

Medical Devices in the European Community

This paper proposes an overview on the Medical Devices legal framework in the European Community, considering the possible regulatory changes.

General overview

The medical devices play in healthcare an essential role in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities. In addition to that, the protection of health and the associated controls should be constantly more effective.

Concerning to its importance the European Union (hereinafter as "EU") has enacted a regulatory framework for market access, international trade relations and regulatory convergence, all aiming to ensure the highest level of patient safety as well as promoting the innovation and the competitiveness of this sector.

The rules relating to the safety and performance of medical devices were harmonized in the EU in the early 1990s. The core legal framework consists on the following directives:

- (i) Directive 90/385/EEC – regarding active implantable medical devices;
- (ii) Directive 93/42/EEC – regarding medical devices;
- (iii) Directive 98/79/EC – regarding in vitro diagnostic medical devices; and
- (iv) Directive 2007/47/EC – amending the Directive 90/385/EEC and Directive 93/42/EEC, which came fully into force on March 21, 2010.

Further, there are the implementing legislation and some legally non-binding Guidance documents which attempt the objective of ensuring uniform application of the relevant provisions of the directives within the EU.

In the terms of the article 1 paragraph 2 point (a) of the Directive 93/42 (hereinafter as "Directive"), and further amendment, medical device means *any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:*

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

In addition, the Directive includes also in its definition of medical devices its accessories which are intended by their manufacturer to be used together with a device to enable it to be used, and as a matter of consequence they are covered by the Directive.

As the Directive aims essentially at the protection of patients and users, the rules relates in general to finished products regardless of whether they are intended to be used alone or in combination. This means that the Directive pursues to act on products with a stage of manufacture, where they are supplied to the final user.

Following this concept raw materials, components or intermediate products cannot be considered as medical devices. Although, raw materials may need to present properties and/or characteristics that will be determinant for the safety and quality of finished devices. The manufacturer of finished devices will be responsible to select and control his raw materials or intermediate products.

Furthermore, nanomaterials are also now being investigated for use in new medical devices, as manufactures are increasingly looking to nanomaterials to improve the functionality and reliability of their products.

Classification

The devices are classified by the Directive in four different classes, such classification will have an impact on the conformity assessment route that the manufacturer should follow in order to affix the CE marking requested on the medical device. The devices are divided in Class I; Class IIa; Class IIb; and Class III.

In order to identify the correct Class there are 18 Rules, disposed by the Annex IX of the Directive, where the manufacturer must take into consideration all the rules in order to establish the proper classification for its device. Such classification rules are divided in: non invasive devices; invasive devices; active devices; and special rules.

The classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device. This classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking account of the potential risks associated with the devices, e.g., if the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use. The following summary is not exhaustive but intend to provide a general overview of the classes:

- (i) Class I – are devices non-invasive with low risk - either do not touch patient or contact only intact skin, such as stethoscopes and bandages;
- (ii) Class IIa – are devices with a low-medium risk, normally intended for continuous use for not more than 30 days, as called short term;
- (iii) Class IIb – are devices with a medium-high risk, normally intended for continuous use for more than 30 days, as called long term;
- (iv) Class III – these are high-risk devices, usually used for long term, some examples are balloon catheters and prosthetic heart valves.

The manufacturers must also take account of additional Directives which may affect the classification of their device or the conformity route to be followed, *e.g.*:

- Directive 2003/12/EC7 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices.
- Directive 2005/50/EC8 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.
- Directive 2003/32/EC9 introducing detailed specifications as regards the requirements laid down in Council Directive 93/ 42/EEC with respect to medical devices manufactured utilising tissues of animal origin.

CE Marking

After complying with the essential requirements established by the Directive, the devices are requested to bear the CE marking of conformity when they are placed on the market, with exception of the devices custom-made or intended for clinical investigations. CE marking has to be placed visibly and legibly on the product or, if not possible due to the nature of the product, to the packaging and the accompanying document.

The CE marking is requested to be affixed only by the manufacturer or his authorised representative. By affixing or having affixed it, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements. The affixing to a medical device of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking is prohibited. Any other marking may be affixed to the device provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.

The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the imposed obligations ensures and declares that the products concerned meet the provisions of the Directive 93/42/EEC which apply to them. It is also requested the inclusion of the manufacturer's details such as name and address, essential characteristics of the product, if applicable the identification number of the Notified Body as well as a legally binding signature on behalf of the organisation.

Since the devices bear the CE marking Member States must not create any obstacle to their placing on the market, in view of art. 4 of the Directive, which lay down the free circulation of medical devices bearing CE marking by abolishing the need to obtain authorisation on a country-by-country basis. Despite the fact that there are special measures prescribed by the Directive that may restrict such free circulation, as article 8 (safeguard clause) and article 14b (particular health monitoring measures). If the devices will be used for exhibition on trade fairs is not imposed the CE marking, although must be clearly signed that the device do not have it.

