Updated medical devices registration on the way for Poland

At present, in Poland, there is a running legislative procedure regarding the amendment of the Medicinal Devices Act, dated 20 April 2004. The intended Regulation should take effect in all proceedings by the end of 2008. Katarzyna Bondaryk takes a look at the legal obligations that accompany the Regulation.

These legislative works were planned with a view to implementing into the Polish legal system the provisions of the Directive on the approximation of the laws of the Member States relating to active implantable medical devices[1]. Currently, an entity that plans to introduce a medical device into the Polish market is obliged to fulfill the requirements stated in the national Medicinal Devices Act, which is generally in line with European law.

...first step

Polish law recognises as entities that are authorised to place on the market and put into service medical devices (the authorised entity): the manufacturer; his authorised representative; an importer; a distributor; or a designated entity responsible for these specific activities.

Polish law divides medical devices into the following classes – class I, IIa, IIb, and III – depending on the potential risk connected with their use. The minister of health determined the mode of classification for medical devices, dependent on their purpose, by way of a Regulation. However, with regard to in vitro diagnostics, these are evaluated based on the potential risk associated with their use, and have either been included in list A or list B (Directive 98/79/EC, which was transposed into Polish law by Health Minister Ordinance 2004), or with in vitro diagnostic devices for self-testing and other devices. The classification and qualification of a medical device are tasks undertaken by the manufacturer.

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocide Products keeps a Register of medical devices and the entities that have been responsible for placing them on the market and putting them into service.

...general rules of registration

Prior to the placing on the market and putting into service of a medical device, a manufacturer or his authorised representative is obligated to ensure that it has undergone a procedure of assessment of conformity with the essential requirements applicable to that device. It shall be presumed that there is compliance with the essential requirements in respect of medical devices that are in conformity with:

- domestic standards adopted on the basis of harmonised European standards for active implantable medical devices, in vitro diagnostic medical devices, and medical devices for various purposes;
- monograph elaboration of the European Pharmacopoeia on surgical threads and materials intended for the storage of medicinal products for medical devices for various purposes; and
- common technical specifications for in vitro diagnostic medical devices.

The medical device documentation concerning conformity assessment procedures and the correspondence between the manufacturer or his authorised representative and the notified body shall be conducted in Polish and kept for reference purposes.

After conducting the conformity assessment, the notified body issues a certificate confirming the fulfillment of the requirements – which is valid for 5 years – or declines to issue such a certificate. A manufacturer that creates custom-made medical devices is obliged to notify the Register, essentially to provide information on the types of medical devices manufactured, and the data required under part I of the Register. This contains: the name and address of the entity authorised to place on the market and put into service the medical device; the identification number of notification; and the identification number assigned to the entity in the Register (this is formed as PL/CA01/ followed by the number of entry of the entity authorised in the Register).

The authorised entities that market medical devices are obligated to label the devices in Polish and to supply the user with instructions for use and the labeling in Polish. The exception to this rule is when a medical device is delivered directly to a healthcare professional. In this situation, the user (be it a doctor, nurse, etc.) has to agree that the medical device will be accepted without a Polish label.

Each of the medical devices (with the exception of custom-made medical devices, medical devices intended for clinical trials and for in vitro diagnostics) has to receive a CE mark. The CE mark has to be affixed onto the device after it has undergone the relevant procedures of conformity assessment and has attained the essential legal requirements. If conformity assessment is conducted under the supervision of a notified body in the field of medical devices, the CE mark must be accompanied by the identification number of this notified body.

Moreover, a manufacturer – or his authorised representative, importer or entity responsible for placing the medical device on the market – that places an active implantable medical device, a class IIb or class III medical device, an in vitro diagnostic medical device from list A or list B, or an in vitro diagnostic medical device for self-testing, is obliged to notify the Register immediately after putting the medical device into service for the first time.

...payment

The registration is obtained following the completion of an application form, which is accessible on the Register Office web site. The application form shall be filed in triplicate, in Polish, and must also be accompanied by an electronic version.

The application fee has to be paid in accordance with the Ordinance of Minister of Health, dated 30 April 2004 on payments for application to the Register of medical devices. The payment for an application for a medical device for various purposes, or for an active implantable medical device that has been manufactured to order is 170 PLN (€44.30). The payment for an application for an in vitro diagnostic medical device is 350 PLN. The payments shall be made to the bank account of the Register Office. ❊

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[1]Directive of the European Parliament and the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.