New European Union Directive Brings Further Changes On Certification Of Medical Devices

The need for each member state to transpose Directive 2007/47/EEC at national level will lead to a further alignment of each member state to the community regulations on certification.
The introduction of such regulations underlines the necessity for dental companies operating within the Community to acquire adequate information to avoid incurring risks.

The need to transpose Directive 2007/47/EEC at national level within the European Community has enabled EU Member States to introduce, with some limitations, further elements necessary to adapt the EU legislation to the specific national contexts.

This article will focus on the implementation of such directive in Italy, through the Legislative Decree 25 January 2010, no. 37, published in the Official Gazette no. 60 dated 13 March 2010.

Given the rapid technical changes occurred in the design, production, use and safety of medical devices, this Decree is intended to make Italian legislation on medical devices more coherent.

As well as transposing the technical aspects of the new Directive, the Italian legislation has undergone adjustments on "supervision of accidents", "clinical trials", "publicity" and "penalty system".

In particular, rules governing the supervision of accidents present significant innovations: all withdrawals of medical devices from the market imposed by the Ministry of Health are under the responsibility and at the expenses of the manufacturer if the manufacturer has wrongly applied the technical regulations of the EU Directives or even if he has applied them correctly but they are not specific and complete for his type of production.

If the manufacturer fails to observe the obligation of withdrawal, it is considered a criminal offense. This subject is governed by Article 9 that replaced Article 10. The different types of accidents to be reported by health profe-ssionals (paragraphs 2 and 3) and manufacturer (paragraph 7) are included in the 1st paragraph of this article, while the methods of communication are currently defined in the Ministerial Decree 15.11.2005.

Lastly, the manufacturer must provide a method for assessing the experience acquired on his devices during commercialization (post-marketing follow-up, Annex II, paragraph 5 and Annex X, paragraph 1.1 c).

In fact, the surveillance and supervision of accidents, operated by competent authorities of the Member States, are subsequent to the phase of commercialization and they occur either through random controls or reports from the parties.

Such method of subsequent controls on the entrance of devices into the market has led to the drafting of a policy that provides more specific requirements to keep records of the devices. For instance, attention was driven towards the inclusion of a deadline that represents a specific time limit required for keeping the documents, thus providing a base for the application of the penalty when rules are broken.

Furthermore, to ensure effective, proportionate and dissuasive force to sanctions, the cases for the use of special penal sanctions have been limited to two: non-disclosure of serious accidents and failure to comply with mandatory provisions of the competent authorities. The formula "unless the act constitutes a crime", was maintained to permit the application of any additional penalties and sanctions in cases of criminal offenses affecting constitutionally guaranteed interests such as health (e.g. Articles. 441, 582, 589, 590 of the Italian Penal Code).

In order to allow competent Italian authorities to run efficient and fast actions of monitoring and supervision to protect public health, two directions have been followed:
- updating of the rules on special measures for health monitoring and safeguard clause (Article 8-8-a and b, L. Decree N.507/92 - Articles. 7:13-ter of L. Decree no. 46/97);
- the provision of pecuniary sanctions for the subject responsible of improper or absent CE marking, alongside administrative measures restricting market entry as well as imposing the withdrawal of the product for evaluation (Article 9 L. Decree no. 507/92 - art. 17, Leg. n.46/97).

Over 90 sheets were drawn for the evaluation of both gravity and extent of the breach of regulations. Many factors were considered in preparing these sheets such as the territorial extension and potential duration of the infringement, the level of adverse effects, the potential illegal economic benefits obtained by the subject responsible, whether the guilt originated from intention or negligence, individual or collective punishable behaviour.

Different categories of subjects potentially involved in the infringement were considered: from the manufacturer to the individual health professional

(taking into account the degree of consciousness of the act, its consequences and the potential economic benefit that such persons might have drawn from the unlawful conduct).

Hence, five levels of indicators were identified for the violations contained in the text which, to ensure effective deterrence, have been associated to five levels of minimum amount of the penalty, setting the highest amount at six times the first.

The central subject in the regulation of medical devices, as it has been outlined for years at EU level, is the manufacturer/authorised representative. Most of the obligations concern this category: manufacturers have to notify the Ministry of Health address and description of devices and they must provide all data necessary to identify these devices, along with label and instructions for use.

If the manufacturer is located outside the European Union, he must explicitly designate a single subject, natural or legal person established within the Union, who acts on behalf of and can be addressed to instead of the manufacturer. Manufacturers are also subject to sanctions ranging from EUR 500 to 128,400.

Among the merely economic implementations, it is also included the payment, to be carried out by 30 April of every year, of a 5% contribution for self-assessment for promotional activities directed towards health care workers. (The obligation to pay is governed by 1st c. 409, Lett. d) of Act No. 266/05, as amended by Article. 1, c. 825, Lett. b), Law No. 296/06).

The contribution is borne by all "companies that produce or market medical devices in Italy, including in-vitro diagnostic medical devices and custom made devices".

The rule applies to the promotion of a product by "doctors, health professionals, including executives of health institutions and pharmacists", if the product meets the definition of "medical device" and is labelled and marketed under the EU sector directives.

"The total expenditure borne in the previous year" is the basis of assessment for contribution. It includes specific "cost items" as by Technical Annex to the Ministerial Decree 23/04/2004 - relating to the pharmaceutical field, but to which this law explicitly refers to - excluding "net costs for the staff".
Failure to pay leads to a penalty of EUR 7,500 to 45,000, besides the sum already due, increased by 5% for each month of delay.

The most relevant administrative penalties are those affecting subjects who place into the market or service medical devices without CE marking or attestation of conformity (both the manufacturer's declaration and any certificate issued by the Notified Body).
In such case, the penalty ranges from EUR 21,400 to EUR 128,400 for any subject placing in the market, selling or servicing non-compliant medical devices, as well as for the manufacturers of custom made devices that are non-compliant or without the declaration required in the relevant technical Annex.
These sanctions are aimed at protecting and ensuring the so-called "public confidence" in the regularity of CE marking. Just as serious are sanctions for the manufacturers/authorised representatives that mark a device inappropriately, as in the case of products falling outside the definition of the Decree, or unduly, because the product does not meet all essential requirements.
Medical devices not bearing CE marking are always subject to administrative seizure.

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