adequate resources for device design, manufacturing, distribution, and servicing;
- (2) Management monitoring and oversight of the quality system;
- (3) A design control system to assure that the device designs meet users' needs, intended uses, and specified requirements;

¹⁰FDA, "Good Manufacturing Practices (GMP)/Quality System (QS) Regulation" (Washington, DC: FDA, Apr. 17, 1998), pp. 1-7, found at Internet address <http://www.fda.gov>, retrieved Jan. 3, 2001.

¹¹Title 21 Part 360[j] of the U.S. Code of Federal Regulations.

¹²The QS Regulation is contained in Title 21 Part 820 of the Code of Federal Regulations.

¹³FDA, "(GMP)/Quality System (QS) Regulation," pp. 1-7; and FDA, "A Plan That Establishes a Framework for Achieving Mutual Recognition of Good Manufacturing Practice Inspections" (Washington DC: FDA, 1998), pp. 1-3, found at Internet address <http://www.fda.gov>, retrieved Jan. 3, 2001.

¹⁴Ibid.

- (4) Manufacturing processes that are validated, monitored, and controlled to assure that devices meet specifications;
- (5) A corrective and protective action system for identifying nonconforming product and quality problems and implementing corrective actions;
- (6) A record keeping system to assure that specifications and procedures are adequate and current and records are maintained for the required length of time;
- (7) Controlled handling and storage of products, including incoming components, in-process devices, and finished devices to assure that only products meeting specifications are used and distributed; and
- (8) Adequate facilities and equipment that are cleaned, maintained, calibrated, and controlled to assure that devices are not contaminated and meet specifications.

Thus the QS regulation helps assure that medical devices are manufactured reliably and consistently. The FDA monitors device problem data and inspects the operations and records of both domestic and foreign medical device developers and manufacturers to determine compliance with the good manufacturing practices (GMP) requirements in the QS regulation.¹⁵

The medical device QS regulation requires a broad system intended to cover the design and distribution of all medical devices from simple surgical hand tools to very complex computerized axial tomography (CAT) scanners.¹⁶ According to the FDA, it is not practical for the regulation to specify details of quality system elements for such a wide variety of medical devices and device manufacturing technologies. Instead, the QS regulation specifies general objectives such as use of trained employees, design reviews, design validation, calibrated equipment, process controls, etc., rather than methods, because a specific method would not be appropriate to all operations. Although the EU directives refer to the international quality standard, International Organization for Standardization (ISO) 9000 as the series of quality management standards to be followed in many of its product

¹⁵FDA, “(GMP)/Quality System (QS) Regulation,” pp. 1-7, found at Internet address <http://www.fda.gov>, retrieved Jan. 3, 2001.

¹⁶Ibid.

related directives, the FDA asserts that its quality system regulation is harmonized with ISO 9000 (specifically 9001:1996) and ISO 13485:1997. In a few areas, FDA has added some requirements that differ slightly from the ISO standards.¹⁷ For instance, ISO 13485 contains supplementary requirements for medical devices.¹⁸

Although QS guidance can assist firms in improving quality in their factories and administrative areas, the QS functions solely as a quality management system. It does not assess product quality. Nevertheless, the QS is likely to result in more efficient operations, greater consistency in manufacturing, and consequently in better quality products. Thus, compliance with the FDA's QS regulation can improve the quality of manufacturers' design development, manufacturing, and administrative areas, and ultimately in the devices they manufacture. Some executives point out that a number of major U.S. firms have had longstanding quality management systems in place that should be taken into account when evaluating the slight discrepancies between the QS and other quality management systems, including ISO 9000. Otherwise, firms exporting to the EU, which has relied on ISO 9000 to a larger extent in its medical regulatory system than has the United States, could be adversely affected by duplications in their operations.

EU Conformity Assessment

Historically, medical device regulation in the EU was the responsibility of the individual health ministries of member states. This made it difficult for both U.S. and EU manufacturers to obtain approval to market their products. With multiple systems in Europe, medical device producers were required to adapt their products to the separate European countries. U.S. firms were greatly inconvenienced by substantial differences among EU member states in their technical and administrative procedures for inspecting and authorizing sales of medical devices. Such differences in

¹⁷Plan for Achieving Mutual Recognition of Good Manufacturing Practices, pp. 1-3.

¹⁸ISO 13485, Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001.

regulatory approval procedures fragmented the European market and added costs to suppliers that wished to sell in more than one member state by requiring them to modify their products or subject them to different national testing procedures.

As part of the EU single market program, popularly known as “EC92,” a “new approach” to regulation was adopted in the early 1990s for a number of highly regulated products, including medical devices. Under the new approach, harmonization legislation lay down only mandatory requirements, such as protection of health, safety, and the environment. The program also relieved firms of the burden of meeting the requirements of, or demonstrating compliance with, a multitude of member state technical regulations, by requiring that a manufacturer or importer now only gain compliance in a single EU country. Once approved, its medical devices could be sold in any EU member state. However, although the same testing and certification procedures apply to both U.S. and EU producers, it appeared that U.S. suppliers would be forced to have their products tested in the EU by approved third-party testing and certification bodies called notified bodies¹⁹ (known as conformity assessment bodies (CABs) under the U.S. EU MRA).

