Regulating the Safety of Implants: Part I—Government Regulation

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I. IMPLANTS

A. Introduction

The use and possibilities of applying implants made from biomaterials has grown tremendously since the 1950s. Implanting foreign materials into the human body has been considered very dangerous. Reactions to foreign material through tissue infections, the effects of wear (through which foreign matter can infiltrate into the body causing injury), and the effects of mechanical stress (which can cause disruption of implant bonding), are issues of grave concern. In biomaterial science, materials and tissue reaction to these materials are studied. In 1982 the National Institutes of Health (NIH) organized a Consensus Development Conference that discussed the clinical application of biomaterials. The meeting’s objective was to clarify questions about the safety and effectiveness of using biomaterials.

The number of implanted devices in the United States amounts to several million a year and varies from pacemakers to dental implants. The passage of the Medical Device Amendments of 1976* was definitely influenced by the many problems connected with the use of implants. A survey described 751 accidents resulting in death connected with medical appliances. Five hundred and twenty-one of the 751 mortal accidents were caused by defective artificial heart valves, 89 by defective pacemakers, and 10 by intruterine devices (for instance, the Dalkon-Shield). More than eighty percent of the examined accidents resulted from problems with implants. The Cooper Committee, which had been instructed to advise Congress about effecting legislation in this field, used the outcome of this survey to encourage Congress to act.

“Spare parts” medical science in the Netherlands has also undergone

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4. Id.
tremendous growth. The number of implants used in the Netherlands in 1985 was estimated at 100,000 a year. This number is expected to double by the year 2000. The implants are used especially in cardiovascular and orthopedic surgery, and in ear, nose, and throat surgery. In the Netherlands during the 1960s there was anxiety about the safety aspects of the use of biomaterials. In 1963 the Health Council advised that "metal objects meant for use inside the body" should be regulated by law. However, the people realized that supervision by law would not be necessary for appliances used in medical practice. Supervision of cardiovascular and orthopaedic implants as well as implants used in throat, nose, and ear surgery was believed to be "most urgent" because of the availability of "unsound material." "Unsound material" was defined as those materials about which there was no certainty they were harmless.

B. Definitions of Biomaterials and Implants

In the final determination of the NIH's Consensus Conference, a biomaterial was defined as: "any substance (other than a drug) or combination of substances, synthetic or natural in origin, that can be used for any period of time, as a whole or as a part of a system that treats, augments, or replaces tissue, organ, or function of the body." In this definition, other materials of non-artificial origin (bone, for instance) were included in the concept of biomaterials. In other words, natural materials still "alive" (transplants, for instance) are included.

With respect to the NIH's definition of implants, the statutory definition adhered to by the Food and Drug Administration (FDA) is: "A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more." This means that an implant is a medical device5 under the 1976 Amendments and it does not really matter what the object is made from. The FDA leaves open what type of material an implant can be made from, thus indicating that implants made out of natural as well of artificial material come under the statutory definition. A "xenograft," e.g., a ligament manufactured out of a bull's pizzle and intended for implantation, would come under the term "implant." A tissue originating from a human body (donor tissue) that is live or not-live, e.g., bone, and meant for implantation into another human being, such as an allograft, can also be defined as an implant and for that reason comes under the Amendments.6

8. 21 C.F.R. § 812.3(d) (1990).
In Europe, the NIH definition was considered "too clumsy and too restrictive." The exclusion of medicine was thought to be incorrect in view of the growing use of biomaterials in combination with medicine (e.g., implanted insulin pumps). A biomaterial's interaction with tissue was considered its most important criteria. The European Society for biomaterials subsequently gave the following definition of a biomaterial: "A nonviable material, used in a medical device, intended to interact with biological systems." In Europe, therefore, the opinion that the field of biomaterials is limited to "nonliving materials" is prevalent. Materials of natural origin do not come under the definition of "living materials."

Consequently, an implant is defined as "any medical device made from one or more materials that is intentionally placed within the body, either totally or partially buried beneath an epithelial surface." The concept of "biomaterials" is omitted from this definition and what materials implants are manufactured from is not considered. An object fabricated out of natural material as well as one composed from living material, can be an implant. Although implants can be manufactured from biomaterials, it is not required. In supplemental criterion, an implant may be covered completely or partially by epithelial tissue. Under this criteria, dental plates, for example, are not implants.

This biomaterial definition does not completely agree with the European Economic Community's (EEC's) legal definitions. Two different definitions are used for implants: one for "active" implants and one for "non-active" implants. A non-active implant is defined as "a medical device placed within the body and totally buried beneath the epithelial surface." An active electronic apparatus that is to be implanted is defined as: "any medical apparatus meant to be permanently implanted in the body through a surgical operation, functioning on electricity supplied by a to-be implanted battery or an external source of current, in concurrence with non-exchangeable appliances (e.g., programming units, external sources of electric current) and regulating apparatus." Therefore, it is stipulated that a non-active implant be completely covered by an epithelial surface. It remains unclear whether an implant which is partially embedded in the skin, e.g., an external fixation material (to be used in healing fractures), is an implant. As far as future EEC rulings go, there is a difference between implants with or without an energy-source (an analogous characteristic is that both are placed inside the body). Active im-

11. EUROPEAN SOCIETY FOR BIOMATERIALS, DEFINITIONS IN BIOMATERIALS (1986).
plants are not required to be completely covered with an epithelial surface. A separate EEC directive has been proposed for active implants that will be totally dedicated to this category of appliances. Examples of these implants are pacemakers, biostimulators, and implantable artificial hearts. Non-active implantable appliances will come under a heading that will refer to all non-implantable appliances with the exception of in vitro diagnostics. Examples of these implants are hip prostheses and heart valves.

Materials from which an implant made are not mentioned in the definition. In the legal definition, an important aspect of an implant is that it is completely covered with epithelial surface. Consequently, there is a risk of a grey area where it is questionable whether some appliances, such as external fixation materials and dental plates, that are not covered by epithelial surface are implants. In the United States, the criterion for an appliance covered with an epithelial surface is not mentioned. It is the same in the Netherlands, whether an appliance is covered with an epithelial surface is not a criterion for regulation.

Also this definition does not discuss the period of time an appliance must be in place to be considered an implant; consequently, a surgical scalpel could in principle be an implant. In the Netherlands, the Law on the Medical Appliances\textsuperscript{14} does not directly define what, in fact, an implant is. In article 1, among others, a medical appliance is understood to be "an object by its origin meant to be used on or inside the human body, with the purpose of replacing part of the human body, to support or further the recuperation, or for affecting results with regard to the functioning of a part of the human body." The Health Council limited itself in 1963 to advise that implants are "metal objects, meant to be placed inside the human body." The phrase "inside the human body" should be understood as placing the object "in the surface of the human body." Metal tooth fillings, for instance, are for that reason exempt, although they are placed inside the body. Consequently, an implant in the Netherlands could be defined as "a medical appliance put in the surface of the human body."

Looking over these different definitions, it is obvious that there are no distinctive criteria used in defining implants. This article argues that the criteria that should be considered for defining an implant should be:

- the material the product is fabricated from,
- the period of time an appliance is implanted, and
- whether the product is covered with epithelial surface.

The FDA uses the most extensive definition: practically everything that is placed inside the human body and remains there for some time, is an implant. In most legal definitions, a reference to the materials from which

implants are made is missing. In this article the category of medical appliances under examination is limited to objects that, by using each of the above mentioned criteria, come under the heading of implants, i.e., hip prostheses. Hip prostheses are made of nonliving materials, are meant to function during a longer period inside the body, and are completely covered by epithelial surface.

C. Classification of Implants

In the NIH Consensus Conference's report, biomaterials are classified according to use and application into three categories:

1. to sustain life or limb viability,
2. to restore or improve function, and
3. to restore or improve contour.\textsuperscript{18}

Implants can be classified according to possible application, that is, cardiovascular and neurosurgical implants like heart valves, pacemakers, and vascular grafts would come within the first category. Replacing orthopedic implants or a joint, or fixing a fracture are examples of implants that would fall in the second category. In the third category would be implantable heart prostheses. Criterion for classification of biomaterials under the NIH report, therefore, are based on the function of the implant. Further classification of implants is not provided for in the Medical Device Amendments; implants come under class III appliances, a rigorously regulated class.\textsuperscript{18}

As indicated above, future European regulations will distinguish between "active" and "non-active" implants. The active implant is determined by the presence of an energy source. The directive under which non-active implants fall, determines the authority of regulation by its arrangement of implants into classes, in conformity with the U.S. system.\textsuperscript{17} However, implants do not automatically fall into the most rigorously regulated class as they do in the United States. Assignment to this class depends on a number of criteria that have been drafted specifically for "implants and long-term surgically invasive devices." These criteria are:

Rule 8: Implants and long-term surgically invasive devices are Class III devices if they are intended to be used in direct contact with the cardiovascular system or the central nervous system; otherwise they are Class II devices.\textsuperscript{18}

Rule 9: Implants and long-term surgically invasive devices that are in-

\textsuperscript{16} 21 U.S.C. § 360c(a)(1).
\textsuperscript{18} Id.
tended to undergo chemical change, have biological activity, can be absorbed or deliver energy or medicinal products, are Class III devices, unless they are placed in teeth in which case they are Class II devices. 19

Thus, the important criteria upon which an implant is determined to be in class III is contact with a vital organ or the activity of the implant.

