

# Appendix 1.—Governmental Regulation of International Trade in Medical Devices: United States, Canada, Japan, United Kingdom, France, Federal Republic of Germany, and Mexico<sup>1</sup>

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## United States

### Regulation of Imports

Two types of government regulations affect the ability of foreign medical devices to compete in the U.S. market. The principal focus of this appendix is the first type—those regulations that directly impose requirements on foreign manufacturers and importers, or on the imported device itself. The second type of regulation indirectly influences the actual sales of imported medical devices by affecting their competitiveness with devices manufactured in the United States.

The regulations of the Food and Drug Administration (FDA) are designed to ensure that only safe, effective, and truthfully labeled medical devices are sold in the United States. In theory, this means that foreign manufacturers and imported devices must meet the same criteria as U.S. firms and domestically manufactured devices. In practice, however, because of budgetary constraints, foreign manufacturers of medical devices are treated somewhat differently, since they are not inspected so regularly as domestic manufacturers, and, unlike their domestic counterparts, they receive advance notice of an upcoming inspection.

The Customs Service, which is supposed to ensure that medical device importers comply with the general rules applicable to all imported products, in 1979 delegated certain of its general responsibilities to FDA (304).

Requirements of the Food and Drug Administration.—FDA regulations impose a number of requirements that must be fulfilled before a device can even be considered for import approval, and these requirements are the same as those imposed on domestic manufacturers (see ch. s). Registration of a foreign manufacturer of medical devices is voluntary, but FDA tries to encourage such establishments to register. Registration is mandatory for the importer (initial distributor) of a foreign medical device (21 CFR 807.20, 1982). Unless the importer is registered, FDA will not allow the import to be released for sale in the United States.

A foreign manufacturer or distributor must also supply FDA with a list of every device that it exports

to the United States (21 CFR 807.40, 1982) or authorize an exclusive distributor to file the medical device listing on its behalf. Failure to list a device will result in its exclusion from the United States.

Foreign manufacturers, unlike domestic producers, usually have at least 30 days notice prior to an FDA inspection. Because of the expense and logistics involved, foreign inspections by FDA are infrequent. Furthermore, it is likely that they will become even more infrequent in the future because of recent reductions in FDA travel funds.

The third set of FDA preimportation requirements involves premarket notification and approval. The scope of these requirements varies based on the nature and history of the product. If a product was being imported into the United States prior to the Medical Device Amendments of 1976, it may continue to be imported without notification. But if a device was not being imported prior to 1976, the manufacturer or importer is required to submit a premarket notification to FDA. If FDA finds that a product is substantially equivalent to a preamendments device, importation and marketing will be permitted. If a device is not substantially equivalent to a preamendments device, it may be subject to the further requirement of premarket approval (see ch. s) In that case, neither importation nor marketing of the device is permitted until approval is received from FDA.

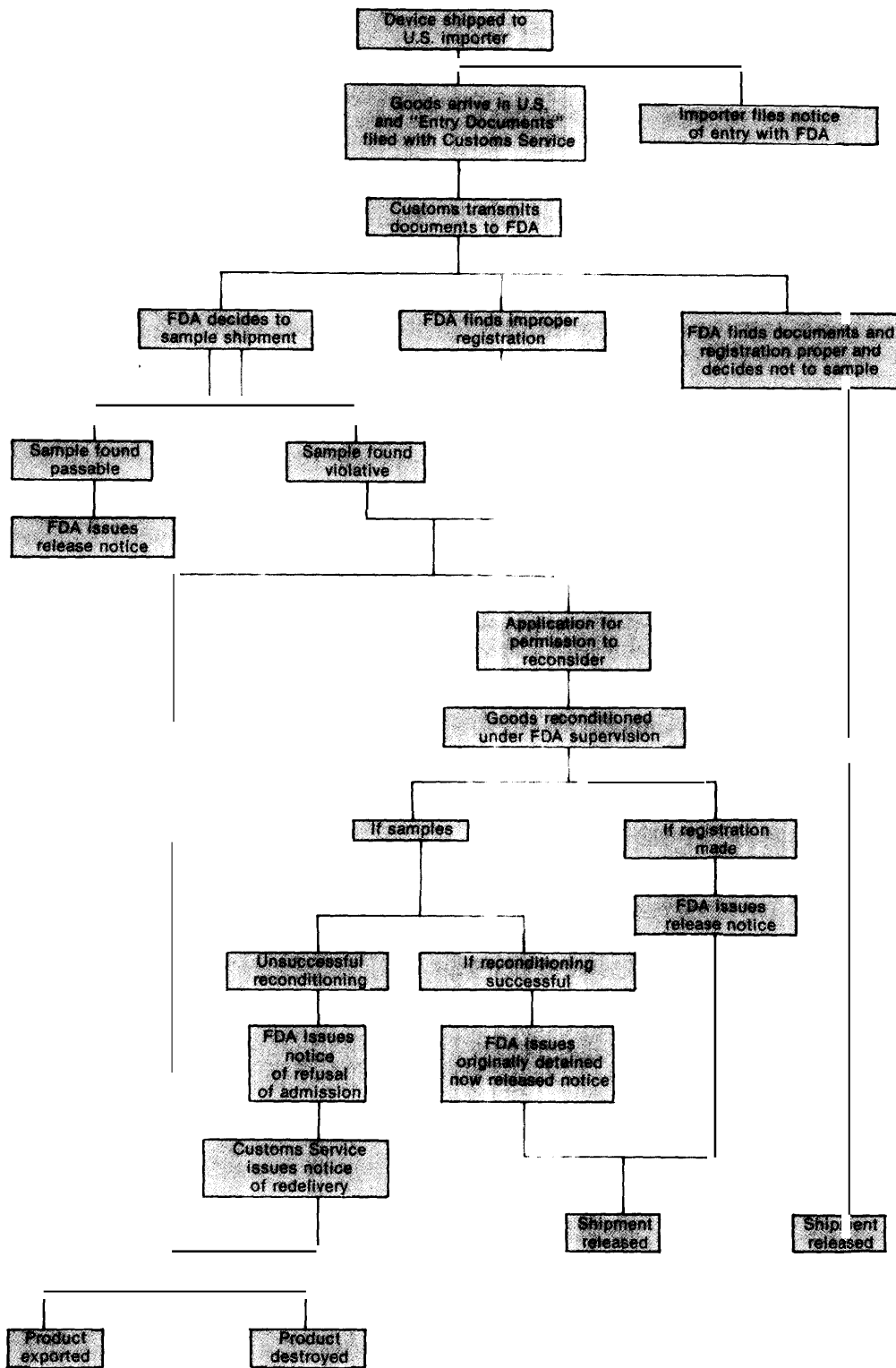
The fourth form of preimportation requirement relates to manufacturing. Both foreign and domestic manufacturing establishments are subject to inspections to ensure compliance with good manufacturing practices, although the right of such inspection may be limited by foreign governments or the foreign firm involved. If a satisfactory arrangement for an inspection cannot be made, FDA has the authority to exclude the product since it would be unable to determine whether the device met the good manufacturing practices requirements of the Federal Food, Drug, and Cosmetic Act. (FDA has encountered few, if any, problems in inspected medical devices firms in the countries included in this appendix (204). )

Pursuant to a 1979 delegation of some of the Customs Service's authority, FDA monitors compliance with customs regulations, collects samples, issues notices of sampling, and issues notices of refusal of admission at certain ports (384). Figure I-1 outlines the steps involved in clearing customs.