In the early 1990s, the United States pressed the EU to allow notified bodies to be recognized in the United States. The EU stated that this could not be done except through a mutual recognition agreement between the EU and the United States so European producers could obtain similar treatment in the U.S. market. This led to the 1998 MRA reached between the United States and the EU that will be discussed in section III of this paper.

Similar to the United States, the EU classifies medical devices so that the extent of required regulatory control can be established. The four categories are I, IIa, IIb, and III. Products that pose the greatest risk if used incorrectly or if a fault develops in the device belong to one of the higher

¹⁹Notified bodies are independent testing houses or laboratories authorized by EU member states to perform conformity assessment tasks. Notified bodies may be private organizations or public entities.

classes. For these products, assessment of compliance with the requirements of the directive²⁰ calls for intervention by a notified body, which, as indicated above, is usually a third-party testing body approved to ascertain that the product in question meets applicable requirements in one of the EU's directives related to medical devices. As in the United States, the higher the category, the more extensive is the participation of the notified body (or CAB).

For class I devices, the manufacturer may self-declare that the product fulfills the essential requirements of the directive. For the other three classes, the manufacturer is provided with choices for demonstrating its fulfillment of the essential requirements of the directive. For example, in classes IIa and IIb, the producer can reduce or forego requirements that a notified body examine and test the product to determine compliance with the directive by allowing a notified body to assess and approve the manufacturer's total quality system.

Under the EU system for assessing medical devices, a U.S. exporter was required to have its product and/or quality system examined or tested by an EU notified body in an EU member state. This presented difficulties for U.S. exporters because only notified bodies located in Europe had been authorized to grant final product approvals of regulated products, although parts of the required procedures could be completed in the United States on a contractual basis. This forced exporters to travel to the EU, which was especially hard on the small exporter.

U.S. industry representatives state that prior to the EU single market initiative, efforts to harmonize conflicting EU standards and establish a single European regulatory approval process in

²⁰ For regulated products, the European Commission has set out the guidelines for harmonized European-wide standards in a number of directives. National Institute of Standards and Technology NIST, "Standards Setting in the European Union—Standards Organizations and Officials in EU Standards Activities," *NIST Special Publication 891 (1997) Edition*, Feb. 1997, p. 11. The applicable EU directives for purposes of the medical device MRA are Council Directive 901385/EEC of 20 June 1990 on Active Implantable Medical Devices, *OJ* No. L 189, 20.7. 1990, p. 17; and Council Directive 93142/EEC of 14 June 1993 on Medical Devices, *OJ* No. L 169, 12.7.1993, p. 1, Appendix 1, U.S.-EU Medical Devices Annex, p. 89.

connection with the EU single market program were too slow.²¹ Those representatives suggest that harmonization of the various mandatory requirements and conformance procedures with respect to medical devices has enabled U.S. suppliers to reduce costs associated with compliance to different individual EU country requirements, to benefit from economies of scale, and to increase productivity. Nevertheless, U.S. medical device manufacturers have been required to have their products for the EU approved by notified bodies in the EU, increasing the costs that would otherwise be incurred by many firms if the products' approval in the United States could be accepted in the EU.

Global Harmonization Task Force

Both the United States and the EU have been working together with several other countries for over eight years in the Global Harmonization Task Force (GHTF) to improve the harmony and efficiency of their diverse regulatory regimes. The GHTF²² was established in 1992 by government regulatory bodies in the United States, Canada, the EU, Japan, and Australia. Both government regulators and industry representatives participate in the GHTF. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness, performance, and quality of medical devices and promoting technological innovation and facilitating international trade. The primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. These documents, which are developed by four different GHTF Study Groups can then be adopted and implemented by member national regulatory authorities.

²¹U.S. industry representatives, telephone interviews by USITC staff, Nov. 2000 and Jan. 2001.

²²According to GHTF proponents, increased harmonization is not only beneficial to the public health and government efficiency, but can also be translated into lower health care costs. Through the GHTF's development of agreements on standards, good manufacturing practices, quality assurance, and pre-market approval records, companies or sponsors will not have to face different requirements from different governments as they participate in the global economy. International harmonization contributes to the rapid entry of medical technology in health care facilities throughout the world.

Many of the same public and private sector representatives from the United States and the EU who have worked in the GHTF also have been major participants in meetings and discussions related to the medical device annex of the U.S.-EU MRA. As such, much of the GHTF's work and cooperation in connection with harmonization and equivalency of medical device standards have complemented and enhanced the work completed in connection with the MRA. European and U.S. industry representatives state that the ultimate goal of the GHTF should be reciprocity of approval among its members.²³ To accomplish that, GHTF work must ensure that different medical device regulatory systems achieve the same level of patient safety.²⁴

III. U.S.-EU Mutual Recognition Agreement

On May 18, 1998, the United States signed an MRA with the European Union that entered into force in December 1998. The MRA consists of a framework agreement and individual sectoral annexes, including an annex for medical devices.²⁵ The framework agreement covers the general aspects of the implementation of the agreement and the requirements governing the conformity assessment bodies (CABs) responsible for the approval of medical devices, such as listing, suspension, and withdrawal.²⁶ For instance, the MRA specifies the conditions by which each party will accept or recognize the results of conformity assessments (regulatory approval) performed by the other party's CABs or authorities. Each exporting party is required to inspect medical device manufacturers to assess their conformance with the importing party's requirements and conducting premarket reviews of select low to medium risk devices according to the importing party's requirements. The MRA also specifies that EU CABs be trained to assess against the regulations of the FDA. Similarly, CABs in

²³Victoria Ann Dedrick, European Medical Devices Industry Group, Global Harmonization Task Force Plenary Meeting, June 29, 1999, p. 12.