An example of an implant in accordance with the first criterion is a heart valve. A hydroxyapatite-covered hip prosthesis is an example of an implant filling the second criterion. Hydroxyapatite is a substance composed of a calcium phosphorus compound that is similar to bone tissue. This means that a prosthesis covered with a coating of hydroxyapatite will set solidly into the surrounding bone after implantation. Hydroxyapatite is applied with the intention of affecting a biological activity, namely, solidly fixing the bone. An implant with a coating like that belongs, therefore, in class III.

It should be noted that the concept of (biological) “activity” is used differently here based on a determination of whether or not the appliance has an energy source. Depending on the criterion being used, there can be several classifications of implants:

• Depending on the period an implant is in the body:
  — permanently, e.g., heart valves and hip prostheses;
  — long term, e.g., internal fracture fixation appliances; or
  — temporary, e.g., injection needles.

• According to the function of the implant (see NIH classification).

• According to the application field.

• Depending on whether the implant creates biological activity, for instance, as in the above mentioned hydroxyapatite coating covered prosthesis.

• Depending on whether the implant has an energy source (e.g., a pacemaker).

• Depending on whether the implant is in contact with a vital organ (see the proposed EEC classification).

It becomes evident that as far as future European regulation, criteria will be based above all on the difference between implants with and without an energy source. Different EEC directives and, thus, different legal measures will be applicable to those implants. For non-active implants it will also be important whether an implant is biologically active and whether it comes in contact with a vital organ. This distinctive criterion will be determined by a preponderance of the legal rulings.

The FDA uses a definition which is very extensive and includes all the above mentioned categories, and, moreover, all implants are subject to the

19. Id.
same regulations. In the Netherlands, no classification is used and all implants fall, in principle, under the Dutch Medical Devices Act.

II. LEGAL REGULATIONS FOR IMPLANTS

A. Introduction

In the Netherlands, the introduction of a product into the market is not regulated. However, it could easily be done. Based on the Medical Devices Act a system could be effected. Until now, this has not been done because of the reasons listed below. If regulation was desired, the question arises as to how it should be done. In the United States, for devices in general, but for orthopaedic implants in particular, a detailed introduction system is obligatory. Practitioners do have certain influence, but, in the end, the FDA gives approval. In France, a special introduction regulation has been reached for orthopaedic implants (homologation). Members of the EEC generally have introduction systems; however, next year special interest will be focused on the unification of the European market. Unification will mean that mutual trade-barriers will have to be removed and that there will be one European, common market.

The developments on the European level are important relative to the way in which the Netherlands currently approves medical devices for market in general and hip prostheses in particular. Currently, the only real trade barrier enacted by the Netherlands concerns admitting rubber condoms to the market (product control on account of the Resolution on Rubber Condoms). For sterile devices, a registration is required and product files must be available for inspection. For these products, no mandatory product inspection could possibly exist as it does for the Resolution on Rubber Condoms. The Dutch market is “open” because medical devices can be brought to the market almost always without any restriction. This means that the Netherlands, as a result of having so few regulations, already complies with its treaty obligations. However, based on other European regulations, regulations concerning a number of issues must be implemented. Among these are the registration of importers and manufacturers, and supervision of self-certification (the appliance of the C.E.-mark) by manufacturers.

The European system and its effect on the Netherlands’ regulatory system will be discussed below. At the same time, attention will be given to the French system, the British system, and the German system. Next the European system and whether, because of treaty commitments that will be in force after 1992, it will need supplementing or change, will be discussed. Questions as to what extent the Dutch legislation is qualified to regulate more or other matters than those in European directives will be discussed. At the same time, the fact that other categories of dangerous products (among others drugs, serums, receines) are submitted to very
strict rules must be considered. Moreover, the patient's position at the
time of the introduction phase (experimentation) deserves attention in con-
nection with the proposed laws on these points. Finally, attention will be
given to the problems legislation, in particular for hip protheses, may
cause.

B. The Netherlands

1. Device Legislation in the Netherlands

In 1959 the Health Council in its advisory capacity was asked if "it
would be possible and desirable" to inspect and supervise the quality of
medical-physical apparatus and materials employed in medical science. In
1963 this question was answered in the affirmative and the "urgency for
setting up supervision" for certain devices was mentioned. The Act on
medical devices was enacted, however, seven years later. This Act is a
framework or cadre-law, that is, the issue is regulated only in broad
terms. Creating a specific regulation was left by the Act to the Crown or
the Secretary. The idea behind this provision is to promulgate decrees in a
fast and efficient way, or to adjust the law without having to change the
law itself. The Act offers only general recommendations for exercising
supervision. For every device, if thought necessary, it can be specified that
inspection and supervision is to be exercised. Notwithstanding the govern-
ment's and Parliament's intention and the Health Council's recommenda-
tion, the law has never been made operative by way of decrees. Connected
problems will be given attention later in this article.

2. The Health Council's Recommendation From 1960

This recommendation is of interest because of the arguments being for-
mulated in support of the position that it is desirable to regulate the qual-
ity of certain medical devices. The Health Council warned that there are
many faulty materials on the market. Surgeons, importers, and dealers
would not be aware of this. At the same time giving information about the
expert use of these materials was considered necessary in view of the risks
associated with using them. In addition, a practitioner would almost never
be able to examine materials. He or she would be dependent on data re-
layed from manufacturers and importers. A critical attitude toward adver-
tsying by the surgeon was expected by the Health Council.

20. Health Coun., 1963 Report Regarding Supervision on the Quality of Medical
Materials (under which metals intended to be placed inside the human body falls).
21. See also L.M.G. Fano, The Medical Devices Act, An Evaluation Survey (Euramer
Univ. Rotterdam 1966). SWOKA FOUND, When There is No Need for There is No Law. Regu-
ulating Safety of Heart-Valves, Dalkonscilds, Pacemakers and Other Medical De-
vices (1988); and Fano, The Dutch Medical Devices Act: Problems with Implementation, 43 Food
The Health Council stated what the (legal) supervision of quality should be based on:

- producing instructions regarding the composition of materials meant for implantation, and
- prohibition for bringing on the market implantation material not meeting requirements.

The Health Council thought that a statutory regulation on the supervision of quality was necessary. However, it did not express an opinion on the structure of this regulation. It was not believed that effective supervision could be arrived at through an agreement among manufacturers, importers, dealers, and surgeons’ associations because to do so would be in conflict with the principle of the free practice of medicine in that surgeons would be forbidden to use other than the allotted materials. A doctor was presumed to be personally responsible for his or her medical actions. Also much material comes from foreign countries which would impede reaching trade agreements.

In view of the principle of the free practice of medicine, surgeons’ associations would never be able to force their members to use certain materials. Consequently, the Health Council drafted a proposed statute that offers a foundation for creating regulations (i.e., a cadre law). This draft statute includes the following elements:

- regulations concerned with the quality and composition of devices should require that the devices be authenticated;
- regulations should include prohibition orders regarding placing on the market or offering for sale materials without authentication;
- regulations should be implemented regarding supervision of the above mentioned conditions; and
- regulations should be implemented granting certification to manufacturers who have demonstrated that they have manufactured their products in a reliable way.

3. The Draft of Law on Medical Devices

In 1965, after the Health Council’s detailed advice accompanied by its recommendations that a draft statutory regulation should be passed, the ultimate proposal was sent to Parliament. Based on this explanatory memorandum, the Secretary emphasized the need for statutory regulation of this field. However, he stated that legislation was needed only with regard to a relatively small number of devices (to be indicated at a later date by an Order in Council): “For the time being there is only a need for a statutory regulation for a relatively limited number of technical devices.”

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The memorandum indicated what devices should come, as soon as possible, within the reach of a statutory ruling. First, following the advice of the Health Council, were objects meant for implantation inside the human body, particularly metal fixing devices and pacemakers. Furthermore, thought was given to regulating anesthesia apparatus, sun lamps, and shock and electrical apparatus. Regulations about the use of suture materials and the inspection of the sterility of articles meant for once-only use (for instance, disposable needles) were also considered important.

In the memorandum, three different categories of medical devices were distinguished:

1. objects used in medical treatment, e.g., surgical instruments and surgical gloves;
2. objects used for examination, e.g., audiometers and stethoscopes; and
3. devices placed inside the body that are used to perform a function in relation to the body, e.g., pacemakers, prostheses, and artificial heart valves.

Of course, supervision for these categories must be different for each category. Statutory supervision certainly was not possible; for that reason, a system of cadre legislation was chosen.

It was not possible to address this problem under an already existing statutory regulation. The Dutch Drugs Act was not believed to be suitable considering how complicated the system will be. A system of approval, judged by certain requirements, was thought to be more fitting, and it seemed impossible to classify a medical device in a law primarily designed to regulate foods and beverages. The law on dangerous tools and the Electricity Act aimed at furthering labor protection by regulating the use of certain tools. Some devices could be regulated by these laws, but their purposes did not include advancing the quality of devices. The Nuclear Power Act did not offer a solution for the majority of devices. The possibility of classifying the issue under the Drugs Provision Act also was not thought appropriate. On the one hand, drugs are differentiated according to the method of use, on the other hand, this Act explicitly determines the different ways drugs may be manufactured, that is, by apothecaries and physicians as well as by industry. Manufacturing devices did not fit in with this scheme, and it was not thought possible to put drugs and devices under one legal denominator. The memorandum was passed without appreciable changes by the Second and the First Chambers of Parliament. In 1970, the resulting Act took effect.23

4. The Contents of the Medical Devices Act

The object of the Medical Devices Act is to make possible regulating

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activities to guarantee the good quality of medical devices as well as to prevent inexperienced use of devices. The contents of this Act offer a general cadre for exercising supervision and inspection on the quality of devices by the government. When a device is indicted by an Order of Council, the government could take measures in the following ways:

- allowing manufacturing with a permit and/or in compliance with the written regulations. (art. 2);
- importing, having in stock, delivering, or applying indicated devices can only be done when the requirements have been satisfied and there is evidence of approval and license for a purpose designated by a government agency;
- packing must meet certain requirements (arts. 3 and 4);
- prohibiting placing on the market or using certain devices that pose a threat to public health through an Order in Council (art. 5); and
- supervision by designated civil servants from the State Supervisor on Public Health.