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<sup>1</sup>Excerpted from a paper prepared for OTA by Kaye, Scholer, Fierman, Hays & Handler (181).

Figure 1-1.—FDA Import Procedures for Foreign Medical Devices



SOURCE: Office of Technology Assessment

There is no evidence to suggest that FDA regulations were adopted for the purpose of erecting barriers to international trade in medical devices, or that they are administered with such an intent. As a practical matter, however, certain regulations do have a different impact on importers than on domestic manufacturers. For example, domestic producers may have an advantage with respect to participation in the notice and comment process and informal negotiations leading to the development of regulations. Not all regulations, however, operate to the advantage of domestic producers. For instance, due to logistical concerns, inspections under the good manufacturing practices regulations are more frequent, and undoubtedly more burdensome, for domestic producers than for foreign manufacturers.

FDA has a variety of administrative sanctions equally applicable to domestic and foreign manufacturers that can be used to prevent the marketing of adulterated or misbranded medical devices. There are, however, important practical distinctions between FDA's authority over domestic medical devices and imported devices. In domestic commerce, FDA has only formal statutory authority to bring enforcement actions such as seizures with respect to devices when those devices are actually misbranded or adulterated. FDA's discretion is therefore limited by the requirement that it be able to prove that a device is in fact adulterated or misbranded. FDA's enforcement authority over imported devices is broader; it has the authority to act when an imported device *appears* to be misbranded or adulterated (21 U.S. C. 381(a), 1976; (294)). The "appears" standard significantly modifies the usual burden of proof and offers more discretion to FDA to detain or otherwise halt potentially defective or hazardous medical devices before they are distributed to consumers in the United States. On the basis of this authority, FDA actively monitors imports to prevent the introduction of offending devices.

On the other hand, it must be noted that FDA has a variety of informal administrative remedies, such as regulatory letters or recalls, which it employs where it does not wish to institute a formal enforcement action. Some of these actions may be more difficult to apply to foreign manufacturers than to domestic manufacturers.

Customs Service Regulations.—The result of the delegation of customs' authority to FDA is that the only customs Service regulations applicable to medical devices are those generally applicable to all imported products. These regulations fall into three categories: those pertaining to "entry" of goods into the United States, those pertaining to the assessment of

duties on imported products, and those which pertain to the physical appearance of imported goods.

This classification system may change in the near future. The U.S. International Trade Commission recently prepared a study in anticipation of the conversion of the U.S. tariff classification into an internationally agreed-upon, harmonized system of tariff classification. If adopted, the system will result in a more uniform classification of medical devices between different countries, and thus make the gathering of statistical data easier, but it will have little economic effect on imports into the United States.

Tariffs applicable to medical devices are now generally in the range of 5 to 10 percent, which is comparable to the rates applied by other countries to the imports manufactured in the United States.

The third set of regulations administered by the Customs Service relate to the physical appearance of, and markings on, devices. Although these requirements must be met by importers, they have no significant impact on the pattern of trade in medical devices.

U.S. Trade Laws.—In addition to being subject to FDA and Customs Service regulations, imports of medical devices are subject to regulation under the general U.S. trade laws. These laws, which are briefly described below, can be used to impose additional duties, quotas, or other restrictions on the importation of medical devices that might cause injury to the domestic medical devices industry. There are two basic categories of such trade laws: those that impose restrictions when imports that are traded "unfairly" injure the domestic industry, and those that permit restrictions on imports where there is injury to the domestic industry, without regard to "unfairness."

The unfair trade laws have not often been invoked in the medical device area. Nor has any part of the medical device industry yet attempted to bring a countervailing duty or antidumping case against imported medical devices.

Two actions have been brought against importers of medical devices on the grounds of unfair trade practices. In June 1982, the U.S. International Trade Commission instituted an investigation involving certain computed tomography (CT) scanner and gamma camera medical diagnostic imaging apparatus. The investigation involved allegations that equipment imported from Israel violated a patent granted to a U.S. company (312). In March 1983, the commission made a preliminary determination that there was no violation and the case was terminated. In September 1983, the commission initiated a second investigation involving cardiac pacemakers and components (322). This complaint was also based on alleged patent infringement and is currently pending before the commission.

## Regulation of Exports

In the United States, the export of medical devices is not regulated to anywhere near the same degree as imports. To the extent that export regulations do exist, they are administered principally by two agencies, FDA and the Office of Export Administration (OEA) in the U.S. Department of Commerce.

**FDA Export Regulations.**—For export purposes, medical devices can be divided into three categories. The first category of devices is by far the largest; any medical device that can be marketed legally in the United States can be exported legally from the United States without prior approval by FDA.

The second category of devices are those that cannot be marketed in the United States, but that can be exported without FDA approval if the product (sec. 801 (d)(l) of the Federal Food, Drug, and Cosmetic Act):

- meets the specifications of a foreign purchaser,
- does not conflict with the laws of the country of the foreign purchaser,
- is labeled for export, and
- is not sold or offered for sale in domestic commerce.

Prior FDA approval is not required for exports under section 801(d)(l), but FDA may at any time require an exporter to show that the exports that it is making under this section comply with the section's four requirements.

The third category of medical devices, those exported under section 801(d)(2) of the act, includes certain types of adulterated or misbranded devices that may be exported only with specific FDA approval and not under the less strict standards of section 801(d)(l). The third category specifically includes products that violate performance standards; that are subject to but have not received premarket approval; that are subject to limited investigational use, or that are banned in the United States. As a practical matter, most devices requiring FDA approval for export are those that require but have not yet received premarket approval or that are subject to limitations as investigational devices.

To obtain FDA approval for export of a medical device in the third category, an exporter must submit to FDA an "Export Request." This request must contain a description of the device and its status under U.S. law, and a letter of acceptance from the government of the importing state. This letter of acceptance must state:

- that the device is not in conflict with the laws of the importing state,
- that the foreign government has full knowledge of the status of the device in the United States, and

- that the import is permitted (along with any restrictions that might be imposed).

On the basis of this information, FDA will approve the exportation of the device if it would not be contrary to public health and welfare.