²⁴*Ibid.*

²⁵U.S.-EU MRA Medical Devices Annex, Sectoral Annex on Medical Devices, Chapter 1.

²⁶"The US-EU Mutual Recognition Agreement: The Medical Device Annex," Meeting Minutes for the June 27, Medical Device MRA Stakeholders Meeting, Aug. 17, 1999, pp. 1 and 2, found at Internet address <http://www.fda.gov>, retrieved Jan 3, 2001.

the United States are required to evaluate products and conduct inspections to meet the EU requirements.

The National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce has an important role in the CAB selection process. That agency’s role is to recommend qualified U.S. CABs to the FDA. For instance, NIST first reviewed and nominated potential U.S. CABs for participation in the MRA (table 1).²⁷ The names of the 10 CABs were forwarded to the FDA, which has final jurisdiction in designation of the bodies. Since then, two U.S. CABs (DNV Certification, Inc. and Perry Johnson Registrars, Inc.) have withdrawn their participation in the MRA.

Table 1
List of U.S. conformity assessment bodies selected to participate in the provisional period of the U.S.-EU MRA

British Standards Institution, Inc. (Reston, VA)	Orion Registrar, Inc. (Arvada, CO)
DNV Certification, Inc. (Houston, TX)	Perry Johnson Registrars, Inc. (Southfield, MI)
Entela Inc. (Grand Rapids, MI)	TUV Product Service (New Brighton, MN)
Intertek Services Corp. (Cortland, NY)	TUV Rheinland of North America, Inc. (Newtown, CT)
KEMA, Inc. (Chalfont, PA)	Underwriters’ Laboratories (Northbrook, IL)

Source: FDA, 2000.

The MRA does not mean that FDA-approved products will necessarily be accepted in the EU or that EU-approved (CE-marked) products will be recognized in the United States. The MRA does not harmonize regulatory systems but maintains independent systems for regulating medical devices in the United States and the EU. The EU CAB assessing EU-manufactured medical devices for export to the United States can only recommend that the FDA approve the devices. Similarly, the U.S. CAB assessing U.S.-made medical devices can only recommend that European notified bodies accept the

²⁷ Medical Devices Mutual Recognition Agreement (MRA) Stakeholders Meeting, Bethesda, MD, June 27, 1999.

product. For both quality inspections and device evaluations, both the United States and the EU member states retain full responsibility for products marketed in their own countries and can take actions necessary to protect the public health.

The MRA's sectoral annex for medical devices covers product evaluation reports for certain low to medium risk devices identified in the medical device annex (tables 2 and 3)²⁸ and quality system inspection reports for all medical device firms. The medical device annex has a 3-year transition period following the date of entry into force of the agreement.²⁹ Since the MRA entered into force on December 1, 1998, the transition period is scheduled to end in December 2001.

Under the MRA, to sell a device in the EU, a U.S. medical device manufacturer submits an application to a CAB in the United States for review based on EU regulatory requirements. After conducting its review, the U.S. CAB recommends approval to an EU CAB. Once the product is approved by the EU CAB, it can be sold in the EU market. Similarly, a European manufacturer who wants to sell medical products to the United States will submit an application to an EU CAB for review based on U.S. (FDA) requirements.

Both the U.S. FDA and EU notified bodies conduct hundreds of quality system inspections in overseas facilities of firms that export to their respective markets. CABs of each party will inspect the appropriate domestic production facilities to assess their compliance with the regulations of the other party. Both the FDA and EU notified bodies will continue to conduct joint inspections and monitoring functions in one another's markets for confidence-building purposes. However, it is expected that such activities should lessen as more confidence is gained.

²⁸The United States and EU are in the process of amending these tables.

²⁹Medical Devices Annex, Chapter 2.

Table 2**Class I Products Requiring Premarket Evaluations in the United States, included in Scope of Product Coverage at Beginning of Transition Period**