Consequently, the Health Council’s 1963 recommendation has been followed; quality requirements regarding the product and the manufacturing process have been implemented, and examination and supervision on observing the requirements of the Act are being arranged. Moreover an “emergency brake” for devices threatening the public health has been included. After the Act’s enactment, the Health Council was asked for a recommendation as to what devices should be quality controlled by an Order of Council. In 1973, the Health Council set up a standing committee, the Core Committee on Medical Devices, to respond to this request for a recommendation. In a number of partial recommendations, this Committee mentioned several devices.

In 1985 the 1970 request for a recommendation was responded to in an advisory from the Committee on Quality Control for Medical Devices. In this advisory, an enumeration was given of all of the devices for which a statutory ruling would be necessary. At the same time, attention was paid to the bottlenecks that had occurred in the execution of the Act.

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24. See Exploratory Memorandum, supra note 22.
5. The Health Council's 1985 Recommendation

The Health Council's duty was to deliberate on an approval system that in a simple way could guarantee the quality and safe application of medical devices. Addressing the present day situation, the Board enumerated the statutory and regulatory bottle-necks:

The medical devices coming under the definition of the Act, are numerous and in relation one to another very different. This implies a lot of regulating by means of Orders of Council. The Committee, however, is of the opinion that if the Act is implemented, regulations should be kept to a minimum. The regulations in force up to this day are very fragmentary and mostly noncommittal. This goes for regulating in the E.E.C. context as well as for existing legislation. Rapid developments in medical technology take place and it seems to take a long time before, for instance, past recommendations come into force as a statutory regulation.27

The recommendation was drafted using the following guidelines that were created by the Council as a basis:

- regulating by law must be limited, that is why only regulations are proposed with respect to those devices where application can lead to unacceptable health risks;
- the to-be drafted regulations must not have a restraining influence on technological innovation;
- the regulations must be just so that there will be a willingness to observe them;
- the cost of observing the regulations must not exceed the benefit of their effectiveness; and
- it should be simple to exercise the implementation of the regulations.

These guidelines must lead to a situation where the ultimate recommendation's conclusions can offer a solution for the above mentioned bottle-necks. The Council has obviously had an eye for problems affecting making the Act operational. The Council considered which medical devices should come under a form of statutory quality control. The answer is founded on the response to the request for a recommendation by the Secretary in 1970. In view of the Council's guiding premise that statutory regulation must be restricted to a minimum, it has not drawn up a list of all the devices being used in the Netherlands; the Council believes that statutory regulations must be limited to those medical devices whose application can lead to unacceptable risks. The Council has drafted a schedule of two categories of devices where no comprehensive list is intended; it must be regularly revised and/or supplemented. At the same time, the

27. Id.
Council pointed out that the amount of risk a device can expose a patient to not only depends on the quality of the device, but also on the methods of application and servicing. Measures should also be directed to regulate these issues. The Council itself determined the times when quality control should take place. The to-be drafted regulation must suffice for every phase in which the device finds itself, such as:

- during manufacturing, the Council refers to the requirements found in the Medical Devices Act with regard to the practicability of compulsory inspections (however, it has expressed reservations about this type of inspection);
- at the time of the acquisition, the Council believes it is sensible to consider the opinions of the user, the technician, an instrumentation expert, and an economist when purchasing a device. In this way, what was discussed by the study group is considered. Reconsideration was given to the Acquisition Policy of Health Care Report;²⁸
- at the time of the application, compulsory instruction and good instructions will be given to control the risks; and
- for maintenance, the owner/user will remain responsible for adequate maintenance of the device.

Obsolete devices are not to be resold. The Council also recommended compliance with the yet to-be drafted regulations. Compliance must be delegated on a macrolevel to designated bodies/functionaries from the meso (governing bodies and, on a national level, active institutions and professional organizations) and micro levels. The government is in principle responsible for regulating the quality of medical devices. However, the meso level could also contribute to responsible quality control by advising and providing refresher courses on application for users. At the micro level, the responsibility for a medical device’s quality control should lie with an instrumentation expert. This expert should be responsible for purchasing, supervision of maintenance, and observing the statutory regulations. Calling in an instrumentation expert for purchasing proceedings and instrumentation supervision could lead to important financial savings. From the Health Council’s recommendation, two relevant conclusions can be drawn:

- government regulation, specifically in the province of medical devices, involves many problems; and
- not only the quality of the device itself, but also its use and maintenance are important.

A broad concept of quality, including responsible use of medical devices, is

used in the recommendation; consequently, not only product quality but also quality assurance of medical devices in a wide context is important.

6. Problems with the Implementation of the Act

In 1970 the Medical Devices Act became operative. As noted above, the actual operation of the Act was to be implemented by enacting a number of Orders in Council addressing specific devices. In 1978 quality control of rubber condoms was regulated by an Order in Council, and in 1982 and 1983 followed decrees dealing with commerce and the use of sterilized medical devices. Among the statutory regulations regarding objects to be implanted into the human body (among others, metal fixing devices and pacemakers), narcissus apparatus, sunrays, and, for instance, suture materials failed to appear. This has occurred notwithstanding the fact that the memorandum in reply to the 1969 government question indicated that there was an intention to bring these devices under the scope of the law, at the latest after the Act became effective and in light of the Core Committee on Medical Devices’ positive recommendations. In fact, the Act has not been made operational, contrary to original intentions; a number of factors have contributed to that situation.

Because of the great diversity and scope of the matter to be regulated, there has been reluctance to create many regulations to implement the Act. At the same time, because of technological changes a great many medical devices are subject to change. The device regulations will have to adapt to these developments. In addition, there is apprehension about too specific regulations hindering innovation of medical devices. The government’s point of view regarding the actual policy of deregulation is as follows: “The cabinet subscribes to the point of view of the study group on deregulation, social-economic planning and quality-advancement, which indicated that introducing a licensing system constitutes an obstruction to trade and industry.” In view of the trouble implementing a system of licensing would bring to all the concerned parties, it was decided to cancel this system. Moreover, the system of cadre legislation with further elaboration by an Order in Council is in opposition to the government policy of deregulation. Deregulation problems appear to have an important influence on the implementation of the original plans (that is, through Orders in Council and a licensing system).

In addition to these problems, a number of issues related to the use of legislation in this area that concern more than simply implementing the Act can be mentioned. Implementation of a licensing system and adjusting

29. Conclusion August 18, 1979 Sb. 498 (containing regulations for rubber condoms) (Rubbercondens decree).
the existing system for implementing the supervisory regulations will carry a steep price. In addition, no department specifically charged with implementing the provisions of the Act has been created; the Act's implementation is currently charged to a department whose section deals mainly with the implementation of the Drugs Provision Act. In view of the low number of Orders in Council that have been drafted for implementing the Act, there appears to be a problem with the ability to draw up regulations. At the EEC level, directives are being drafted which will be incorporated into the Dutch legislation after 1992. Connected with the pending EEC decrees, an attitude of "wait and see" has been adopted by the Dutch legislature.

It also appears that in the last few years there has not been a necessity to implement the Act; very few situations have occurred that have received attention in the press or political arena. The Health Council has let: a considerable period of time pass before offering advice; also, in the department section, the matter has been limited to preparatory activities for regulating a limited number of devices. There have been no "triggers" to legislation.

In a 1986 recommendation by the Health Council, attention was given to these problems. It had been established that medical devices generally do not undergo the kind of testing that is customary for drugs. This situation was not believed to be conducive to realizing two objectives in health care policy: keeping and improving the quality of care, and pursuing cost control. In the recommendation, the possibility of submitting devices to the same method of "admittance control" as drugs was discussed. Based on article 3, paragraph 5 of the Drugs Act, it is prohibited in the Netherlands to make drugs that have not been approved by the Board for Approving Drugs. It is not believed necessary to implement a similar evaluation/admittance program for medical devices. Consequently, it has been proposed to split medical devices into "risk classes." The stringency of the measures taken against a product will depend on the risk associated with using it. For the high risk class (for instance, artificial heart valves) an admittance or control type of inspection will be required; the emphasis in this class is on government regulation. In the moderate risk class (for example, lithotriptors), a combination of government regulation and self-regulation is recommended, while for quality care for devices from the low risk class (for instance bandages) attention should primarily be on self-regulation.

A proposal from 1986 to establish a "board for judging medical devices" was turned down in the recommendation. "A Board like that would have great difficulty in maintaining itself in the midst of the supply

34. See L.M.C. Fars, supra note 21.
of thousands of different devices. The bureaucracy's expenditure would not counterbalance the profits and these are also obtainable in a different way." The government, referring to the recommendation on the limits of care, also turned down this proposal.

In the health care field, other groups are already intensely occupied with the matter. It is therefore not thought necessary to set up a government department. However, there is a need to set up within the Board of Health a permanent panel whose duty would be to ensure quality control of medical devices. The withdrawal of the government is leading to more procedure directed, and less content directed, government regulation. Consequently, the government office supervising the public health (the Inspectorate) will have to pay special attention to setting quality control standards and protection. A number of legislative solutions to these problems in the Netherlands have been suggested. From various parties different points of view on possible solutions have been offered. The reticent role government has reserved for itself, as shown in the government's point of view on the limits of health care recommendations, seems on the one hand to be dictated by the complexity of the problems and, on the other hand, by developments in the EEC. With regard to hip prostheses, the government has not been able to arrive at any policy.

