MEDICAL DEVICE LEGISLATION— A POLISH VIEW

Poland brings medical device law into line with European regulation

The Polish government is currently engaged in bringing its regulations on implantable medical devices into line with the laws of European Union member states.

The Minister of Health determines the mode of classification of medical devices for various purposes. The manufacturer classifies and assures the quality of the medical device.

The President of the Office for Registration keeps a Register of medical devices and of the bodies responsible for introducing them to the market and putting them into use.

In an article produced for *Biomedical Materials*, Katarzyna Bondaryk, an Associate in pharmaceutical law and biotechnology practice with Hogan & Hartson Jamka spk, notes that the obligation for compliance with the law belongs to the manufacturer, or to an authorized representative of the manufacturer.

Before the manufacturert can start selling a medical device, it is the responsibility of the manufacturer to ensure that the device has undergone a procedure of assessment of conformity with the essential requirements applicable to that device.

The presumption is that medical devices are in conformity with:

- Domestic standards adopted on the basis of harmonized European standards for active implantable medical devices, *in vitro* diagnosis medical devices and medical devices for various purposes:
- Monograph elaboration of the *European Pharmacopoeia* on surgical threads and materials intended for storage of medicinal products for medical devices for various purposes;
- Common technical specifications for *in vitro* diagnosis medical devices.

Documents must be produced in Polish

Bondaryk notes that the medical device documentation concerning conformity assessment procedures and the correspondence between the manufacturer and the notified body have to be kept and conducted in the Polish language.

After conducting the conformity assessment, the notified body issues a certificate confirming the fulfilment of the requirements, valid for five years. Alternatively, the notified body refuses to issue such a certificate.

The authorized entities marketing the medical devices are obligated to label the devices in Polish and to supply the user with instructions for use and the labels in Polish.

The exception to this rule is when there is a delivery of the medical device to a health professional. In this situation, the doctor or nurse or other professional has to agree that the medical device will be accepted without a Polish label.

All medical devices, except for custom-made medical devices, medical devices intended for clinical trials and for *in vitro* diagnosis, have to have the CE mark. The CE mark has to be affixed to the approved device.

If conformity assessment is conducted under the supervision of a notified body, the CE mark will be accompanied by the identification number of the notified body, according to Bondaryk.

Registration and payment

A manufacturer making custom-made medical devices is obliged to notify the Register, to provide name and address of the body authorized to market the medical devices, identification number of notification and the identification number assigned to the body in the Register and the information on the types of medical devices being manufactured.

Registration can be carried out using the application form available on the Register Office web-site.

Three copies of the application form have to be provided in Polish and electronically.

The application fee has to be paid in accordance with the Ordinance of Poland's Minister of Health, brought into being on 30 April 2004. Payment has to be made to the Register Office.

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