Esophageal stethoscope	Breathing mouthpiece
Medicinal nonventilatory nebulizer (Atomizer)	Rebreathing device
Nonpowered oxygen tent	Tracheobronchial suction catheter
Karaya and sodium borate with or without acacia denture adhesive	Dental mercury
Dental handpieces and accessories	Dental operative unit
Short increment sensitivity index (SISI) adapter	Gustometer
Air or water caloric stimulator	Toynbee diagnostic tube
Hearing aid	Epistaxis balloon
Ent examination and treatment unit	Powered nasal irrigator
Antistammering device	Urological clamps for males
Enema kit	Urine collector and accessories
Neonatal eye pad	Pressure infusor for I.V. bag
Pediatric position holder	Patient examination glove
Patient lubricant	Protective restraint
Ataxiagraph	Electroencephalogram (EEG) signal spectrum analyzer
Ventricular cannula	Shunt system implantation instrument
Neurosurgical suture needle	Skull punch
Retinoscope	Tonometer sterilizer
Powered corneal burr	Keratome
Sunglasses (non-prescription)	AC-powered goniometer
Calipers for clinical use	Mechanical wheelchair
Manual patient rotation bed	Hot or cold disposable pack
Scintillation gamma camera	Positron camera
Nuclear rectilinear scanner	Nuclear uptake probe
Nuclear whole body scanner	Nuclear electrocardiograph synchronizer
Radiographic-film illuminator	Radiographic grid
Radiographic intensifying screen	Radiographic ECG/Respirator synchronizer
Manual radionuclide applicator system	Introduction/drainage catheter and accessories
Removable skin clip	Surgeons' gloves
Non-powered, single patient, portable suction apparatus	Removable skin staple
AC-powered, battery-powered, and pneumatically powered surgical instrument motor	Air or AC-powered operating table and air or AC-powered operating chair and accessories
Liquid bandage	

Source: Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community, May 18, 1998.

Table 3**Class II Medical Devices Included in Scope of Product Coverage at Beginning of Transition Period**

Nonfetal ultrasonic monitor	Ultrasonic pulsed doppler imaging system
Ultrasonic pulsed echo imaging system	Diagnostic ultrasonic transducer
Angiographic X-ray system	Image-intensified fluoroscopic X-ray system
Stationary X-ray system	Mobile X-ray system
Tomographic X-ray system	Computed tomography X-ray system
Electrocardiograph	Electrocardiograph lead switching adaptor
Electrocardiograph electrode	Electrocardiograph surface electrode tester
Electroencephalograph	Infusion pump (external only)
Ophtalmoscope	Retinoscope
AC-powered slip-lamp biomicroscope	Vitreous aspiration and cutting instrument
Phacofragmentation system	Surgical lamp
Transcutaneous electrical nerve stimulator for pain relief	Blood pressure cuff
Noninvasive blood pressure measurement system (except non-oscillometric)	Steam sterilizer (greater than 2 cubic feet)
Clinical electronic thermometer (except tympanic or pacifier)	Nebulizer
Powered emergency ventilator	Hypodermic single lumen needle
Piston syringe	Intramedullary fixation rod
Single/multiple component metallic bone fixation appliances & accessories	Smooth or threaded metallic bone fixation fastener
Gold based alloys and precious metal alloys for clinical use	Resin tooth bonding agent
Dental cement	Impression material
Tooth shade resin material	Base metal alloy
Condom	

Source: Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community, May 18, 1998.

During the transition period, the relevant regulators and CABs will engage in confidence-building activities to obtain sufficient evidence to make determinations concerning the equivalency of conformity assessment bodies of the other party with respect to the ability to perform quality system and product evaluations.³⁰ Equivalence in this regard refers to the ability of CABs in the United States and EU to assess products and quality systems to one another's requirements. During the transition period, the United States and the EU are to conduct joint inspections, training, and auditing, and set up a market surveillance system.³¹ The surveillance system will enable the United States and the EU to notify one another's regulatory system when there is any immediate danger to public health.³²

During the final six months of the transition period, the parties are scheduled to jointly assess the equivalence of the CABs that participated in the confidence building activities. Those determined to be equivalent, and thus allowed to participate in MRA activities as a CAB, will be listed in an appendix of the MRA, including the extent of any specifications and limitations with regard to the listed CABs. The operational period of the medical device annex is scheduled to start at the end of the transition period, or in December 2001, after the United States and EU have developed the list of CABs found to be equivalent. Regardless of whether CABs are able to demonstrate equivalence by the end of the scheduled transition period, the FDA has expressed its willingness to continue to work with EU CABs who wish to demonstrate their competence to conduct work for the FDA until they too have had sufficient opportunity to demonstrate their competence. There will also be opportunities for other qualified conformity assessment bodies to be listed as CABs for purposes of the MRA in the future.

³⁰Allen R. Bailey, "Mutual Recognition Agreements" (Brand Consulting Group, 1998), pp. 1-3, found at Internet address <http://bogiso.com>, retrieved, Nov. 17, 1999.

³¹FDA, The "U.S. -EU Mutual Recognition Agreement," (Rockville, MD: FDA, Aug. 7, 2000), pp 1-2.

³²U.S. industry representatives, personal and telephone interviews by USITC staff, Dec. 6, 1999.

IV. Assessment of the MRA

This section first provides information on the trade potentially affected by the MRA. It then reviews U.S. industry and government support and criticisms of the agreement. There has been a significant amount of U.S. and EU industry support for the MRA. Much of the criticism of the agreement has been based on concerns that the product coverage is limited and that regulatory approval of medical devices in the United States does not automatically confer approval in the European Union and vice versa. However, it may be difficult to fully assess the MRA until after it becomes fully operational in December 2001.³³