C. Some Relevant Points from the Draft Proposal of Law Regarding Medical Experiments on People

As discussed above, medical device legislation in the Netherlands has brought about little change. Currently, admittance to the market is not regulated for medical devices (except rubber condoms). For hip prostheses, this means that problems associated with moving from an experimental stage to use in daily practice is not covered by any regulation. This is problematic because there is no difference between a device's introduction and the distribution stage. In the past, this has resulted in prostheses moving too quickly from one stage into the other stage. The danger that this will happen again will continue to exist as long as no regulations address this transition.

Moreover there is a possibility that new prostheses, developed in a country where the introduction requirements are stringently regulated, will be tested in vivo in the Netherlands for the first time. The question arises whether the protection of patients against insufficiently tested, newly developed prostheses is sufficiently regulated. To be able to answer this question, it first must be decided whether implanting a recently developed prosthesis is within the meaning of the proposed bill on experimen-

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35. Recommendation on the "Limits of Health Care," supra note 33.
37. See supra notes 21, 33, and 36.
Article 1, paragraph 1, subsection 6 defines experimentation as follows: "Scientific research is in the province of medical science, of which subjecting persons to rules of conduct is part." What is written in the second paragraph of the first article is also important: "Subjecting persons to acts and to rules of conduct exclusively for their benefit is not included under what is written in the first paragraph under b." These statements are elaborated in the explanatory memorandum. The proposed bill deals with "research" and not with the normal practice of rendering assistance or with "experimental treatments." The object of research is primarily the development of knowledge and not advancing the health of the experimental subject. Normally, health care practice is directed exclusively at the individual care of patients and actions are performed which are expected to be successful.

In normal practice "experimental treatment" can be carried out very well. Experimental treatments are treatments which are new in the sense that they have "not been tried before" or are "totally different from the usual." Their effects and suitability are not always studied in a scientific setting. Their primary objective is improving the health of the patient; not advancing science. In that situation there is no question of "research" and for that reason it is not an "experiment" in the meaning of the Act. When a physician treats his or her patient differently from what his or her fellow physicians believe is normal or usual, he or she does it within the scope of his or her own professional responsibility and the dealings can be tried in the usual way by the inspectorate, disciplinary, civil, and criminal judges. The special protection that a patient definitely has when involved in research is lacking in experimental treatment. This special protection guarantees that research can only be done if it complies with certain requirements and instructions. The requirements specifically relate to the experiment's ethical and scientific acceptability. The instructions refer to giving information to and asking for the permission of the patient, and arranging for insurance beforehand that will cover any damage experienced as a result of the experiment. Moreover, a procedure for conducting the experiment has to be established. Conducting experiments will be done by medical-ethics committees, a number of which have been functioning for the last few years (mainly in academic hospitals). In the bill, these committees receive legal authority. At the moment, however, there is no statutory requirement to report experiments to these committees.

Implanting a recently developed prosthesis is an experiment when there is a question of participating in a trial, and when another interest is being served besides that of the individual patient. Because it is not obligatory to submit new prostheses for research (as is the case in the United States), a

remarkable situation arises in which a decision on whether the experimental (research) stage of a prosthesis has been reached is based on whether it has or has not participated in a trial based on its experimental phase. The proposed bill relates to research and offers protection as soon as the experimental activities diverge from the patient’s exclusive interest. It does make a difference for the patient (such as obligatory insurance coverage versus the possibility of insurance coverage and the discretion to make a choice whether to participate in the research) whether the prosthesis he or she receives as an implant is or is not the object of research. There is also a difference for industry; the creation and execution of a clinical trial will be tied to future rigorous stipulations. Consequently, companies may look for other means of assessing prostheses.

The draft bill does not improve a patient’s legal status in all cases. A solution can only be reached when the definition of “experiment” is adjusted, and also when there exists a regulation connecting the admittance of a new prosthesis to market to entrance conditions and a regulation for experiments. That is, there should be a regulation which stipulates when a device moves from the experimental stage to use in daily practice.

III. France

A. Homologation (Homology) in General

Since 1982 France has been following an admittance system called “homologation.” The devices coming under this law were mentioned in a limited fashion in a decree of May 23, 1984. There are five main categories of products:

- image forming (e.g., ultrasound);
- surgery and therapy (e.g., lasers and electro-surgical apparatus);
- *materiels de suppléance fonctionnelle* (for instance, joint prostheses, dialysis apparatus, and blood pumps);
- anaesthesia and intensive care apparatus; and
- monitoring and cardiology apparatus.

For each of the five categories a subcommittee has been established to advise the Commission Nationale d’Homologation on the homology of a device in the category in question. Homology is granted by the Secretary of Public Health. This decision is based on the results of two tests: technical tests and clinical tests. Technical tests must show that the device satisfies specific safety standards. When no standards for the device exist, a special test protocol is drawn up. These special tests are drawn up into

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40. *Id.* at 28.
groupes de travail and are composed of practitioners, engineers, manufacturers, and representatives from public administration.

If it appears from the technical tests that the device is safe, than it still must be tested clinically. It must be established that the device is suited to the purpose for which the manufacturer intended it. This happens on the basis of a protocol drawn up by the study group, and also in two specifically designated hospitals. For most devices, clinical testing is limited to a period of almost two months in each of the designated institutions. After four years experience with the system, it was concluded that clinical testing was useful. Defects were regularly proven in these tests. This happened in products manufactured by smaller companies as well as in those of larger companies. Clinical testing has proven to be a necessary prerequisite for establishing a device’s safety. Conforming only to technical standards does not offer a sufficient guarantee of safety.43

In principle, homologation means that public (government) hospitals are allowed to purchase only those devices that have successfully passed the test or homologation has been applied for. The intention is to apply this regulation in the future to private hospitals also. A proposal to amend the bill has been introduced in the EEC Commission (every new national regulation that could possibly imply a new trade-barrier has to be announced and reviewed by the Committee (a “stand-still” regulation)). As of 1989 no approval had yet been received. The list of the to-be homologated devices is regularly supplemented; however, the EEC Committee has to approve even these extensions. This list also has not been approved.

Next to the homologation procedure, which mainly deals with a product, a manufacturer can have its production method certified on a voluntary basis. This QUALIMECA certificate is given after inspection by an institution (CERTIMECA) which is assigned that task by the Trade Department.44 The qualification obtained under this procedure entitles a manufacturer to put the “NF” (norme française) sign on its products. This voluntary quality control system has the advantage for the manufacturer that fewer testing obligations are applicable to its products during the homologation procedure.

In 1986 a new system of reporting risks was begun. By way of a departmental circular, all public hospitals were told that important incidents involving medical devices had to be reported centrally.45 Up to February 1989 eighty-eight reports were received. This number is evenly spread over the years and more than half of the reports related to accidents with a device from the anaesthetic-intensive care category. Consequently, the

43. COMMISSION NATIONALE d’HOMOLOGATION, APPROVAL PROCEDURE FOR MEDICAL DEVICES IN FRANCE: BENEFITS FROM CLINICAL TESTING (1987).
French system of quality guarantee for medical devices exists in two parts: homologation of the product (obligatory for detailed devices) and certification of the manufacturer (voluntary).

B. The Homologation of Joint Prostheses

Among implants, pacemakers, implantable infusion pumps, catheters, and joint prostheses are regulated by the homologation regulation. On October 1, 1987 the homologation obligation for joint prostheses took effect. A special Sous-Commission Suppléance Fonctionnelle Orthopédique was set up and was charged specifically with the duty to organize homologation. This subcommittee is composed of practitioners, engineers, and government representatives. It set up a study group, Prothèses Articulaires, which for two years has worked on test protocols for hip prostheses. In particular, they have discussed the homologation of hip prostheses. Currently 526 prostheses have been presented for homologation. They have come from twenty-one distributors. Up to January 1991 approximately thirty to thirty-five prostheses had been homologated.

According to article 3 of the applicable arrêté, manufacturers are allowed to continue introducing prostheses to the market provided homologation has been applied for before March 31, 1988. Considering that there is little experience with this procedure, it has been difficult to draw conclusions about its effects. For that reason, this section will specifically discuss the contents and functioning of this system.

C. The Homologation Procedure for Hip Prostheses

The main objective of the homologation procedure is, as far as possible, to establish the safety of an implant. Also, the system encourages didactic efficacy. Practitioners should be able to become acquainted with the specific properties of a certain prosthesis in a more efficient way. Also, internationally it was believed important to stress safety aspects through this system.

Before describing the procedure, it is necessary to indicate what homologation applies to. It includes all hip prostheses, including those with a femoral and acetabular part. Homologation is requested for a famille of prostheses. Famille includes a group of prostheses bearing the same commercial brand, that are based on the same principle, and where the model can be mutually compared. Every famille can contain several series; every series can contain all sizes of the same model.

The manufacturer submits a request for homologation. This is done by submitting various files:

- a file on the manufacturer’s company, including an eventual certification of the company (QUALIMECA);
- a file on the product; the most important document in this file is the *bulletin d’identification* on the prosthesis in question, in which all specifications are included;
- a technical file; and
- a clinical file.

