BEYOND THE DIRECTIVE 2007/47: RECAST, NEW "NEW APPROACH", GLOBAL ARMONIZATION

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Slide 1

The first medical devices directive, the directive on active implantable medical devices (AIMDD), was published in nineteen ninety, twenty years ago. Later, in nineteen ninety three, it was published the medical device directive (MDD) and in nineteen ninety eight the in vitro diagnostic medical devices directive (IVMDD).

The aims of the three directives are the same: the free movement of medical devices in the community market (obtaining the internal market) and the fact that the medical devices circulating are safe and achieve the performances intended by their manufacturer in order to ensure a high level of health protection in the community.

Now, twenty years later, we can ask if we have succeeded in achieving these two objectives.

Slide 2

Regarding the first aim, in fact, the medical devices which bear the CE marking are free to move within all Member States. However, there are some elements that disturb the smooth functioning of the internal market. The most important are:

- Different interpretations of the legal definitions, beginning by the own medical devices definition, that lead to different decisions on the legal consideration of a product (particularly controversial are the terms "modification of the anatomy" and the borderline cases medical devices/ pharmaceuticals).

- Member States have introduced in their national transposition of directives different measures intended to allow the competent authorities to fulfil the responsibilities that the directives impose to them in the article two.

These two elements create a fragmentation of the internal community market, reduce the benefits of the free movement of devices and lead to legal uncertainty for the industry.

On the other hand, there are, also, some elements that affect to the security of internal market, such as:

- Lack of traceability. According to the general regulation on products marketing, the manufacturer is obliged to take the appropriate steps, such as ceasing the marketing or withdrawing the product when a risk appears. But, actually, the manufacturer has not always the possibility to know where the products are marketed. There are other economic operators, for example importers or distributors, different from the manufacturers, who have the control of the trade chain. These operators are not regulated in the medical devices directives.

- Finally, we have to accept that there are economic operators that take advantage of the New Approach regulatory system to place on the community market false CE marked devices or, even, counterfeit devices.

Slide 3

Regarding the second aim, the directives envisage that Notified Bodies designated by the Member States perform an assessment on the product conformity with the requirements and quality assurance systems established in the regulation. That should give the guarantees of health protection pursued by the system.

However, there are, again, some elements that disturb the full attainment of this aim. The most important are:

- Member States do not apply the same criteria to check the Notified Body competence in the designation process and they do not perform in equal way the monitoring task of these bodies. The work done in the NBOG group, composed of the national authorities, is not enough to assure the consistency in this matter.

- One issue where the differences on the interpretation of the Notified bodies' tasks are more evident is the way how Notified bodies perform the assessment of the clinical data. That led, in some cases, to insufficient clinical evidence on the safety and efficacy of the device.

- On the other hand, the high rate of development and innovation in the medical device sector produces the introduction on the market of new technologies that constitute a challenge in relation with their assessment process.

- Finally, we assist to a proliferation of false manufacturers, the named "own brand labellers", who buy from the original manufacturers the rights to market the products with their name. This fact generates a confuse situation where the legal manufacturer of the product does not fulfil the requirements of having an assurance quality system and he has not the sufficient product' knowledge to take the responsibilities imposed by the directives.

Slide 4

In view of the exposed current situation, it emerges the necessity of finding solutions that respond to the lacks that have been pointed out. These solutions have to be implemented in two fields, regulatory and operational.

Regarding the regulatory actions to be taken, we can focus on some strategic ones, such as:

- To create a decision-maker body that deals with the differences on legal interpretations, both in definitions/ classification rules, and in the criteria to apply in the Notified Bodies designation process. The decisions of his body have to be followed in a mandatory way by the national authorities.

- To introduce in the directives traceability requirements that provide means to find in the community market a device that can present a risk and to take the appropriate healthy measures quickly. Systems such as UDI (Unique Device Identification) can be useful to this aim.

- To modify the assessment conformity procedures foreseeing the participation of competent authorities in the assessment process of certain devices that pose special concerns considering their technological novelty or their consequences on the health.

- To improve the provisions related to the information provided to the competent authorities in order to allow these authorities to have a complete knowledge of the products placed in their markets. That will be an important tool for carrying out their surveillance activities at the same time that it contributes to eliminate the national particular regimes and to reinforce the internal market.

- To foresee a legal procedure to establish mandatory guidelines on key subjects. For example the designation Notified Body process, the implementation of the Vigilance System, the performance and evaluation of clinical investigations, the application of legal measures on market surveillance, etc.

Slide 5

Besides the regulatory measures commented, there are, also, other actions that can be taken in an operational level, such as:

- To elaborate a coordinated program between designating authorities to share experiences in the evaluation of the competence and independence of Notified Bodies through peer-review and training activities.

- To re-design EUDAMED as a complete system of medical devices community market information. To reach this aim, it is necessary that the different actors (manufacturers, notified bodies, authorities) can provide directly data to the system and that the access to this information be opened to another agents that can be interested in because of this work, users (health professionals or patients).

- To reinforce the competent authorities' cooperation activities on market surveillance, through the elaboration of coordinated control programs and the definition of more harmonized criteria to deal with the different situations and cases.

- To extend the surveillance activities that carry out the competent authorities beyond the fields strictly covered by the medical devices directives, in application of the other legal instrument of horizontal application to all sectors. That will cover the surveillance of the activities of distribution, sales and advertising of devices, and, also, a very important control activity: the survey of the borders traffic of devices, in order to perform appropriate checking on the fulfilment of European regulations by the products imported in the community.