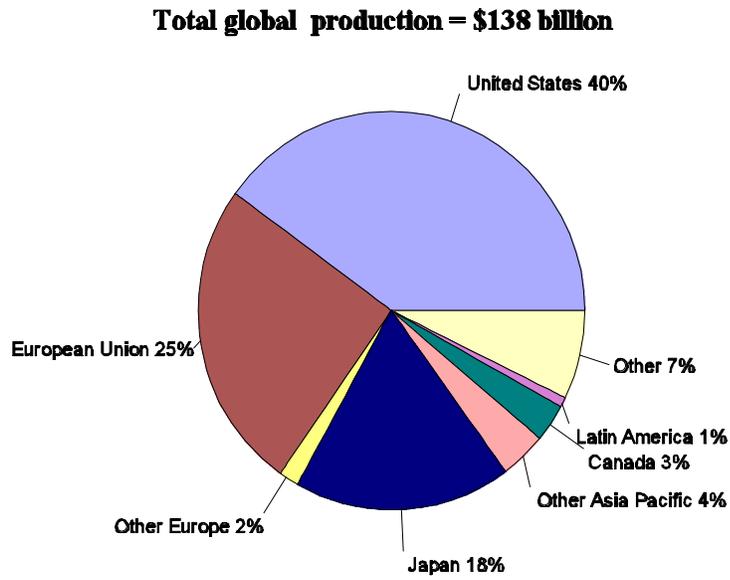
Production and Trade Affected by the MRA

The United States is the world leader in the manufacture of the medical devices and supplies potentially affected by the agreement (tables 2 and 3), accounting for about 40 percent of the estimated \$138 billion of such medical devices produced in the world in 1999 (figure 1).³⁴ The European Union was the second leading producer, accounting for about 25 percent in global production of such devices in that year. The United States and the EU are also one another's most important trading partners in these products. The EU accounted for 45 percent of U.S. exports in 1999 (table 4) and almost 42 percent of U.S. imports (table 5). During 1995-99, the U.S. trade surplus with the EU increased from \$1.8 billion in 1995 to \$2.7 billion in 1997 before declining to \$2.4 billion in 1999.

³³Michelle Egan, *Mutual Recognition and Standard-Setting: Public and Private Strategies for Regulating Transatlantic Markets*, American Institute for Contemporary German Studies Policy Paper No. 10 (Washington, D.C.: Johns Hopkins University, 2000), p. 16.

³⁴Estimated by USITC staff based on estimates of the U.S. Department of Commerce and Advanced Medical Technology Association (AdvaMed).

Figure 1
Global production of medical goods, 1999



Source: Estimated by USITC staff based on official statistics of the U.S. Department of Commerce, and various European and Japanese government and industry sources.

Table 4
Medical devices: U.S. exports of domestic merchandise, by principal markets, 1995-1999

Market	1995	1996	1997	1998	1999
	<i>Value (1,000 dollars)</i>				
Japan	1,686,581	2,028,572	2,041,247	1,986,015	2,119,631
Germany	1,047,694	1,218,463	1,171,461	1,174,391	1,349,633
Canada	976,422	1,000,785	1,078,565	1,224,114	1,347,820
Netherlands	621,572	826,764	1,083,047	1,026,458	989,433
France	666,440	692,656	801,977	882,420	939,409
United Kingdom	532,485	599,358	666,620	735,782	764,095
Mexico	252,561	379,880	459,247	522,296	578,679
Belgium	347,572	383,829	336,474	416,571	487,669
Australia	345,267	360,445	416,101	450,247	437,767
Italy	273,014	282,342	334,464	350,946	424,770
All other	3,076,399	3,408,766	3,847,715	3,866,133	4,025,966
Total	9,826,007	11,181,861	12,236,916	12,635,373	13,464,872
EU	4,091,676	4,692,670	5,230,162	5,554,642	5,999,171

Note--Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

Table 5
Medical devices: U.S. imports for consumption of merchandise, by principal sources, 1995-99

Source	1995	1996	1997	1998	1999
	<i>Value (1,000 dollars)</i>				
Germany	1,134,167	1,110,107	1,081,951	1,267,182	1,443,233
Japan	1,024,458	1,030,668	1,113,844	1,218,443	1,279,550
Mexico	667,296	779,463	923,327	987,014	1,097,986
Ireland	74,656	104,519	117,491	202,872	464,204
China	167,529	270,962	338,456	371,964	424,641
Israel	79,728	105,729	148,410	381,363	389,055
United Kingdom	280,831	289,734	305,564	348,716	365,257
Dominican Republic	282,641	301,171	307,788	330,852	359,021
France	240,451	257,335	276,540	291,034	327,606
Netherlands	191,397	201,074	242,413	280,373	325,246
Sub total	4,143,154	4,450,762	4,855,782	5,679,814	6,475,800
All other	1,398,737	1,493,260	1,712,916	2,017,504	2,324,388
Total	5,541,891	5,944,022	6,568,698	7,697,318	8,800,188
EU	2,332,217	2,414,609	2,549,839	3,004,847	3,637,926

Note—Because of rounding, figures may not add to the totals shown.

Source: Compiled from official statistics of the U.S. Department of Commerce.

MRA Support

Many U.S. medical device manufacturers and associations support the MRA.³⁵ They state that the MRA has a potential to improve patient access to safe and effective technologies, reduce unnecessary regulatory redundancies, enhance the access of the United States and EU companies to each other's markets, provide significant savings to both companies and regulators, and set the stage for further regulatory cooperation and harmonization. A number of larger U.S.-based companies with extensive European operations likely will continue to conduct product evaluations and factory quality reviews in the EU rather than in the United States although they gain some flexibility in choosing where the evaluations occur. Small- and medium-sized firms will likely benefit the most from the MRA.