A technical file is based on data obtained from a series of technical tests. Three devices are tested from each type of prosthesis. These three are technically tested in the Laboratoire Nationale d’Essai. When a manufacturer has the QUALIMECA qualification, only one prosthesis is tested by the Laboratoire Nationale; the manufacturer can test the remaining two and reach its own test results. The tests that are conducted concern the chemical, physical, mechanical, and histomorphological (biological) characteristics of the prosthesis.

A clinical file, depending on the prosthesis’ classification, is based on the results of the clinical trials, which are generally carried out by two different hospitals. These hospitals are selected by the manufacturer and must be endorsed by the subcommittee. They must be selected from a special list drawn up for this purpose by the Department of Health. Clinical trials are only allowed to be conducted by hospitals where members of the French orthopaedic association are on staff.48

These files will have to prove that the prosthesis meets certain criteria. These criteria determine the class into which the prosthesis will be classified. The manufacturer will apply for a certain class. The subcommittee has the responsibility to evaluate an application for a certain class and the results of the tests. Next it proposes homologation for a prosthesis to the Commission Nationale d’Homologation which ultimately grants or refuses homologation. If granted, homologation is for a maximum of five years.

1. *Classification of Prostheses*

The system has five classes with the following characteristics:

- Original prostheses: the classification includes prostheses whose first implantation dates back for more than five years, beginning from the date of the homologation application, and its successive implantations.49

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48. See Christel, *supra* note 44.
49. That is, "a group of absolutely identical prostheses, implanted by a specified institution and during a specified period." *Procédure d'Homologation*, *supra* note 48.
that are followed-up, and prostheses of which there are greater or
equal to fifty within one institution.

- Identical prostheses: these prostheses are identical to the original pro-
  theses, yet they are manufactured by a different manufacturer; the first
  implant dates back to less than five years.
- Modified prostheses: these are original prostheses that have been modi-
  fied; the modification can be to the geometry, the materials used, or the
  manufacturing process.
- Special prostheses: these prostheses can only be implanted by applying
  with a special medical file and by receiving official permission; the
  number of implants will always be under ten.

2. Original Prostheses

Homologation can be granted based on proof produced in three files:
administrative files, files applying to the product, and clinical files. The
product file contains all of the specifications for a prosthesis. The clinical
file consists of three parts: publications in scientific magazines, a statement
from the producer discussing institutions that have performed more than
fifty implantations, and a completed questionnaire regarding the prosthesis' clinical functioning. After selection and approval by two institutions,
enquiries are made about the fifty implants, that is, a questionnaire must
be completed by the surgeon and entered into the file. The file also con-
tains information about the prosthesis' use as well as the results of supple-
mental research being done with the prosthesis.

Along with the clinical file the prosthesis must be technically examined.
This is done in accordance with a protocol drawn up by the Prothèses
Articulaires study group. The group is devoted to examining the files and
makes proposals about homologation to the Commission Nationale
d'Homologation. Homologation can be granted for a maximum of five
years or it can be refused. After five years an extension must be requested.

3. Identical Prostheses

The procedures for this prosthesis proceed in essentially the same way
as with an original prostheses. When it is established a prosthesis is ident-
tical to an original prosthesis (prothèse de référence), the data regarding
this prosthesis can be used. However, a second clinical phase is built into
this category; for the purpose designated, institutions must conduct a pro-
spective clinical evaluation. In the first instance homologation will be
granted for two years; after that a three year extension may be granted
until a clinical file is compiled, as is done for the original prosthesis. Also,
the fact that the prosthesis is still in the homologation phase must be mentioned on its label.

4. *Modified Prostheses*

The procedure to be followed is in principle the same as the procedure followed for an original prosthesis; the second clinical phase is the same as that for an identical prosthesis. However, it must be indicated at which points the modified prosthesis differs from the original prosthesis. Depending on these differences, the subcommittee may eventually require supplemental information. Most important, however, is whether the manufacturer has obtained homologation for the referenced prosthesis or not.

5. *Innovative Prosthesis*

The procedure to be followed is fundamentally the same as the procedure for original and identical prostheses. There is a difference in that permission to test the prosthesis clinically must be requested separately from the subcommittee. Moreover, a special protocol (*dossier innovation*) has to be submitted. This file contains specific innovative aspects of the prosthesis. Depending on the test results, homologation, on the recommendation of the subcommittee, may be granted for two years. Homologation is granted as long as the following three requirements are met:

- a special label must be affixed on which the fact that the prosthesis is still in the homologation phase is mentioned,
- the subcommittee must be informed systematically about all problems occurring with the prosthesis, and
- ultimately, a clinical file must be compiled similar to the clinical file of an identical prosthesis.

After two years, approval for homologation can be prolonged until the clinical file has been completed. If a period of five years has expired since the first homologation request, the existing clinical file is reviewed and a decision is made.

6. *Special Prostheses*

Every year a manufacturer must state how many special prostheses have been sold. If the number is greater than ten, a normal homologation procedure must be started. For the first implantation, the same files must be submitted as is the case with an original prosthesis.

D. *Conclusion*

A number of side-notes need to be made about the French procedural system:
• It is clear that the French system is very time-consuming, especially for the manufacturer requesting homologation and the subcommittee. There is the risk that the system will slow down the admittance of new products to the market. Although there is an awareness of this, and manufacturers and the government try to prevent delay, the procedure does not move rapidly at this time. Currently, of the 526 different hip prostheses up for approval only a limited number have been homologated.

• The field’s experts can have an important impact in view of the fact that the subcommittee plays a central part in the entire procedure. They influence how the testing protocols are drawn up, participate in the decision on classifying a prosthesis, and judge the files on which the ultimate decision on homologation is based.

• The subcommittee is composed of practitioners and engineers with an orthopaedic surgeon for chairman. Consequently, expertise from the field is directly introduced into the subcommittee’s decisionmaking. This is different than the American system where the panel plays a less direct part and only offers advice on the classification of implants. This panel, as is the French subcommittee, is composed of experts from the field and does not play a part in drawing up the testing protocols. This is decided by the FDA, that is, FDA regulations are much less specifically directed to the issues surrounding hip prostheses.

The following can be observed about the contents of the French system:

• It is still too early to draw conclusions concerning efficacy, that is, does the system promote quality.

• It can be stated that it is not clear which prostheses are in an experimental phase and which are not. When a prosthesis is in the homologation phase, it must be mentioned on the prosthesis. Only the existence of an admittance system can have a useful effect on this issue.

• The five year term is essential. It is a reasonable period of time to properly examine a prosthesis.

IV. THE EUROPEAN ECONOMIC COMMUNITY

A. Introduction

Section 2 of the EEC treaty describes the objectives of the Community as the “harmonic development of economic activity throughout the whole Community, a steady and balanced expansion, a greater stability, an increasing improvement of the standard of living and closer relations between the Community and the member States in the Community.”

These objectives should be reached by "instituting a common market and gradually drawing the economic policies of the member states nearer to each other."33

The concept of a common market is not clearly defined in the EEC treaty. Professors Kaptyn and Verloren van Themaat describe the concept as follows: "A common market is a market where every market participant from the concerned community is free to invest, produce, work, buy, sell, or render services under truthful competitive conditions where the economic conditions are most favorable."35 The common market includes all the member states in which marketing regulations exist that are similar to the market of one state.36

Intending to expedite the realization of this common market, the European Commission published in June 1985 a paper that would complete the internal market by 1992.37 In this paper approximately 300 directives are described that must be met before 1992. The completion of the internal market is further laid down in the Single European Act which was enacted in July 1987.38 This treaty amends the Treaty of Rome and was intended to facilitate taking measures to complete unification by December 31, 1992.

Striving after one common market will have consequences for admittance requirements (the "technical" trade barriers) for medical devices. The admittance requirements of the member states still vary very much and constitute a "trade barrier." Consequently, the future must focus on pulling down these barriers. The chosen form of harmonization for medical devices requires that after 1992 a device that in one treaty country is admitted to the market, must be admitted to the market of all other countries without additional requirements. This method will be employed with various other categories of products and is designed to remove technical trade barriers.

In view of the principles of community law (free traffic of people, merchandise, and services), the sovereignty of national authorities is limited to a certain degree by this law. It will be important whether the states will be allowed to take measures on a national level with respect to the quality of implants, in particular regarding hip prostheses. This approach differs from European policy on admitting drugs to the market: after 1992 treaty countries will continue to separately admit a drug to market.

This section discusses the consequences of the EEC law on government policy regarding prostheses' quality. In particular, the problem as to what

34. R.H. LAUWAARS & J.M. MAARLEVLD, HARMONIZATION OF LEGISLATION IN EUROPEAN ORGANIZATIONS (December 1987).
35. Completing the Internal Market, COM (85) 310 final (June 1985).
extent does the common law affect national regulatory policy is discussed. In finding an answer to this question, the directives applicable to medical devices in general and into the consequences these directives may have for national quality control policies is discussed.

In enacting the Single European Act, it was anticipated that the realization of directives by the EEC would be expedited (section 100A). These directives form, in addition to ordinance rules, the means to realize the internal market and are principally directed at abolishing trade barriers. Directives are established by the Council through a majority of votes (section 100A) in favor of the Commission’s proposal. When the drafting of a directive is complete, it must be accepted by the European Parliament, and the Economic and Social Committee must be consulted (section 149). The directives are binding on every member state. The national authorities have the power to choose the form and means by which a directive is implemented. Often national legislation will have to be adopted.