The FDA approval process for exports under section 801(d)(2) raises two problems for U.S. exporters. The first arises from the need to obtain explicit authorization from the foreign government for the importation of a device and is also faced by exporters under section 801(d)(l). Since many countries have no laws governing the approval of medical devices, it is difficult for these countries to inform FDA that a device is approved for import. In such cases, FDA will accept a statement from a foreign government that it has no laws prohibiting the importation of a particular medical device. This procedure may only partially alleviate the difficulty because in many of these countries no one is authorized by law to make even such a limited statement to FDA. The second problem is the vagueness of the "public health and welfare" standard used in section 801(d). Neither the Medical Device Amendments of 1976 nor the legislative history indicate whose health and safety is to be protected by FDA.

In practice, FDA's reliance on the standard is minimal; the decision to allow an export is usually made simply on the basis of whether the foreign government approves the importation of the device. From October 1, 1981 through September 30, 1982, FDA issued 260 letters approving export of medical devices under section 801(d). In the same period, eight requests were not approved. From October 1, 1982 through March 31, 1983, 116 approvals for export were given, five devices were not approved, and one previous approval was rescinded.

**Department of Commerce Export Controls.**—Medical devices, along with all other U.S. exports, are subject to the export controls in the Export Administration Act of 1979. That act authorizes the President to impose controls on exports for reasons of national security, foreign policy, and short supply.<sup>2</sup> The principal authority to administer these controls has been given to the Commerce Department's OEA; other agencies including the Departments of State, Defense, Energy, and Treasury have an advisory role in OEA licensing decisions.

<sup>2</sup>The Export Administration Act originally expired on Sept. 30, 1983. The controls under the act were at first extended on a temporary basis by the President pursuant to the authority of the International Economic Emergency Powers Act. Congress later passed a bill extending the act until the end of February 1984. Congress is considering reauthorization with a variety of amendments, but it is not possible to predict what new provisions will be included.

All exports from the United States must be authorized by either a general or a validated export license. A general license is an authorization to export granted by regulation rather than by specific application. General licenses can be used to export any good to any destination, as long as neither the good nor the destination is controlled. Validated licenses are required whenever the export of a specific commodity is controlled to a specific destination.

Determination of whether a particular commodity requires a general or validated export license is made with reference to the Export Administration Regulations and the Commodity Control List.

Medical devices fall into several product classifications of the Commodity Control List, depending on the nature of the product and its technological sophistication. For example, most medical, surgical, and dental supplies are classifiable within the miscellaneous product group item 6999 G, "other commodities not elsewhere specified," which can be exported under general license except to Cuba, Kampuchea, North Korea, and Vietnam. Most X-ray equipment is classified in the Electronic and Precision Instruments Product Group in item 1533A, which requires a validated license to any destination other than Canada.

In most cases, the requirements applicable to medical devices are less than clear because the Government's interests in restricting exports are based not on their status as medical devices but on the fact that they include some form of technology that the United States wishes to control, such as computer or laser technology. An example can be seen in item 1522A, "lasers and laser systems including equipment containing them," for which a validated license is required for all destinations except Canada. Although most medical laser systems would appear to be covered by this classification, the explanation of this item in the Commodity Control List provides no further specific guidance. Treatment of medical equipment incorporating semiconductor or computer technology can be even more complicated and can depend on the speed of the computer, its capacity, the capability of the computer, and the materials from which the semiconductor is made. Thus, similar medical devices could be classified as different items, with one requiring only a general license and the other a validated license because the latter has a computer that operates at a slightly higher rate of speed or because its semiconductors are made of a different material.

This export control process and the intricate classification system raise the level of uncertainty for medical device exporters. Whenever a validated license for a transaction is required, an exporter cannot be sure whether the export will be approved, in what form it will be approved, or how long approval will take.

The eventual destination of the device raises additional questions. It is probable that export licenses will be granted for the export to Western Europe or Japan of a medical device incorporating controlled technology. Export of the same device to a country in Eastern Europe or to the Soviet Union may or may not be allowed, depending on the discretionary decision of the Commerce Department as to whether the release of the technology may hurt U.S. national security. Even if export approval is granted, conditions may be imposed, including substantial modification of a device in order to prevent the release of sensitive technology. The question for the exporter is whether a prospective buyer would be willing to accept a device that is significantly different from that which the buyer originally intended to purchase.

Regardless of whether the export of a medical device is eventually approved, the length of time involved in the licensing process is a disincentive to export. In most cases, the Commerce Department issues an export license in 4 to 6 weeks. This time frame, however, rests on the assumption that the export does not involve highly sensitive technology and is not destined for a sensitive country such as the Soviet Union, and that the exporter has supplied all the correct documentation to the Commerce Department. Delays occur when the exporter submits insufficient or incomplete information or when other agencies, usually the Departments of State and Defense, exercise their right to review an application. In such cases, delays of months and, in extreme cases, years may result.

A number of proposals currently being considered to facilitate export while protecting national security, such as elimination of export licenses to most Western European countries, reduction of controls in situations where identical technology is available from other foreign sources, and reconsideration of which technology is deemed to be militarily sensitive, may remove many medical devices from controls. Similarly, Administration moves to ease restrictions on exports to China will open up that market to increasing numbers of U.S. medical devices.

### U.S. Government Export Promotion Activities

Department of Commerce.—Most Government export promotion activities are centered in the Department of Commerce. Among the department's export promotion activities are the Export Trading Company program, the dissemination of information about standards, the development of market research data, and the activities of the Foreign Commercial Service.

Under the Export Trading Company Act (Public Law 97-290) groups of U.S. exporters are able to combine their resources to aggressively seek export mar-

kets. Groups of medical device exporters or even a single medical device manufacturer may obtain a certificate from the Department of Commerce enabling them to engage in certain activities that would otherwise be prohibited under antitrust laws. There has been little experience in the operation of export trading companies, and it will be some time before it can be determined whether the program will in fact significantly promote U.S. exports. At the present time, no medical device manufacturers appear to have attempted to establish export trading companies.

A second Commerce Department function of potential significance to the medical device industry is the compilation by the National Bureau of Standards of lists of applicable foreign standards. This project has not yet been completed, but when it is, the ready availability of applicable foreign standards will be of help to U.S. medical device exporters. There is currently no compilation of medical device standards. FDA's Bureau of Medical Devices publishes an annual survey of standards for medical devices, but it simply identifies relevant standards of most major U.S. trading partners and does not reproduce them. The actual standards are available only from sources in the foreign country, or, in some cases, from private organizations in the United States, such as the American National Standards Institute, Inc.

The Department of Commerce also provides a variety of resources for potential exporters, including market research and computerized lists of market opportunities. The department has, for example, commissioned detailed market surveys of the medical device markets in a variety of countries. These Country Market Surveys include information about market conditions, the status of foreign competitors, the major end-users, and forecasts of the markets for particular medical devices. Also included are brief reviews of foreign government regulations. The department also maintains lists of potential purchasers of U.S. goods.