According to medical device industry representatives, a major advantage of the MRA is that medical device producers will be able to work with a CAB in their own country and own language. Moreover, industry experts indicate that the MRA between the United States and EU will benefit manufacturers even more by providing a consistent approval system for all trading countries. However, the US-EU MRA and medical device annex do not harmonize the regulatory systems but maintain independent systems for regulating medical devices.

Some industry analysts assert that as equivalence³⁶ is achieved between the U.S. and EU regulatory systems, many of their responsibilities can be transferred to the private sector. As such, there will be reduced need for importing countries to engage in resource-intensive foreign inspection, sampling, and examination of products from countries with equivalent systems. This can expedite approvals of

³⁵U.S. medical device manufacturers, telephone interviews by USITC staff, Jan.-Apr. 2000.

³⁶U.S. government trade and regulatory officials assert that the MRA is not based on equivalence. It is an agreement to let entities operating in the jurisdiction of the exporting country conduct conformity with the requirements of the importing countries. At no time will regulatory officials try to find that the U.S. and EU systems for regulating medical devices are equivalent. U.S. regulatory and trade officials, e-mail communications to USITC staff, Dec. 15 and Dec. 21, 2000.

safe and effective products and in more comprehensive and effective surveillance of quality systems.³⁷ In addition, during the transition period, collaborative confidence-building activities between the FDA and EU member state authorities and CABs can result in harmonization of requirements at a high level of consumer protection.

The Transatlantic Business Dialogue (TABD), made up of U.S. and European business persons, has indicated that it regards the MRA as an important first step, leading to the harmonization of technical regulations and standards.³⁸ The TABD strongly encourages governments to use the Transatlantic Economic Partnership (TEP), made up of U.S. and EU government trade and regulatory officials, to expand the scope of the MRA in the direction of harmonizing regulations and ensuring the primacy of international standards.

One of the most significant aspects of the MRA for the United States is the use of private third-party reviewers as the CABs. Historically, the FDA has been responsible for all 510(k) evaluations and quality inspections. The Food and Drug Administration Modernization Act (FDAMA) of 1997³⁹ provided authority to the FDA to begin a third-party premarket review program for selected low to moderate risk medical devices. The premarket review program to be conducted by EU CABs under the MRA is similar to the domestic third-party review program established under FDAMA.⁴⁰ Although FDAMA, and not the MRA, provided such authority, the FDAMA authority should facilitate the use of third-party testing bodies under the MRA.⁴¹ In May 1999, the FDA's Office of Device Evaluation

³⁷FDA, "GMP /QS Regulation," pp, 1-2, found at Internet address <http://www.fda.gov>, retrieved Jan. 30, 1999.

³⁸Transatlantic Business Dialogue, Working Group 1, Standards and Regulatory Policies: Chapeau, *Mutual Recognition Agreement*, October 1999, p. 4.

³⁹Public Law No. 105-115.

⁴⁰FDA, *Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997*; *Fed. Reg.*, Nov. 2, 1998 (Vol. 63, No. 211), pp. 58746-58747.

⁴¹ James G. Dickinson, "Third-Party Device Reviews Beat FDA's," *Medical Device & Diagnostic Industry*, Aug. 1999, p. 34.

reported that the median review time of its pilot third-party-review program for selected low- and moderate-risk devices that ended on November 21, 1999, was 29 days faster than the median review time of the FDA staff for 510 (k) product reviews.⁴² Total elapsed time from the date of a third party's receipt of a 510 (k) to the date of the final FDA decision was a median of 54 days (a mean of 78 days), while the median review time for all in-house 510(k)s was 83 days. Many industry representatives believe that these results provide an indication of the potential benefits of the U.S.-EU medical device MRA for both U.S. and EU medical device manufacturers, which should be able to get their products to market more quickly.

The FDA is interested in the MRA because of its view that public health protection can be better assured through enhanced regulatory cooperation. Although the FDA agrees that cost savings to industry and to government regulatory authorities can be realized by an actual decrease in the number of inspections that are unnecessarily duplicative, there are additional benefits that may be achieved by the activities required under the MRA that make the endeavor worthwhile. According to the FDA, both the United States and EU will likely be able to save resources, including foreign travel time and expense.⁴³ However, CABs will have to participate in rigorous joint activities to show their proficiency in conducting FDA and EU evaluations. Based on such proficiency, both the FDA and the EU are expected to normally endorse product evaluations conducted by the other party, while reserving the final decision to themselves and maintaining the right to conduct their own evaluations if significant deficiencies are found in any reports.

⁴²Ibid.

⁴³Food and Drug Administration, *Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community*, Jan. 6, 1999, p. 3, found at Internet address <http://www.fda.gov>, retrieved Jan. 3, 2001.

According to the FDA, the equivalence of QS and other conformity assessment reports and evaluations between the FDA and EU member state authorities and CABs can be relied on to help ensure the safety, quality, and effectiveness of products exported to the United States while also reducing the regulatory burden on manufacturers. As EU CABs conduct more inspections for FDA, the MRA may permit FDA to redirect some of its inspectional resources away from the EU and to other countries where regulatory oversight is needed to assure that the devices exported to the U.S. are safe and effective. Currently the FDA and EU regulatory bodies conduct hundreds of overseas inspections each year. The FDA may thus be able to better target its limited foreign inspection and other resources devoted to imports and other regulatory concerns.