B. Consequences of European Unification

To ensure free movement between the member states, there should be no tariff measures nor qualitative restrictions on rationing imports or imposing quotas between member states. This means that quantitative restrictions and all measures that have the same effect as quantitative restrictions are prohibited between member states (section 30 of the EEC treaty). Existing restrictions must be abolished and new restrictions cannot be allowed. It is important to define the concept of “measures of equal effect as quantitative restrictions.” These are measures that member states try to take to protect their market and that do not directly come under the categories of tariff measures or quantitative restrictions. One and the same sort of effect originates from these measures: the measures would restrict in a more indirect way free interstate movement and, for that reason, may be in conflict with the objectives of the EEC treaty.

The European Court of Justice has passed judgment on the concept of equal effect many times in the last few years. In those judgments can be discovered a distinct policy from which it can be deduced whether national regulation is threatening to become a part of equal effect or not.

In the Dassonville judgement the European Court’s point of view was laid out: “Every trade regulation of the member states that can restrict directly or indirectly potential, intercommunal trade is to be regarded as a measure of equal effect as a quantitative restriction.” In the court’s opinion the prohibition applies as well to measures regarding import and export without discrimination. It appears that the court employs a very wide definition of the concept.

Section 36 of the EEC treaty lays out a number of possible exemptions

on the prohibition found in section 30: "The regulations of sections 30-34 form no impediment to the prohibitions or restrictions on import, export or transit, designed to protect the public order, public safety, health and life of persons, plants or animals . . . etc." This means that national measures coming in principle under the prohibition in section 30 are allowed when the interests of public health would demand it. In the medical device field particularly, this has led to different admittance regulations between member states. This exemption is subject to a number of important stipulations. The most important one concerns a "temporary" exemption, i.e., meaning that when a matter has become the object of community regulation, the exemption of section 36 will no longer be feasible.

C. The Harmonization Exemptions in Sections 100A and Sections 36

As described above, the adoption of the Single European Act met the need to expedite the realization of the common internal market. For that purpose, section 100A was adopted. Through this section the Council can establish with a qualified majority of votes measures on the mutual adoption of regulations by member states for setting up and putting into effect the internal market. Proposals about these measures are considered and approved by the Committee. Proposals in the field of public health, safety, environmental protection, and consumers protection, must meet a high protection level (section 100A, subsection 2 of the EEC treaty).

On the basis of subsection 4 of section 100A it appears to be possible to apply for an exemption under section 36, even after the matter has become subject of community regulation:

When a member state, after the Council has adopted with a qualified majority of votes a harmonization measure, considers it necessary to apply national regulations, warranted by weighty considerations as described in section 36 or to be connected with industrial environmental protection or environmental protection, this State must notify the Commission. The Commission will confirm the regulations in question after having determined that they do not constitute a device for arbitrary discrimination nor a disguised limitation for trade between the member states.

The adoption of section 100A means also that the "temporary" quality (as described above) is taken from section 36.

Verloren van Themaat has stated that with the adoption of section 100A "with every certainty in 1993 all trade restrictions in interstate trade will be removed."58 In this context Professor Ter Kuile mentions the danger of "innovative deterioration" that has sprung up with the introduction of section 100A; it is innovative because the potential is created to

58. INTRODUCTION TO THE LAW, supra note 53, at 206.
accelerate the unification process to ensure completion no later than December 31, 1992 (this should already have been realized according to the Treaty of Rome) and there is deterioration because possibilities remain to limit interstate trade.  

Other literature has argued that subsection 4 has been included exclusively to preserve national regulations that offer a higher degree of protection than the communal ones. With this view, apprehension has been expressed by several member states that realizing the internal market will be at the expense of certain interests such as the protection of the environment or the public health. It is feared that the communal regulations offer only minimal protection. When a member state believes a higher degree of protection is necessary and is forced by the communal regulations to lower this level, subsection 4 of section 100A can be involved. It is the generally accepted view that the member state in question voted against the realization of the communal regulation and that it is a state that is maintaining its existing national regulation. These views cannot be based on the phrasing of subsection 4. In certain cases, eventually new, national regulations with a higher level of protection will be reached. According to James Flynn this can happen when a new government, which has made environmental protection an important policy consideration and thinks the communal level of protection is insufficient, comes to power.

The Commission has to determine whether national regulations are a device for arbitrary discrimination or for disguised trade limitation between member states. After it has been confirmed this is not the case, a regulation is approved. The Commission or member state can apply directly to the Court of Justice if it is of the opinion that a member state has violated subsection 4. After harmonization of section 100A, there are still (limited) possibilities to take national measures on the basis of the exemption of section 36, in principle coming under the prohibition of section 30. When harmonization is based on section 100 (as, for example in the drug field) and after the establishment of the directives, invoking the exemption of section 36 will be excluded.

D. European Normalization Policy

There is an attempt to have free traffic of industrial products on the European level through technical harmonization and normalization. In

61. See J.M. De WILMARS, supra note 60, at 615; and P.J. Slot, Harmonisatie van wetgeving in de EEG, Ars Aequi 38, at 143-51 (1989).
1985 the Council accepted a resolution regarding a new approach in the field of technical harmonization and normalization. In this resolution, a policy was mapped out, the so-called “New Approach.” This policy is based on the sentence passed by the European Court (in the *Cassis de Dijon* case) where it was established that a product rightfully manufactured and brought on the market in one treaty country, must be admitted in all remaining member countries.

Medical devices are categorized as industrial products and trade restrictions for these devices must be removed in the same way as for other categories of industrial products. Consequently, this section will discuss the European normalization policy. From the new approach it appears that normalization will contribute to an important degree to free traffic. The following premises of this new approach are particularly important for medical devices:

- member states are committed to permanently establish a survey for technical regulations in their territory, applicable to abolishing out-of-date or superfluous regulations;
- member states are committed to mutually recognize the results of tests, if necessary, to establish harmonized regulations for institutions issuing certificates;
- extending the system of reference to European standards and, if necessary, to national standards; and
- rapid intensification of the normalization capacity with priority to the European level.

The new approach is based on the principle that harmonization will be limited to the adoption, by means of directives, of the most important safety requirements. Products brought on the market will have to meet these requirements to be allowed to move freely in the Community. Normalization institutions are assigned the task of drawing up technical specifications (standards). Trade and industry need these specifications to be able to meet the essential requirements established by the directives. These standards are, in principle, not binding. The authorities, however, are obliged to approve products having been manufactured in accordance with harmonized standards (or temporarily in accordance with national standards) on the presumption that they meet the essential safety requirements established in the directives.

A manufacturer is free to produce a product that is not in conformity with the standards, but it will have to provide proof that its product meets the requirements of the directives. For this system to function, it is essen-

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tial that the standards offer quality guarantees regarding the essential requirements established in the guidelines. In this way the extension of a system of specific, extreme technical standards for every product can be discontinued. The field of application for the directives has to be defined according to large categories of products and to the type of danger they possibly can pose.

The Committee for European Normalization (CEN) and the Committee for European Normalization of Electrotechnology (CENELEC) have the authority to establish harmonized European standards in the field of application. Based on guideline 83/189 EEC, which concerns an information procedure for standards and technical instructions, national normalization institutions must inform the EEC about their normalization activities. The EEC may freeze activities on a national standard and give the preparation for a European standard to the CEN or the CENELEC. Technical instruction in preparation must also be announced. When the Committee has decided that this instruction forms a new trade restriction, approval will be postponed. Through this action national activities which are contrary to the European policy are prevented (a "standstill convention").

E. The EEC's Directions for Medical Devices

Statutory regulations from the various countries differ. This means that a manufacturer attempting to market its medical device broadly, depending on the country where it entered the market, must meet a variety of requirements. For instance, different labeling requirements, different registration methods, or different good manufacturing practices (GMPs) may have to be employed. These different requirements are, in the sense of community law, trade restrictions and in principle come under section 30 of the EEC treaty. By using the exemption possibility of section 36 of the treaty, national authorities, however, can take measures of a trade restricting nature and which are, for that reason, contrary to the aim of creating a common market by the end of 1992 (with the exception of measures meant to protect the public health). To prove through the European courts that the exemption of section 36 is rightly used by the national authorities (negative harmonization) would require many legal proceedings. The necessity for a positive harmonization policy, that is, the same statutory policy in the different member states, is for that reason argued for, especially by manufacturers; an initiative has been taken to arrive at some such policy.

One of the first matters raised at the deliberations for this policy, is the
question of whether the statutory quality policy for medical devices has to be based along the same lines as the one for drugs. That is, does the system have to be based on premarket approval (supervision of the product) as it is for drugs or should it be based on GMPs (the supervision of the manufacturing process). Manufacturers have chosen a policy in which manufacturing according to the GMPs is the basis. The argument for this policy is that the majority of the devices on the market are not particularly risky to use, and that the best guarantee for product safety and quality can be achieved by drawing up standards the product and the manufacturing process must meet.

On the EEC level, four trade organizations are involved in drawing up draft guidelines:

- the International Association of Medical Prosthesis Manufacturers (IAPM) (concerning active implantable medical devices),
- the Coordination Committee of the Radiological and Electromedical Industries (concerning active medical devices),
- the European Confederation of Medical Suppliers Associations (EUCOMED) (concerning all non-active medical devices), and
- the European Diagnostic Manufacturers Association (concerning in vitro diagnostic medical devices).

The directive regarding active implantable electro-medical devices is the first draft (from the IAPM) which has been accepted by the European Commission.88

In the Netherlands, this directive has been commented on by the Health Council; it is believed that adoption, supervision, and observance problems will be encountered in view of the different admittance procedures employed for the same category of products.89 Also, the directive does not group products into risk classes. The Health Council is of the opinion that the products the directive is addressing belong in the highest risk class. Supervision of these products should therefore be equal to the supervision applied to admit drugs to the market. Consequently, a clear, but strong admittance procedure is desirable, but missing in the directive. Also, no requirements on a product’s efficacy (performance) were included in the directive. This means that a product that meets every safety requirement, but still does not bring improvement in the patient’s health, can be brought into the market.90 In the EUCOMED proposal grouping into risk classes was proposed. This proposal will be discussed in this section.