Although the services provided in the Department of Commerce are not a substitute for individual market analyses by an exporter and do not eliminate the exporter's need for competent assistance in the foreign market, they do provide some help, particularly to first-time exporters to certain markets.

Department of the Treasury.—The most significant financial export incentive provided by the U.S. Government and available to exporters of medical devices is the "DISC" export tax system. Under the DISC provisions of the income tax code, a corporation engaged in export trade may set up a corporation called a Domestic International Sales Corp. (DISC), through which it channels its export sales. It is then permitted to defer tax on portions of the income of the DISC.

Under the complicated accounting rules applicable to DISC taxation, the amount of income thus sheltered varies, depending on the level of export sales made by the DISC, but generally up to 20 percent of the income generated by export sales can be sheltered.

The DISC system is currently under congressional review. International criticism of the DISC system as an illegal export subsidy persuaded the United States to make a commitment to its foreign trading partners to eliminate it. There are several possible replacements for the DISC system pending before Congress.

U.S. Trade Representative.—The U.S. Trade Representative (USTR) is the principal U.S. negotiator for international trade agreements. USTR represented the United States at the Tokyo Round of the Multilateral Trade Negotiations, held under the auspices of the General Agreement on Tariffs and Trade (GATT), which led to the development of the Standards and Government Procurement Codes. The Standards Code is an agreement among the signatory countries, including most major export markets for U.S. medical devices, not to use standards as nontariff barriers (see app. H). The Government Procurement Code is an agreement to expand the opportunities of foreign sellers to compete for Government contracts. By seeking to enforce U.S. rights under these agreements, and by negotiating for an expansion of their scope, USTR can play a role in expanding foreign markets for U.S. medical devices.

USTR also conducts bilateral negotiations to remove specific trade barriers to U.S. goods. The issues are usually brought to the attention of the USTR by private industry. For instance, USTR has been negotiating a reduction in Japanese medical devices trade barriers for the last year. The U.S. medical device industry brought to the attention of USTR a number of Japanese import procedures that had the effect of significantly limiting the access of U.S. products to the Japanese market. Among these barriers were regulations requiring chemical testing for devices, restrictions on changes in import agents, complex procedures for approving minor device changes that do not affect health and safety, and the generally slow process leading to approval of medical devices. Negotiations between the Japanese and USTR have had limited positive results, with some restrictive procedures having been modified to accommodate U.S. concerns (see below).

## Canada

The Canadian market for medical equipment, including medical devices, was approximately \$440 million in 1981 (241). By 1980, imports of medical equipment had reached an estimated \$391 million annually, constituting 88 percent of the total market. By far the

largest share of the imports, 82 percent in 1980, came from the United States, and many of the domestic Canadian medical device manufacturers are owned by U.S. firms. Canada has had universal health insurance since the early 1970s.

### Import Requirements

There is no import license required for medical devices. However, under regulations issued by the Ministry of National Health and Welfare, it is illegal for any person to import for sale any device which does not meet the specific requirements relating to safety, efficacy, and truthful labeling of the Canadian Food and Drug Act or the Medical Device Regulations (255). As in the United States, goods found to be nonconforming may be relabeled or modified by the importer to meet Canadian requirements.

In addition, within 10 days of the first sale of a device in Canada, importers are required to provide information to the Health Protection Branch of the Ministry of National Health and Welfare regarding the foreign manufacturer or importer, the Canadian distributor, the model number, any drugs present in the device, statements of the uses for which the device is being offered, and the method(s) of sterilization, if any, recommended by the manufacturer.

Extra-oral dental X-ray equipment is subject to special import restrictions (254). Imported radiation-emitting devices must comply with all applicable standards regarding design, construction, and function. Canada will accept X-ray devices certified under U.S. FDA performance standards.

Tariffs on medical devices now average approximately 15 percent and are expected to be reduced to 9.5 percent by 1985 under GATT commitments already made by Canada (241).

### Product Approval Process

Both imported and domestically manufactured medical devices are regulated by the Health Protection Branch of the Ministry of National Health and Welfare, which carries out laws such as the Radiation Emitting Devices Act, the National Health and Welfare Act, the Food and Drugs Act, and the Hazardous Products Act, which concern the types of information required to be submitted and the timing of the submissions.

Under the Canadian product approval system, the manufacturer or importer of a medical device must conduct premarket tests and present the results to the Health Protection Branch. The data must indicate the benefits and performance results claimed for the device. In addition, at any time the manufacturer must be prepared, if requested, to provide to the Assistant

Deputy Minister of the Health Protection Branch information on test methods and test results (255).

Only recently has the Canadian Government begun to develop regulatory standards for medical devices. The Bureau of Medical Devices in the Health and Protection Branch of the Ministry is concerned with the technical and scientific aspects of medical device regulation regarding the quality, safety, and efficacy of medical devices (241). The bureau conducts research to allow it to enact specific safety and performance standards for various types of medical devices and to develop test methods to evaluate conformity with these standards. It also tests devices for compliance with standards, to assess manufacturer's claims for safety and efficacy, and to evaluate newly suspected hazards in previously approved devices.

In addition to its scientific duties, the bureau accumulates information on sales of medical devices in Canada and monitors recall developments in foreign countries. When appropriate, it also initiates recalls of imported devices.

Only a few types of medical devices are presently subject to mandatory standards promulgated by the bureau (241). In addition to the standards for radiation-emitting devices, there are now national standards on leakage of current from electromedical devices and the design and operation of oxygen inhalators. These standards tend to be similar, though not identical, to U.S. standards.

The bureau has also enacted regulations requiring premarket review of all implantable medical devices and submission by the manufacturer of safety and effectiveness data. It is expected that the bureau will issue additional standards for a number of medical devices in 1984—including labeling and packaging standards for radioenzyme testing devices, infant incubators, medical gas cylinders, and ozone emissions from medical devices.

Medical devices that are "new" within the definition of the Canadian Food and Drugs Act are subject to additional regulatory requirements first imposed in 1975 (255). At the present time, the only products that fit this category of "new" devices are intrauterine devices, cardiac pacemakers, prolonged-wear contact lenses, and intraocular lenses. Even these devices are considered new only if they have not previously been sold by the same manufacturer in Canada, differ from a device previously sold by the same manufacturer in Canada, or are identical to a device previously sold in Canada by the same manufacturer but recalled or withdrawn from the Canadian market. To be sold in Canada, new devices must receive a Notice of Compliance from the Health Protection Branch.

In addition, it is usually necessary for manufacturers of certain medical devices to comply with standards

set by the Canadian Standards Association, an independent, private body. The association has two general specifications that govern X-ray equipment and electromedical equipment. Provincial governments enforce compliance with these standards (241).