Criticisms of the MRA

Despite general support for the MRA by U.S. manufacturers and regulatory officials, there remain some reservations about certain aspects of the agreement. For instance, several major medical device manufacturers, with global operations, indicated that while they had hoped the MRA would remove redundancies in medical device approval in various countries, the MRA, in fact, combines both region's requirements, thereby resulting in more complexity.⁴⁴

Medical Device Manufacturers Association (MDMA) representatives stated that it is too early to judge the success of the MRA since it will not be fully operational until late in 2001.⁴⁵ Nevertheless, the association representatives indicated that they believe the structure of the agreement was good but would like to see more products eligible for conformity assessment covered by the agreement eventually.⁴⁶

⁴⁴U.S. medical equipment industry representatives, telephone interviews by USITC staff, March 28-29, 2000.

⁴⁵Medical Device Manufacturers Association (MDMA) representative, telephone interview by USITC staff, Mar. 29, 2000.

⁴⁶U.S.-government trade officials indicate that the United States and the EU are in the process of amending the product coverage in the MRA medical device annex. U.S. trade official, facsimile transmission to USITC staff, Nov. 30, 2000.

MDMA pointed out that as the MRA stands now, it is not true global harmonization because each side is merely conducting conformity assessment to the other party's rules.

The National Electrical Manufacturer's Association (NEMA) indicated that to be effective, the U.S.-EU MRA as it pertained to medical devices would have to be conceptually different,⁴⁷ with FDA accepting a device approved in the EU, and the EU accepting a device approved in the United States without further evaluation (U.S. trade and regulatory officials state that it is doubtful that such acceptance ever will occur).⁴⁸ Right now, the NEMA representatives state that the MRA is simply an exercise of accrediting test houses in Europe and the United States. A representative of the association indicated that this is not a great advantage over the previous situation. U.S. manufacturers are already used to going through EU notified bodies.

NEMA representatives indicated that one advantage of U.S. firms using third-party conformity assessment bodies under the MRA would be to increase the speed of conformity assessments under 510(k) procedures.⁴⁹ This could occur immediately since third-party assessments are covered in the current transitional period. However, there has been little awareness in the medical device industry concerning the possibility of firms having their products for the EU market evaluated through private third-party testing bodies in the United States. The association pointed out that if the CABs did a better job of promoting awareness of their bodies to U.S. medical device manufacturers, more U.S. manufacturers could get 510(k) applications approved at around the same time as EU approvals. NEMA representatives indicated that CABs have to better promote themselves or manufacturers will be reluctant to change.

⁴⁷National Electrical Manufacturer's Association (NEMA) representative, telephone interview by USITC staff, Mar. 29, 2000.

⁴⁸U.S. government regulatory and trade officials, e-mail communications to USITC staff, Dec. 15 and Dec. 21, 2000

⁴⁹Ibid.

Some medical device firms have indicated that the MRA should cover more devices than currently listed in the MRA annex.⁵⁰ A major problem in expanding the MRA to more products is the insistence of the United States in maintaining the priority of safety and effectiveness information over the safety and performance criteria required by the EU.⁵¹ In other words, the FDA is interested in not only the safety of a medical device but also its effectiveness in treating patients. The EU is more interested in the performance of the device and allowing the market determine how well it operates according to the manufacturer's claim.

U.S. industry representatives are concerned that some EU member states have enacted their own regulatory requirements that are in conflict with, or in addition to, EU requirements.⁵² Although medical device producers who obtain marketing approval in one country should be permitted to sell in any EU member state, they often face individual member state demands in addition to those laid out in EU directives. Even though member states are required to inform the European Commission of draft regulations to prevent the occurrence of new trade barriers, some member states have allegedly continued to introduce national regulations without notifying the Commission.⁵³ Because both U.S. and European industry representatives believe the level of these national regulations often greatly exceeds that contained in EU directives, there have been increased concerns that the EU single market is being

⁵⁰The FDA asserts that in February 1998, the FDA proposed to the EU a significant expansion of the list of devices eligible for 510(k) review under the MRA. It is FDA's understanding that the EU will accept this expansion in the near future. That agency states that it is willing to propose additional devices for 510(k) review when it expands the devices eligible for review under its domestic Accredited Persons Program. The FDA anticipates proposing such an expansion in 2001.

⁵¹Norbert Sparrow, "Global Harmonization Hits a Positive Note," Medical DeviceLink (Los Angeles: Canon Communications, 1999), pp. 1-4, found at Internet address <http://www.deviceLink.com>, retrieved June 20, 2000.

⁵²TransAtlantic Business Dialogue (TABD), "Medical Devices: Transparency of Regulatory and Reimbursement Decision," *TABD Mid Year Report*, May 10, 1999, p. 24.