In general, the devices must be designed and manufactured in such a way that, when used under the conditions and for the purpose intended, they will not compromise the clinical condition or safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

The achievement of the essential requirement is made through clinical data evaluation, as set out by Annex X of the Directive. Clinical evaluation is based on the assessment of the risks and the benefits, associated with use of the device. The manufacturer must demonstrate whether the available data is sufficient to establish conformity with the Directive.

However, before to be placed on the market the device may be subject to a clinical investigation, which consist in a systematic study or investigation of safety and performance of a device being used by human beings in accordance with the device normal use. For such investigation the manufacturer, or its authorized representative, must comply with procedures established by the Directive. The objective of clinical investigation is to provide clinical data in order to:

- ascertain that, under normal conditions of use, devices performance is conforming with the performances intended by the manufacturer; and
- verify any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the indented performance of the device.

Notified Body

The Notified Body is an organization designated by the Competent Authorities in the Member States to carry out one or more of the conformity assessment. Their competence, in most of the cases, is to verify the quality management of the manufacturer, in particular, to examine the basic safety and design of the device and its compliance with the essential requirements and, finally, to issue a certificate that indicates what has been verified. Subsequently, the manufacturer has different options as how to assess the conformity of the device. The stringency of the conformity assessment procedures depends on the class of the medical device.

Prior to submission of an application to the Notified Body, it is requested to the manufacturer to establish the technical documentation, which enables the assessment of the conformity with the requirements of the Directive. The technical documentation must be kept for a period of at least 5 years, after the last product has been placed on the market.

It is important to establish whether the manufacturer can assess the device by himself or whether he has to involve a Notified Body, for example, the involvement of the Notified Body may not be necessary for medical devices of class I, unless they have a measuring function or are placed on the market in a sterile condition.

Whether is requested the involvement of a Notified Body in the conformity assessment procedure, its identification number must also be displayed.

Import of medical devices in EU

Europe has three of the five largest medical device markets in the world: Germany, France and UK. The import of medical devices in the Western Europe has been growing and the imports tend to account for around 80% of the market.

In particular in Italy, whose market is the third largest in Europe, the consumption of medical equipment and supplies is valued at US\$ 8 billion in 2010, equal to US\$133 per capita. Even in Italy, with a sizeable medical manufacturing industry, the overall medical device market remains reliant on imported goods, the value of which was US\$ 6.3 billion in 2009.

Despite the economy downturn there is economic analysis which signs that the Western Europe market is committed to investing in the latest technologies and are still projected to grow.

As mentioned above, devices to be placed on market within the European Union must comply with the Directive 93/42/EEC, especially in what regards to the bearing the CE marking. Therefore, devices produced outside the EU must comply with the Directive in order to be placed on the European market.

Since the device is correctly CE marketed, *i.e.*, in due form and subsequent to the correct application of the respective conformity assessment procedure, it does not need any additional approval or certification to be marketed in the entire EU, in the European Economic Area and in Switzerland.

Controls and rules applied to products coming from extra EU countries are as rigorous as the ones applied to internal products. In addition, custom houses must ensure controls at the entrance. A manufacturer without a registered place of business in EU must designate a single authorized representative and the address of the Representative must be placed on the label of the device.

Authorized Representative

It is required to all manufactures based outside the European Community to have a single authorized representative located in Europe, as provided on art. 14 paragraph 2 of the Directive, in order to enable the Competent Authorities to contact the manufacturer.

The authorised representative is a natural or legal person established in the EU, who is designated by a non-European manufacturer to act on his behalf in carrying out certain tasks required in the applicable directives. While in no circumstances the manufacturer will be discharged from his responsibilities. The manufacturer has sole and ultimate responsibility of the product to the applicable directives, whether he designed and

manufactured the product himself or is considered as a manufacturer because the product is placed on the market under his name.

For the purpose of the New Approach directives of the EU, *i.e.* measures adopted to simplify the movement of goods throughout the EU, the authorised representative must be established inside the Community and may be addressed by authorities and bodies in the Community instead of the manufacturer. The manufacturer remains generally responsible for actions carried out by the authorised Representative on his behalf. Additionally, authorized representative of Classes IIa, IIb and III must inform the Competent Authority of the Member State in which he has his registered place of business.

The delegation of tasks from the manufacturer to the authorised representative must be clear and take place in writing, in particular to define the contents of the tasks and the limits of the representative's powers. It is essential to ensure that the responsibilities of the manufacturer and the selected authorised representative are clearly outlined and stipulated in a contract. Further, the authorised representative is not allowed to modify the product on his own initiative, in order to bring into line with the applicable directives.

The duties of the authorised representative consist in: observing the manufacturer's compliance with the conformity assessment procedure set out in the European directives which apply to the product; ensuring if his contact information is available to the manufacturers in order to be fixed on all the products he is representing, thus acting as a primary contact for the EU authorities; and, finally, keeping the product technical file available at any time for the EU Member States authorities and maintaining confidentiality with manufacturer's sensitive product information.

Regardless of the tasks that may be delegate to the authorised representative, the appointment of a representative does not mean a sale and marketing function, it describes a CE compliance/regulatory affairs function only. Even if the authorized representative may be able to act on post sales issues, like: incident reporting, product recall, complaint handling and post market feedback.