### Other Market Factors

Other than tariffs, which are temporarily somewhat higher than in the other developed countries in this study, the Canadian market remains remarkably free of direct and indirect import barriers. The health care delivery system does not discriminate overtly against purchase or use of foreign medical devices. However, the Canadian Federal Government has had a practice of granting a preference to goods of Canadian origin when making purchasing decisions. This has taken the form of accepting bids by Canadian suppliers that are within a specified range (5 to 15 percent) of the lowest bid offered by a firm importing similar goods.

Some provinces, particularly Ontario and Quebec, have adopted similar preferences for products from within the province. Although the Federal and Provincial governments purchase most of the medical devices sold in Canada, the effect of their procurement policies on imports has not been as great as might have been expected, probably because except for disposable the Canadian medical devices industry is not well developed.

### Japan

The Japanese market for all medical equipment, including medical devices, was estimated to be about \$1.24 billion in 1982 (122). The share of the Japanese medical equipment market held by imports has in recent years been only about 23 percent, one of the lowest percentages for any industrialized country except the United States. The United States is the largest supplier of medical equipment in Japan, providing approximately 60 percent of all such imports in 1982.

### Import Requirements

Special technical import requirements apply to many products, including medical devices. When a device is subject to one of these technical requirements, a firm must apply to the Ministry of International Trade and Industry (MITI) for an import quota certificate. In addition, U.S. products that require an export license under the U.S. Export Administration Act or are subject to other U.S. export controls must also have an import certificate. Most medical devices are also subject to technical inspection at the point of en-

try to Japan to assure that any applicable standards have been met.

Under the Pharmaceutical Affairs Law, importation of medical devices into Japan must be approved by the Ministry of Health and Welfare unless the devices bear the Japanese Industrial Standards Committee (JIS) mark of approval (243). The term medical device includes instruments for use in the diagnosis, cure, or prevention of disease in man or animals, or intended to affect the structure or function of the body and which are designated by Cabinet Order.

Two types of licenses are necessary to import a medical device. The first is a license for professional importation, a general license required of all importers, which signifies that a company or person is qualified to sell medical equipment in Japan. The purpose of this licensing procedure is to ensure that each company importing medical equipment to Japan has the capability and knowledge to service the equipment and instruct purchasers in its proper use. Each office of an importing firm must be separately licensed for professional importation. These licenses are valid for only 3 years.

Each type of medical device to be imported must also be granted a separate product license, which is to ensure the quality, safety, and efficacy of the device (243). To be granted a license, the device, if it has not already received the JIS mark, must go through a time-consuming and rigorous testing and approval process. Virtually any modification in the design or type of a device being imported, even if it does not change the product's performance, requires a repetition of the product approval process discussed below, as though an entirely new product was being licensed.

Until August 1983, only an importer could apply for a product license. The theory behind this requirement was that the importer, rather than the foreign manufacturer, actually stood behind the device in Japan for product liability and all other purposes. For this reason, transfer of a product license from one importer to another was forbidden. The effect of this requirement was to limit drastically the ability of overseas suppliers to change their Japanese distribution agents, since switching agents required submitting a new product license application, causing delays of 6 months to 2 years.

In response to growing pressure from European and U.S. Government agencies (3) and trade groups, the Japanese Ministry of Health and Welfare in April 1983 announced planned changes in the importer and product licensing process (173). The most significant modification was that, effective August 1, 1983, a foreign manufacturer could apply for a product import license. The foreign manufacturer must submit the same docu-



ments and data relating to a device's safety and efficacy that are required of an importer applicant and designate an "in-country caretaker," who handles the responsibilities ordinarily imposed on a domestic manufacturer.

Approval of a foreign manufacturer's product import application also depends on the payment of all costs for an onsite inspection of the foreign manufacturer's overseas facilities. Theoretically, all U.S. manufacturers importing new devices to Japan will be subject to inspection. A "grandfather clause" limits the applicability of this new system to medical devices not currently on the Japanese market. A recent change in the regulations issued under the medical device law allows product licenses to be transferred from one importer to another in certain cases.

Japan applies GATT tariffs to medical devices. The rates now average between 6 and 8 percent and are scheduled to decrease by 0.5 percent on average in 1984 (122). Japan has adopted the basic Customs Cooperation Council Nomenclature (CCCN) for purposes of classifying imports, including medical devices.

### Product Approval Process

Applications for approval of the product license discussed above are made to the local prefectural government and must be accompanied by the results of clinical tests conducted in Japan (242). If the device is identical to an already approved item or has received the JIS mark, approval by the Pharmaceutical Affairs Bureau is automatic. Otherwise, a minimum of two clinical studies conducted in authoritative general or university hospitals is required. Because tests conducted only on Japanese nationals are acceptable, U.S. firms have to repeat clinical tests in Japan that have already been conducted elsewhere (3).

The time elapsed between submission of an application and the receipt of final approval is a minimum of 3 months and can be as much as a year or more (215). The Government official responsible for the review need not inform the manufacturer in advance of the data needed and may require additional studies and information. As a result, considerable time elapses if the Ministry of Health and Welfare returns applications for more data.

Another problem that has been raised during U. S.-Japan discussions of medical device regulation is the need to apply to local prefectural offices, which then forward data to the Ministry of Health and Welfare. The U.S. Government has urged Japan to allow local prefectures to approve routine applications, such as changes in the color and size of a product.

JIS, a part of MITI, has broad powers to establish standards for industrial products. JIS standards are not

usually identical to the corresponding international or U.S. standards. Although devices are not required by law to conform to JIS standards, and some domestically manufactured items that do not conform are actually sold in Japan, it is very difficult to import and sell products that do not conform to JIS standards.

Foreign manufacturers can apply for permission to attach the JIS emblem to their products under the Industrial Standardization Law (Law No. 185, 1949, revised 1980). Permission to use the mark is given on a plant-by-plant basis after an onsite inspection by officials of the applicable Ministry. Depending on the nature of the medical device, permission to use the JIS mark must be approved by MITI. JIS has promulgated hundreds of standards relevant to medical devices (122). The general standards are usually similar to the standards promulgated by the International Electrotechnical Commission. Specific JIS standards have been established for some electromedical devices including cardiographic, electroencephalographic, and audiometric. A program is now under way to put into place specific standards for 38 additional electromedical devices.

Under the Pharmaceutical Affairs Law, the Ministry of Health and Welfare has developed its own standards for certain medical devices such as contact lenses and artificial heart valves for which sterilization is particularly important. Products for which Ministry standards have been developed require for importation certification that they conform with the standards. Obtaining this certification involves testing samples in Japan.

### Other Market Factors

Both established business practices and Government regulation hinder the importation of medical devices into Japan.