⁵³Michelle Egan, *Mutual Recognition and Standard-Setting: Public and Private Strategies for Regulating Transatlantic Markets*, American Institute for Contemporary German Studies Policy Paper No. 10 (Washington, D.C.: Johns Hopkins University, 2000), p. 22.

thwarted.⁵⁴ Not only do such measures impede the effective and efficient function of the single market, they also, in some cases, negatively affect the MRA.⁵⁵

For instance, a major sticking point that concerns both U.S. and EU medical device manufacturers is the French government's belief that other EU members' technical regulations for medical devices are not enough to guarantee product safety.⁵⁶ The French proposal would institute a separate approval process for certain high-risk medical devices manufactured by both domestic and foreign producers.⁵⁷ Both U.S. and EU trade associations are working with France and the European Commission to ensure the current situation is resolved so U.S. and other EU medical device manufacturers may take advantage of the long-anticipated European single market.

V. Outlook

Most U.S. medical device manufacturers conclude that the present medical device MRA with the EU should not be seen as a solution but as a starting point.⁵⁸ They indicate that the ultimate goal should be an MRA whereby if a firm obtains approval for a product in either the EU or the United States, it will automatically be approved or accepted by the other party. They believe that as the FDA gains experience working with both U.S. and EU CABs, it should gain greater confidence in the third-parties. U.S. industry representatives hope that when the FDA has confidence in the EU CABs and the EU has confidence in the U.S. CABs, they may get to the point where CE-marked (European approved) medical devices are accepted as just as good as FDA-approved devices and vice versa.⁵⁹

⁵⁴U.S. and European industry representatives, telephone interviews by USITC staff, Jan. 29, 2001.

⁵⁵Ibid.

⁵⁶"A French Twist on CE Marking," *Medical Device and Diagnostic Industry*, Feb. 1998, pp. 24 and 26.

⁵⁷Ibid.

⁵⁸NEMA representative, telephone interview by USITC staff, Mar. 29, 2000; MDMA representative, telephone interview by USITC staff, Mar. 29, 2000; and U.S. industry, trade, and regulatory officials, interviews by USITC staff, 1999-2000.

⁵⁹U.S. trade and regulatory officials disagree with industry officials that such a scenario could come about without significant policy, legislative, and regulatory changes.

Even though U.S. industry and government trade and regulatory officials are generally supportive of the present MRA with the EU, they are not enthusiastic about negotiating further MRAs with other trading partners. The officials state that negotiation of the MRA with the EU was time and resource intensive, requiring trade, regulatory, and technical experts for all of the sectors covered by the MRA to meet frequently to exchange information, participate in workshops, and negotiate terms of the agreement.⁶⁰ Moreover, some of the officials indicate that the multi-sectoral approach to the U.S.-EU MRA resulted in complexities that were difficult to address. They also point out that the European Union refused to complete the MRA until work was completed for all of the six sectors, leading to significant delays in completing the agreement. Based at least partly on recent MRA successes completed in the telecommunications equipment area, trade and regulatory officials indicate that any future MRA negotiations should be conducted for one industry sector at a time rather than as a package.

However, both U.S. business and government officials agree that the United States should not support or seek multiple MRAs with other countries “because the United States is utilizing its limited resources to ensure the success of this MRA.”⁶¹ Further they indicate that separate MRAs between developed countries would result in “piecemeal and complex arrangements” rather than one global system agreed to by all developed countries. They also point out that separate MRAs among advanced countries would result in several hundred MRAs which would be unwieldy and unmanageable.

⁶⁰U.S. industry, trade, and regulatory officials, interviews by USITC staff, Jan.-Apr. 2000.

⁶¹U.S. Department of Commerce, in cooperation with Advanced Medical Technology Association (AdvaMed), MDMA, and NEMA, “U.S.-EU Medical Device MRA Update,” Mar. 19, 1999, pp. 1-4, found at Internet address <http://www.ita.doc.gov>, retrieved Nov. 15, 1999; and U.S. industry representatives and government officials, telephone interviews by USITC staff, Jan. 3 and 11, 2001.

In the future, U.S. government officials recommend that MRAs be established only when other often less stringent means such as unilateral recognition or “suppliers declaration”⁶² and other less resource-intensive approaches are not feasible. Although the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) encourages use of MRAs when appropriate, a 1997 report of the WTO TBT committee recognized that MRAs are not the only solution to technical trade barriers. In that report, a WTO review of the operation of the TBT agreement highlighted members’ obligations to ensure that conformity assessment procedures are not too strict or applied more strictly than is necessary to give importing members adequate confidence that products conform with relevant technical regulations and standards.⁶³

Specifically Article 6.1 of the TBT encourages unilateral recognition by stating that “Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. Further, Article 2.7 states that “Members shall give positive consideration to accept as equivalent technical regulations of other Members even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations.” Thus, in instances where a party’s technical regulations are deemed to meet the other country’s regulatory objectives, even though the regulations are not identical, approval of the

⁶²Suppliers’ declaration (also known as manufacturers’ declaration or self-certification) is a form of conformity assessment in which a manufacturer or supplier provides its own written assurance of conformity to a standard or technical regulation. National Research Council, *Standards, Conformity Assessment and Trade Into the 21st Century* (Washington, DC: National Academy of Sciences, 1995), p. 68.

⁶³WTO Committee on Technical Barriers to Trade, Report of the First Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, Geneva, Nov. 8, 1998.

product in one country can be recognized by the other party. Such recognition precludes the need to conclude mutual recognition agreements.

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