The Global Harmonization Task Force

With the rapid growth in the global market for medical devices, there is a need to harmonize national standards in order to minimize regulatory barriers, facilitate trade and improve access to new technologies, such harmonization should also reduces the cost of implementing regulations for governments and local industry.

Hence, in order to respond to this need, the Global Harmonization Task Force (GHTF) was conceived in 1992 by the governments and industry representatives of Australia, Canada, Japan, the EU and the United States of America to address these issues.

The purpose of the GHTF is to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical devices. The GHTF also promotes technological innovation and facilitates international trade.

The primary means by which its goals are accomplished via the publication and dissemination of harmonized guidance documents for basic regulatory practices. These documents, which are developed by four different GHTF Study Groups, can then be adopted and implemented by each member national regulatory authorities and others. Technical committee members include representatives from national medical device regulatory authorities and the regulated industry.

In general terms, the benefits of the GHTF are the following:

- (a) By following recommendations from the GHTF, countries can ensure that their regulatory controls are not in significant conflict with global harmonization recommendations. The GHTF is directing and converging the harmonized guidance documents;
- (ii) Critical issues such as safety and performance requirements, quality systems, standards and procedures of post-market surveillance are studied in-depth by experts from different countries to reach consensual recommendations and these are incorporated into the GHTF final guidance documents;
- (i) Global harmonization and cooperation in post-market surveillance will facilitate an international devices data bank that allows rapid, global access to device information, alerts or recalls. This will promote the safety and effectiveness of medical devices;
- (ii) Where a country's programme is harmonized with the programmes of other countries, regulatory burdens and costs for local government and industry will be significantly reduced, while regulatory cooperation, commerce and international trade will be enhanced.

It is important to note that one of the key elements of this task force is the use of a single nomenclature system that is available for regulatory purposes. It is proposed a Global Medical Device Nomenclature - GMDN coding system which is already being utilised by some of world's medical device regulators and industry.

Amendments

The European Commission identified that the current system does not always offers a uniform level of protection of public health in the EU, therefore they have started to valuate a revision of the Medical Device's legal framework, even after the last technical revision, which brought the Directive 2007/47/EC.

Bearing in mind that the main objectives of the Directives enacted is a high level of safety for the patient and user; deliver a transparent system whereby citizens can be confident in the safety of medical devices; and a simple and easily-understandable regulatory environment to ensure the efficient functioning of the internal market. The initiative follows the same principles.

Therefore a public consultation regarding the general features of the possible recast of the Medical Device Directive was launched in May 2008; the result of the 200 responses was published in December 2008.

Some problems were identified after this public consultation held, leading to a fundamental revision of the existing directives in order to simplify and strengthen the current legal framework. Particularly the Directives has been criticised as being too fragmented and difficult to pursue, for the most part for micro, small and medium enterprises, third countries manufactures or trade partners.

The emerging technologies are challenging the current framework, highlighting some gaps not covered. Additionally, due to the flexibility given by the directives (which is a legislative act not self-executing and do require implementing measures to the Member States) caused a regional variation such as in the areas of definition of a medical device, national registration procedures, classification and interpretation of guidance, has impede the progress of the Medical Devices legal framework.

Thus in this recast of the Medical Devices Directive is being considered as options:

- merger of Directives 90/385/EEC and 93/42/EEC, and their codification;
- separate legislative proposal would address the fundamental revision of the Directive 98/79/EC on in vitro diagnostic medical devices; or
- adoption of a regulation, if technical, scientific and administrative tasks in the field of medical devices are to be conferred on a European body.

The adoption of one of the options would lead to significant impacts. Such impacts will affect, within the EU, the Notified Bodies as involved in the evaluation of medical devices and in the manufacturers' quality system and the medical device industry. There may also be an impact on public authorities but, on the other hand, a centralization of certain procedures could create synergies and reduce duplication of tasks at the level of the individual Member States.

As regard the public consultation on the "Recast of the Medical Device Directives", most respondents confirmed that the current legal framework for medical devices left room for improvement to strengthen the regulatory system.

Further elements of centralization were considered useful, although the suggestion to expand the role of the European Medicines Agency (EMA) to include medical devices was rejected by a majority of respondents. This was based on the fear that the involvement of the EMA would represent a move towards the adoption of a pharmaceutical-like regulation for medical devices.

In particular, on the issue concerning the legal simplification, the majority of respondents opted for the merger of Directive 90/385/EEC relating to active implantable medical devices and Directive 93/42/EEC relating to medical devices, including their amending and implementing measures and keeping Directive 98/79/EEC on in vitro diagnostic medical devices separate.

There was full support for the view that the New Approach provides the right regulatory framework for medical devices and the following issues were mentioned:

- the possibility of delegating the designation and monitoring of Notified Body to non-governmental bodies is considered unsuitable;
- the current expertise of the European co-operation for Accreditation is considered insufficient for the medical devices sector;
- the need to ensure that the specific competencies of Notified Bodies are verified;
- a specific CE marking to distinguish the medical device from other products (e.g. "CE med"), greater involvement by the regulators in standardization work.