The Japanese Government has set up the GOTODA Committee to study ways of bringing the Japanese certification process and standards more in line with international practice (195). The committee's recommendations have led to Government modification of some regulations, such as the product import license scheme above. However, a number of regulatory barriers have remained, such as the requirements that clinical testing be performed on Japanese people; that electromedical devices remain at the point of entry until they have been inspected and approved for release; and that the product approval process be repeated for very minor modifications not affecting a device's performance or safety.

Many U.S. firms operating in Japan also believe that the Japanese Government enforces its product licensing requirements unequally, to the disadvantage of im-

porters. Because the Ministry of Health and Welfare lacks a domestic enforcement arm similar to the FDA's field force, violations of the product licensing requirement may go undetected.

The existing system of distribution is also a stumbling block to expansion of the import market in medical devices. U.S. firms and their subsidiaries have generally relied on domestic sales agents to sell their products. Direct sales by importers to end-users were unheard of until the recent changes in Japanese regulations effective August 1, 1983. Direct sales will probably remain rare for a while, given the importance of personal ties to the market and the requirement that foreign firms wishing to sell to an end-user must obtain a license for professional importation which involves inspection of each plant where the product is manufactured. Such licenses, however, are not required for import sales to distributors or other firms that resell the equipment to end-users.

Although most U.S. manufacturers of medical devices have not had Japanese subsidiaries, a growing number of U.S. firms, including Beckman Instruments, Inc., American Hospital Supply Corp., and Baxter Travenol Laboratories, Inc., have set up subsidiaries to promote Japanese sales. Using subsidiaries assures buyers that the seller has the knowledge and ability to give proper instruction in use of the device and to service it after sale, both important factors in selling very sophisticated electromedical devices.

Sales to an agent remain the most common form of product distribution, not only for medical devices but also for many other imported products. However, the system of selling through agents results in one or more markups of the device's price, which pushes the price of foreign products above those of comparable Japanese products.

## United Kingdom

The United Kingdom has traditionally been a major market for medical devices because of its extensive and sophisticated health care system. In 1982, total sales of medical equipment in the United Kingdom were in excess of \$600 million<sup>(52)</sup>. The size of the U.K. medical device market is linked directly to expenditures for the nationalized health care system, which has slowed considerably during the 1980s.

In 1982, the United Kingdom imported \$537 million of medical devices. The United States had the largest share of the total U.K. import market for medical devices with 28 percent, up from 25 percent in 1980 (52). It is expected that the U.S. share will continue to increase to nearly 36 percent of total imports by 1987. Increases in medical device imports from other

major suppliers will reflect both increased competition among foreign suppliers to maintain their sales and decreased sales by U.K. domestic suppliers. The major new products in which U.S. suppliers are expected to do well over the next 5 years are high-technology items, such as laser technology, fiber optics, and micro-surgical equipment.

## Import Requirements

The general British import regulations applicable to all imported goods do not appear to significantly impede the importation of medical devices (105). Nor are foreign manufacturers of medical devices required to obtain Government-issued clearances when their goods are imported into the United Kingdom. Foreign concerns are permitted to negotiate directly with the end-user, and there is no requirement that the transaction be reported to the Government. Imported medical devices are subject only to routine customs procedures.

As a member of the European Community, the United Kingdom does not impose tariffs on the products of European Community member states. Therefore, members can sell medical devices in the United Kingdom at a competitive advantage. The United Kingdom along with many other European countries adheres to the CCCN for the classification of medical devices. Having a standardized category of goods simplifies the import and export of medical devices.

British tariff duties do not impose a substantial barrier to the importation of medical devices. The duty rates on most medical devices range from 5 to 8 percent ad valorem and are generally comparable to or slightly below similar tariffs in the United States. Certain medical device imports, such as those intended for training and research or for sale to nonprofit institutions may be exempted altogether from the imposition of duties.

In addition to being subject to duties imposed on devices from non-European Community countries, all imported medical equipment is subject to a 15-percent value-added tax (VAT) imposed on the duty-paid value of the goods. The VAT is imposed in order to equalize the treatment of imported devices with those manufactured in the United Kingdom, which are already subject to a VAT.

## Product Approval Process

Although medical devices sold in the United Kingdom are not generally subject to the drug laws or to any mandatory scheme comparable to the controls exercised by the FDA, regulations do apply to the medical device market. Many medical devices are regulated by two divisions of the Department of Health and

Social Security. The Medicines Division controls the manufacturing, licensing, clinical trial, certification, safety, efficacy, pre-market approval, labeling, quality control and adverse-reaction reporting of those devices subject to the provisions of the Medicines Act of 1968, as amended. Although the Medicines Act applies primarily to drugs, it also covers such devices as surgical sutures, dental filling substances, contact lenses, intrauterine contraceptive devices, and certain radioactive medicinal products (174).

The Supplies, Industries, and Exports Division administers the Drug Tariff, which lists products that may be prescribed and distributed through the National Health Service (NHS). In addition, this division sets specific purchasing requirements for such medical devices as X-ray equipment, hemodialysis machines, and surgical implants (174). The activities of the division are focused on devices that the Government purchases in large volume and on products that, if found to be defective, would pose a substantial hazard to the public health and welfare. Through the Supplies, Industries, and Exports Division, the Government, which is by far the largest purchaser of medical devices, routinely sets quality and safety standards for the products it purchases. These standards, adhered to by domestic procedures, must be complied with by importers in order to sell in the U.K. market.

The Government also influences, unofficially, the types and specifications of other medical devices through a voluntary system of manufacturer registration that operates through the National Health Service (174). Under the control of the Scientific and Technical Branch of the Supplies, Industries, and Exports Division, this system allows manufacturers of medical devices to voluntarily register their businesses under certain "good manufacturing practice" guides that have been developed in consultation with British trade associations.

Registration certifies that equipment manufactured by the concern meets certain safety and effectiveness criteria. The guides cover the entire manufacturing process, from training of personnel to packaging, labeling, and possible recall. The first guide, applicable to sterile, single-use medical devices, became effective in 1982. Guides are expected to be issued for numerous areas in the future.

Although NHS hospitals are not required by law to make purchases from registered manufacturers, the system contains incentives to encourage registration. The Health Service Supply Council will circulate lists of registered manufacturers along with a recommendation that products should be purchased only from listed manufacturers. In effect, then, the Scientific and Technical Branch's advisory standards will guide the

purchase of medical equipment by NHS hospitals. Because these hospitals do most of the medical equipment purchasing, it will generally be good business practice for a device manufacturer to register under a "good manufacturing practice" guide, if one applies.

The combination of standards for Government purchases and reliance by private purchasers on those standards acts as an unofficial regulatory scheme for both imported and domestic medical devices sold in the United Kingdom. The result is a degree of regulation of medical devices, that, though lacking a statutory basis, is as pervasive as that existing in almost any other country. The "voluntary" registration procedure will soon augment the power of these indirect controls even further.