68. OFFICIAL J. EUROPEAN COMMUNITIES (July 20, 1990).
70. Id. at 10.
The four directives started from the same definition of the concept of a medical device. A "medical device" was defined as:

any instrument, apparatus, implement, material or other article (used singly or in combination) which is intended by a manufacturer for use in humans for:

a. Control of conception;
b. Diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
c. Investigation or modification of the anatomy or of a physiological process which does not achieve its principal intended action by pharmacological means but which may be assisted in its functioning by such means.\textsuperscript{71}

In comparison with the American definition, it is important to note that the phrase used is "intention for use" of a device as indicated by the manufacturer. Through this phrase a subjective element, which must be established by the manufacturer, is brought into the definition. In the event of a disagreement, the manufacturer's intention is decisive, not the objective appreciation of the device's use.

Harmonization will take place on the basis of section 100A through the realization of directives. As described above, directives can be established by a qualified majority and can be based on the new approach. This means that the standards are no longer imperatively dictated, but are a means to establish that a product meets the essential requirements. The requirements are imperative. A manufacturer can meet these requirements by producing a product that conforms with the harmonized standard or that is approved by a national institution. Consequently, the standards are voluntary; a manufacturer is permitted to indicate in a different way that its device meets the essential safety requirements. For instance, one of the requirements can be that a device is to be manufactured from a biocompatible material. By using material that meets a certain standard (a harmonized European or, in the alternative, a national or international standard) for biocompatibility, the manufacturer can prove that its device meets the requirement. A manufacturer can also meet a requirement through its own test results from which biocompatibility of the device is evident. The member states have the responsibility to see that these declarations of compatibility are rightly issued and list the institutions allowed to issue a declaration.

In the case of self-certification that occurs when a manufacturer has declared that the apparatus is in agreement with technical instructions included in the directive, a government must supervise the manufacturer. It must ensure that marks are placed in the right in position. This Euro-

\textsuperscript{71} See infra note 74.
pean CE-mark is, once it is admitted in one member state, a guarantee for admittance to the market in all member states without other limiting measures being imposed. In the EEC directives two official bodies are charged with supervisory duties: the "notified body" and the "competent authority." The first body is charged with issuing a declaration of compatibility; the latter has a more general supervisory duty concerning the execution of a guideline by member states.

F. Consequences of the European Directives for the Netherlands

If the directives are to be accepted on the EEC level, they will have to be implemented by the member states. The manner in which this is done will be determined by every member state. In the Netherlands, implementation can be accomplished by activating the already present Medical Devices Act. The realization of the guidelines also means that general measures based on the Medical Devices Act must be made operational. The contents of these Orders in Council, however, will, for the most part, be settled by European regulations.

The Dutch Health Council has made general comments about the European policies on the quality of medical devices as follows:

- the design directives are predominately dominated by economic concerns; public health aspects are insufficiently addressed;
- there are different plans (as far as those already existing) and there are no communal starting-points, resulting in an inconsistent policy for medical devices.  

Moreover, the Health Council has signaled a number of hiatuses in European quality policy:

- grouping of medical devices into danger classes has not been proposed for all directives;
- there is no obligation to show patients' safety and efficacy via clinical investigations;
- there is no uniform policy regarding registration of products and reporting dangers; and
- there are no demands made about a user's proficiency and expertise.

Orders in Council must be drafted for realization in the Netherlands of a European quality policy for medical devices. The directives can be admitted through Dutch legislation in this way. The "notified body" and the "competent authority" will have to be specifically chosen and charged with specific duties.

72. HEALTH COUN., PERMANENT COMMITTEE ON MEDICAL DEVICES, RECOMMENDATION REGARDING EUROPEAN DIRECTIVES FOR MEDICAL DEVICES (1989).
G. The EEC Directive Under Which Hip Prostheses Come

In April 1988 a design directive that had been drawn up by EUCOMED for non-active medical devices was published.73 On May 26, 1989 the directive was adopted by the Commission.74 In July 1990 a new draft for a directive concerning both active and non-active medical devices was published by the Commission. This new draft replaces the original drafts of directives for active and non-active medical devices. The object of this new draft specifies the conditions under which the CE-mark is to be applied. Hip prostheses are going to come under this new draft. The following principles can be found in the directive:

- proportionality between the weight of the proposed measures and the risk that is run in the normal use of the device,
- producing a device according to a GMP-based system is the best guarantee for product safety and quality, and
- self-certification is appropriate for many devices.

The design directive concept is based on a system in which products are classified into “danger-classes.” Product classification could lead to complex charts for products that are, however, in practice never complete and often controversial. The American system is an example. For that reason a different approach has been chosen and general classification guidelines have been formulated. Through this approach it will not be necessary to classify products separately (as is done in the United States). When designing classifications, the risks involved in using the device must be looked at. “Use” is understood to be defined according to the manufacturer’s directions and intentions. The three-class system imposes measures in relation to the risk associated with a device.

To the “low risk” class (class I) belong devices that, when used according to the directions do not present a foreseeable risk of irreversible illness or injury. In class II (a + b) “intermediate risk” devices this risk is indeed present. However, there is no risk that there will be an injury resulting in death or serious irreversible illness or injury. For devices classified in class III, the “high risk” devices, there is a risk of death or serious damage. Depending on the classification measures, in general the following can be imposed:

- class I: “Low risk”: Manufacturers’s declaration of conformity with the requirements of the directive, notification to the competent authorities;
- class II (a + b): “Intermediate risk”: Declaration, notification, and

73. EUCOMED, RECOMMENDATIONS TO DG FOR A MEDICAL DEVICE DIRECTIVE (Apr. 1988).
74. COMMISSION OF THE EUROPEAN COMMUNITY, DRAFT PROPOSAL FOR A COUNCIL DIRECTIVE RELATING TO NON-ACTIVE MEDICAL DEVICES (1989).
certification of a quality assurance program for design, production, and final testing;

- class III: "High risk": Same procedure as class II; additionally, design approval by the notified body.

On the basis of the two following rules from the design directive, it will be established whether a hip prosthesis will be classified in class II or class III:

Rule 8: implants and long-term surgically invasive devices are class III devices if they are intended to be used in direct contact with the cardiovascular system or the central nervous system; otherwise, they are class IIa devices.

Rule 9: implants and long-term surgically invasive devices that are intended to undergo chemical change, have biological activity, can be absorbed, or deliver medicinal products, are class III devices, unless they are placed in teeth in which case they are class IIa devices.

According to rule 8 implants belong in class III if they are used in direct contact with a vital organ or tissue (such as the cardiovascular system and lungs) and in class II if this is not the case. In principle, hip prostheses will be classified in class II unless they are covered with a bio-active coating, then they will belong in class III.

The essential requirements hip prostheses must meet are described in the design directive. A hip prosthesis must be suited and safe (as far as physical, mechanical, biological, and chemical qualities) for use in conformity with the manufacturer's intended purpose. This purpose must be evident from the labeling or instructions, unless the use is self-evident. Measures must be taken so that the manufacturer can be traced. When a prosthesis is brought on the market and appears to have a deficiency that may place patients or users at risk, the manufacturer must have a suitable system to take corrective action.

In addition, the directive includes articles on the basis of which a member state can take suitable measures. When a device is unsafe, even if it has been manufactured in accordance with the directives, the member state is obliged to report the device to the remaining member states and the Commission.75

It is remarkable that, contrary to the American and French systems, in the design directive admittance to the market is evaluated exclusively on the basis of whether the prosthesis meets the essential requirements. The prosthesis' clinical functioning, from the results of clinical trials, is not included in the procedure regarding admittance to the market unless this should be a subject of the quality assurance system (obligatory for classes

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75. This concerns the "safe guard clause" (section 36 of the EEC Treaty).
II and III) or design approval (obligatory for class III). Other than directions for use the manufacturer is obliged to supply, the directive settles nothing as to the prosthesis' user phase. Post-marketing controls do not come under the directive because they do not constitute a check for bringing a device to market. Perhaps it is still too early to draw conclusions as far as the efficacy of these future regulations. Still, it is clear that priority has been given to drawing up measures specifically directed at the manufacturing phase: GMPs, sterilization, and biological safety. Currently, the other phases of the life duration are only being paid summary attention.

With respect to hip prostheses, by 1993 the Dutch government must have settled a number of matters raised by this directive. At the minimal, a registration system for suppliers must be arranged. For that reason an Order in Council must be drawn up that will not only be applicable to hip prostheses, but also to a great number of other devices. These measures will have a general character and admittance of a device to market will not occur on the basis of the results obtained from long-term clinical tests.

V. GREAT BRITAIN

To get an impression of the system of government that guarantees the quality of medical devices in Great Britain, it is necessary to discuss briefly how the British health care system works. In principle in Great Britain, every citizen is insured for health care via the National Health Service. The Department of Health and Social Security (DHSS) has approximately 1900 hospitals that come under the National Health Service's management. This means that it arranges financial management and quality assurance programs. That management task has resulted in the DHSS becoming the medical device industry's most important customer. Annually about 650 million pounds sterling is invested in this task. Based on these efforts, the DHSS puts its stamp on the quality policy for medical devices. The most important part of this policy is the Manufacturers Registration Scheme. The registration of manufacturers was started in 1981 and now lists more than 400 manufacturers. The objective of this registration is to supervise and check the quality of the devices produced by drawing up standards and making inspections. In this way, information is obtained that may possibly help to procure medical devices.