Certain medical devices, including electrical and radiological medical equipment, must also comply with standards issued by the British Standards Institution (BSI) (52). These standards may pose significant obstacles to U.S. manufacturers, since compliance with U.S. standards does not always satisfy all U.K. requirements. In general, compliance with the standards of BSI is now as important in the sale of electrical medical devices as compliance with a standard developed by the Supplies, Industries, and Exports Division.

## Other Market Factors

Since Government agencies purchase the vast majority of all medical devices sold in the United Kingdom, marketing strategy must be aimed at Government, rather than private, procurement. Purchases by Government hospitals and other agencies have in the past been made primarily at the local level, rather than through a centralized purchasing system. This decentralized purchasing system for NHS hospitals has resulted in hospitals' buying equipment which may not be exactly what they need, or paying more for equipment because they are not buying in large quantities. In an effort to overcome these problems, NHS has recently revised its purchasing procedure to set up 17 regional purchasing centers and a new, national Supply Council to act as a central purchasing agency for high-volume equipment purchases (52).

## France

The French market for all medical equipment was an estimated \$356 million in 1980, with imports accounting for about 70 percent of that market (286). Exports of French medical equipment have averaged about 80 percent of imports to France. During the last decade, the United States replaced West Germany as

the leading exporter of medical equipment and in 1980 provided about 24 percent of all imported medical equipment to France.

### Import Requirements

In addition to the regular documents for import, numerous medical devices require technical visas, which permit surveillance of the quantity and price of imports (286). Technical visas are required for anesthetic equipment, syringes and surgical supplies, special diagnostic equipment, blood transfusion apparatus, and electrostatic units containing artificial radioactive elements.

Tariffs on most imported medical equipment range between 5 and 13 percent (286) and apply only to goods outside the European Community. Under commitments made at the Tokyo Round of GATT, these tariff rates should decrease slightly over the next few years. France does impose a VAT of 17.6 percent on most goods, including medical devices, regardless of their source.

### Product Approval Process

A combination of technical standards and product approval requirements necessary for government purchases and reimbursement payments constitutes an indirect but comprehensive system of regulation. The effectiveness of this system is increased by the reliance private parties place on official standards in making their own purchasing decisions.

The French Pharmacopoeia<sup>3</sup> sets forth detailed purity standards for drugs and “sterile devices,” such as surgical dressings, sutures, certain implants, absorbent cotton, and a variety of plastic products. Pharmacopoeia requirements technically apply only to products that are sold to public institutions or to products that claim to comply with the Pharmacopoeia. However, their role in practice is far broader, since private purchasers also rely on compliance with Pharmacopoeia requirements as an indication of quality (164).

For certain medical devices that are to be sold to public institutions, French law requires official government approval through “homologation.” The Commission d’Homologation periodically lists certain categories of devices that must be approved before they can be purchased by a public institution. Manufacturers must formally apply to the commission, which requires submission of test reports by the manufac-

turer. At the end of the process, a proposal is made to the Ministry of Health, which issues an approval decree and a homologation number (164). Many manufacturers submit their products to the homologation process even when they are not required to do so, because products with official approval have a larger market.

Certain medical devices sold to public agencies are also subject to technical standards developed with the cooperation of industry and the Association Francaise du Normalization (AFNOR), a governmental standards body. These standards are imposed by various agencies of the national government (286). These products may not be imported unless the Ministère de l’Industrie, du Commerce et de l’Artisanat has certified that they conform with the applicable technical standards. If the relevant standards are developed or administered by a department other than the Ministère de l’Industrie, initial testing and approval of the device will be done by that department.

The difference between the AFNOR standards and those under the homologation process is that the AFNOR standards cover very technical matters such as the electrical workings of a device, while the homologation process is a much more general product approval process dealing with both electrical and non-electrical devices. Compliance with AFNOR standards can be useful in marketing a product. Conformity is shown by an “NF” mark on the label, which can only be used with permission of AFNOR after testing of the product and inspection of the manufacturing premises.<sup>4</sup>

### Other Market Factors

Government procurement is a very important factor in the French medical device market, with purchases by public hospitals accounting for the largest segment of the market. A central purchasing group representing public hospitals, the Union de Groupements d’Achats Publiques, accounts for over one-half of the medical equipment purchases by all public hospitals (376). Acceptance by this group can assure a product’s success, particularly since private purchasing decisions tend to follow government procurement decisions.

Government purchases are made in one of three ways: through privately negotiated contracts, through competitive bidding, and through bidding where factors other than price are considered. But despite France’s adherence to the Agreement on Government Procurement under GATT, a 1975 “Buy French” policy does apply to purchases of numerous products—including external blood collection systems, hyperbaric

<sup>3</sup>The French Pharmacopoeia has semiofficial status in France, under the authority of the Ministry of Public Health. Although its definitions, procedures, and standards do not have the same force and effect, as for example, FDA regulations in the United States, it is used as a guideline to identify health and safety violations associated with various drugs and medical devices.

<sup>4</sup>See *Exporters’ Encyclopedia*, at 2:481-482 (105).

chambers, body scanners, and artificial kidney machines (286). The requirement for Ministry of Public Health “advice” on purchases of “innovative” equipment by the public sector (previously limited to “heavy equipment”) often takes the form of approved lists of suppliers.

In addition, an effort is being made to strengthen the capabilities of regional health authorities for providing advice on contemplated purchases. Such “advice” is unlikely to favor U.S. suppliers if viable local alternatives exist, or where a manufacturer is a significant local employer. Indeed, U.S. manufacturers have been informed that new products will not be approved by the French authorities for purchase where there is a competitive French-manufactured device (284).

France also requires companies importing diagnostic products to set up a quality control laboratory in France to recheck every shipment, regardless of whether it has undergone quality control audits in the country of origin. No shipment of medical devices will be licensed without testing in a Government-approved laboratory (444).

## Federal Republic of Germany

In 1980, sales of medical equipment and supplies in the Federal Republic of Germany totaled more than \$1.5 billion (188). In 1979, the United States was the leading foreign supplier of medical equipment with 25 percent of imports (377).

### Import Requirements

Products of European Community, Western European, and developing countries are not subject to import duties (188). Tariff rates applicable to medical equipment from other countries average 6 to 9 percent, with a maximum of about 11 percent. Most imports are subject to a VAT of 13 percent, similar to the VAT levied on domestically manufactured products. Some imported manufactured products are subject to special excise taxes in addition to the “import equalization tax.” Foreign exporters to West Germany who must pay both the tariff and the “import equalization tax” face a significant disadvantage (216).

### Product Approval Process

Regulation of medical devices is similar to that existing in the United States prior to the passage of the Medical Device Amendments of 1976, with regulation of some products as an outgrowth of the regulation of pharmaceuticals. The 1976 Law on the Reform of Drug Legislation pertains to “fictitious drugs,” which include devices containing a drug, devices to be intro-

duced into the body, dressings and surgical sutures, and diagnostic products (94). Specific regulations have been promulgated to govern manufacture, licensing, clinical trials, reporting of adverse effects, and liability for damage caused by drugs.

Although fictitious drugs are not now subject to these regulations, the regulations could be extended to them in the future. Under the Drug Reform Law, the government also has a number of enforcement tools that can be used against regulated devices considered misleadingly labeled, unsafe, or ineffective.

Two provisions of the law are of special interest to importers. First, surgical suture material and certain diagnostic products may be imported outside the European Community countries only if the importer obtains certification from a competent authority of the manufacturing country (such as FDA in the United States) that the World Health Organization’s good manufacturing practices have been adhered to or that the import is in the interest of the general public. West Germany is in the process of adopting its own GMP regulations for the pharmaceutical industry, and these will apply to manufacturers of fictitious drugs.

Second, the law requires any person who markets a medical device that comes under the Drug Reform Law to maintain a place of business within West Germany. The European Community recently ruled that this requirement is illegal and has asked that it be abolished, but its future is uncertain.

Although the Drug Reform Law covers a relatively small segment of the medical device industry, a much larger segment is indirectly regulated. Regulations issued under the German General Technical Law require that the manufacturer of technical medical equipment is in proper condition and that either the manufacturer or an expert has subjected the devices to final inspection (192).

Test protocols may be required from the manufacturer for certain types of equipment, and testing must be carried out at one of 34 designated institutions. Testing for most medical devices is voluntary, but is often performed because it has some commercial value for the manufacturer. However, proposals have been circulating in West Germany to make testing under this law mandatory for all electromedical devices.

Regulation of medical devices also occurs on a piecemeal basis through the work of the Deutsches Institut Fur Normung (DIN), the official standards body in West Germany. DIN has developed standards in such areas as the testing, storage, labeling, and packaging of products, and the materials, dimensions, and tolerances to be used in manufacturing for a large number of medical devices. Among the medical items for which standards exist are surgical dressings, implants, and transfusion and hematological equipment. Although

compliance with an applicable DIN standard is not required by law, in practice it can be a major advantage in the marketplace to have a DIN mark of approval on a product. Moreover, much interpretation of DIN standards is done in practice by West German test laboratories whose approval is very important for marketing a product in West Germany (458).

West Germany has a pharmacopoeia, but with only limited applicability to medical devices. Its main focus is drugs and only a few medical devices, such as surgical sutures and dressings, are included.

### Other Market Factors

West Germany is a signatory to the GATT Agreement on Government Procurement. Although government spending represents a substantial portion of all health care expenditures, purchases of medical devices are for the most part decentralized without the direct involvement of Government agencies. In practice, the chief physician in a hospital or in one of its departments makes all purchasing decisions. The major exception involves purchases of \$75,000 or more by university clinics. Such purchases must be approved by the German Research Association. There is no official "Buy German" policy, but the tendency of publicly financed health care institutions is to purchase West German products.

## Mexico

The market for medical equipment in Mexico is small but growing. Approximately \$44.2 million was spent during 1980 on medical equipment, including medical devices (28). Imports account for nearly 85 percent of all purchases of medical equipment. The United States is the largest exporter, with 38 percent of the market in 1980. The Federal Republic of Germany (18 percent in 1980) and France (9 percent in 1980) are closest U.S. competitors. Devices for which production is labor-intensive are generally supplied domestically, while devices that require highly technological processes are often imported.

### Import Requirements

The Mexican system of import control involves a dual scheme of licensing and tariffs (105). Importers may obtain a license by applying to the Ministry of Commerce. The request is considered by one of 13 committees that specialize in a particular portion of the tariff or by a special committee that considers license requests by Government agencies. Requests are usually acted on within 2 weeks. Imports by govern-

ment agencies must be approved in advance by the Public Sector Imports Committee, and approval will be withheld if a domestic product is available which is reasonably competitive in price and quality.

Mexico maintains no special import requirements for most medical devices. One exception to this is that all devices to be physically connected to a patient require import permits from the Ministry of Industry and Commerce and the Ministry of Health and Assistance (378). However, these permits are neither difficult nor costly to obtain.

The majority of medical devices imported into Mexico are subject to tariffs which range from 2 to 35 percent (28). The median tariff is in the 10- to 15-percent range, somewhat higher than other countries in this study. The Mexican tariff generally follows CCCN. Mexico is not a signatory to the GATT. However, the only countries with preferential tariffs are other members of the Latin America Integration Association (Argentina, Bolivia, Brazil, Colombia, Chile, Ecuador, Paraguay, Peru, Uruguay, and Venezuela) (378).

### Product Approval Process

There is no specific system of product approval for medical devices under Mexican law. Certain devices, however, require approvals from Mexican commissions that act as counterparts to U.S. utility commissions. For example, all electrical devices must be approved by the Federal Electricity Commission, a state-owned corporation, and equipment incorporating radioactive materials must receive approval from the Nuclear Energy Institute (378). There are also no official standards governing the design or use of medical equipment in Mexico. Medical products, for the most part, can be brought directly into Mexico without any preimport procedures.

### Other Market Factors

The size of the Mexican medical device market and the import share of that market are limited by a number of factors. First, over 70 percent of all health care expenditures in Mexico are Government-controlled (28). The emphasis of the two major Government agencies involved in the provision of health-related services, the Institute for Social Security and the Secretariat of Health and Security, and of Mexican health care providers in general, is on the provision of basic health care services. As a consequence, there is a very limited market for sophisticated high-technology medical equipment, such as CT scanners and cardiac diagnostic equipment, in which the U.S. medical device industry is particularly strong.

Mexican governmental purchasing practices evidence a strong preference for domestically produced items. The Government will procure medical equipment from foreign manufacturers only when the equipment cannot be domestically supplied. Indeed, the Government has a "closed border" policy under which it will ban imports of products that compete directly with goods manufactured in Mexico, including those manufactured by the Mexican subsidiary of a foreign corporation. The effect of this policy on U.S. imports has not, so far, been great.

Finally, there is a highly developed system of import agents who take responsibility for obtaining

licenses and negotiating with foreign suppliers. The agents arrange for the import of a good and supply the ultimate end-user. Direct sales to end-users, although not rare, are not significant in volume when compared either to sales to import agents or those made directly to the Government.

The medical devices market has also been affected by the foreign exchange difficulties that Mexico is currently experiencing. In late 1982, exchange controls were placed on all foreign remittances from Mexican banks. These controls include Government approval of import contracts requiring payment outside of Mexico, even for purchases by Government agencies.