To be registered, manufacturers must state that they manufacture in

conformity with the applicable *Guides to Good Manufacturing Practices* that have been drawn up by the DHSS. When no applicable GMP exists for the device in question it must be produced to conform to the relevant part of British Standard 5750: Quality Systems. A manufacturer is only registered when an inspection by the DHSS has proved that its devices are being produced in conformity with GMPs or a standard. Registration is valid for a period of three years; if it becomes obvious that the conditions are no longer being met, the registration can be canceled by the DHSS.

Participation by a manufacturer is voluntary. Hospitals belonging to the National Health Service are strongly advised to procure exclusively devices coming from a registered manufacturer. In reality the consequence of the registration system is that if a manufacturer is not registered, it does not sell. In 1981, registration was limited to manufacturers of sterile products and pacemakers. Now the system has been extended to electro-medical apparatus meant for diagnosis or treatment, orthopaedic implants, revalidation apparatus, wheel chairs, and surgical devices.

Supplemental to this registration system is a registration system for problems with medical devices. For several years the DHSS has instructed that National Health Service hospitals should record centrally proven defects in medical devices. Although this is a recommended policy and is not followed 100% of the time, great interest is attached to the registration. About 1000 reports are received annually, and in ten percent of the cases a warning is issued by the DHSS after the report is received.

In 1984 a “Good Manufacturing Practice for Orthopaedic Implants” (the “Gold Guide”) was drawn up by the DHSS in cooperation with the United Kingdom Trade Associations. In this guide, GMP requirements for a quality-watching system that should be employed by manufacturers of orthopaedic implants was specified. This system principally concerns production, but also contains elements regarding checking the design of an implant. Section 4.8(h) of the GMP dictates the evaluation of new material under suitable environmental conditions. For orthopaedic implants, the “environmental conditions” should exist out of *in vitro* testing under full load and/or in contact with a chemically active environment, *in vivo* testing on animals, and testing in clinical trials. This GMP has no statutory force and must not been seen as an interpretation of any kind of statutory regulation. The GMP does form the basis for registration of manufacturers through the Manufacturers Registration Scheme.

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79. *Id.*


For a number of medical devices in Great Britain premarket approval is required by the Medicines Act and is not based on other statutory measures. By influencing the purchasing policies of hospitals, it has attempted to induce manufacturers to supply a certain level of quality in the manufacture of their devices. In general, there is satisfaction with the functioning of this British system and there are intentions to extend the Manufacturers Registration Scheme to other groups of medical devices.

VI. WEST GERMANY

In West Germany quality policy for medical devices is realized through two different categories of legal measures. The first category concerns drugs. The concept of "drug" as it is used in the Arzneimittelgesetz must be understood to mean "classic" drugs, as well as a number of products of which many are defined and regulated as medical devices. This group includes sterile devices for once-only use (disposables), implants, sutures, and in vitro diagnostica. To the "classic drugs" group also belong certain dental implants, bone cement, and implants made out of animal material.

The second category of measures primarily concerns medical apparatus. The most important regulation is the Medizingeräteverordnung which took effect January 1, 1986. In this regulation, medical devices are classified into four groups:

- **group 1**: indicated active (that is, furnished with an energy source) medical apparatus, such as defibrillators, infusion pumps, and anaesthetic apparatuses;
- **group 2**: active implants;
- **group 3**: active medical apparatus not coming under group 1 or 2; and
- **group 4**: all remaining apparatus.

For devices exclusively in groups 1 and 2, a premarket approval is obligatory. A device from these groups must be tested in a testing institution (the Technischer Überwachungs-Verein). In this inspection, the emphasis is on the apparatus' safety and not so much its efficacy. Testing is done with German standards as the focal point.

For devices from groups 1, 2, and 3 notification of defects in apparatus by the user is obligatory. For implants from group 2, the manufacturer must attach a registration card to the implant. On this card the manufacturer's name, type of device, serial number, and expiration date must be...
indicated. Room must be left for inserting the implantation date, the answerable person with respect to the implantation, and data and results of a follow-up. The obligations for these active implants are not applicable to orthopaedic implants. These come under the drug legislation and are regulated as drugs. For these implants, as for classic drugs, it is forbidden to bring an unsafe drug (in this case an implant) onto the market. The most important regulation applicable to orthopaedic implants concerns a notification duty to the respective authorities on the development, experimentation (clinical trials), and introduction to the market of a new implant. Special mention is made of the clinical trial regulation, especially protection of the subjects of the experiment. There are specific instructions for labeling and a device must be produced according to GMPs. Contrary to the situation for classic drugs, premarket approval is not obligatory for orthopaedic implants and quality inspection is based on inspection of the product process.

VII. SUMMARY OF THE DIFFERENT STATUTORY REGULATIONS FOR IMPLANTS

In the Netherlands, the Dutch Medical Devices Act has been implemented in only a limited way. This means if an implant's life cycle is taken as a starting point, only during the production phase can requirements for sterility be implemented. In time, when concern about experiments on people is turned into law, the experimental phase will be reviewed more strictly. Currently admittance to the market is not regulated by the government (except for rubber condoms). When, after 1992, the European quality policy for medical devices is implemented into Dutch legislation, this situation will change.

Production and the remaining parts of the diffusion phase (purchasing, application, and follow-up) are not regulated by the government. This means that within an institution everybody is free to procure a certain implant and apply it, although that application must be done by a qualified practitioner in the field. Compared to a country with detailed medical device regulations, the United States, the situation is completely different. The Medical Device Amendments see to it that there is government regulation in a great number of phases in the life cycle of a device. In principle, implants belong to class III devices, meaning that the FDA's premarket approval is necessary before bringing an implant to market. When a manufacturer wants to introduce a new implant, the FDA has to be notified through the premarket notification procedures found in section

87. Id. pt. 2, para. 4, subsec. 2.
88. Arzneimittelgesetz, para. 2, subsec. 2 (2).
89. Id. para. 5.
90. Id. para. 67.
91. Id. para. 40.
510(k). When a manufacturer can prove that the implant is equivalent to an implant that was brought onto the market before the enactment of the Medical Device Amendments or is equivalent to a reclassified implant, consent is given immediately by the FDA. When substantial equivalence cannot be proved, the manufacturer, by way of the results of clinical trials and other tests, must prove that its product is safe and effective. The FDA’s consent is required to carry out these trials (the investigational device exemption). Thus, the experimentation phase is also submitted to government regulation. During the production phase, general control measures must be applied according to a GMP. During the users phase, the medical device reporting regulation is applicable, meaning that every problem with a medical device, as well as with an implant, that becomes known to the manufacturer, must be reported to the FDA.

In France, the production phase is governed by voluntary government regulation. A manufacturer can have its production process certified (QUALIFERCA). Admittance to the market is, for a number of medical devices, subject to obligatory approval through homologation. In principle, the system is only obligatory for medical devices used in public hospitals. In those hospitals, only sanctioned medical devices are permitted to be purchased and applied. For implants, pacemakers, implantable infusion pumps, catheters, and joint prostheses, it is obligatory to apply for homologation. In principle, all joint prostheses must be sanctioned. This classification has resulted in further elaboration of the regulation for hip prostheses. Classification depends on the prosthesis’ character, and whether it is innovative or has already been applied in practice for a period of time. Next to the results obtained from technical tests, the results of clinical trials are involved in the evaluation. A prosthesis with an innovative character, after approval from the Sous-Commission, must be tested experimentally. In the application phase, registration of problems (device alerts) are obligatory for prostheses implanted at public hospitals.

In Great Britain the existing regulatory system is, in fact, not statutory. For that reason, the regulations are not obligatory. For orthopaedic implants, the regulations include working according to GMPs and registration in the manufacturer’s registration scheme. Hospitals belonging to the National Health Service should purchase only devices from registered manufacturers. A provision for voluntary reporting of problems experienced with medical devices exists in the application phase.

In West Germany, implants can come under the purview of the drug legislation or under the regulation for medical apparatus. Implants coming under the purview of the drug legislation, for example orthopaedic implants, must meet a number of conditions. The most important condition is that it is forbidden to bring an unsafe device to market. Labeling instructions and production must be conducted according to GMPs. Premarket approval is not obligatory for these implants, contrary to active
implants which fall under the medical apparatus legislation (e.g., pacemakers). Premarket approval is obligatory for these implants.

The EEC policy is aimed at eliminating the trade restrictions between treaty countries. In the field of medical devices, these trade restrictions consist of different market admittance requirements enacted by each treaty country. For that reason, future EEC quality policy for medical devices will emphasize admittance to the market, as well as the way in which production takes place. The directives will indicate the essential requirements a device must meet for its manufacturer be allowed to introduce it to market. By observing standards during production (which must be drafted on the European level), a manufacturer can show that the requirements have been met. It is not obligated to do this and can also make out its case in other ways. The device will then be tested by an external body. When a device in one treaty country has been admitted to the market, the manufacturer will automatically obtain access to the whole European market because a different treaty country cannot make different demands for the device to meet. In view of the points of departure in EEC policy, the remainder of the diffusion phase has not come up for much discussion. The attention for the users' phase limits itself to the users, labeling, and maintenance directions a manufacturer must produce with the device. For active implantable medical devices, a separate EEC directive has been drawn up; the remaining implants will come under the directive being drawn up for non-active medical devices.