[PL] New obligations on owners of media or advertising media for medical devices

IRIS 2022-8:1/28

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The new Polish Law on Medical Devices has come into force., repealing the previous Medical Devices Act of 2010. The new law has been issued in connection with EU Regulation 2017/745. An EU Regulation is a legal act of the European Union that becomes immediately enforceable as law in all member states simultaneously. Regulations can be distinguished from directives which, at least in principle, need to be transposed into national law. However, it leaves the issues of advertising and administrative penalties, among others, to be regulated by the member states. The entry into force of the above-mentioned Law on Medical Devices puts the legal situation in this area in order.

The new law imposes new obligations on media service providers related to medical device advertising. A media service provider or publisher will be obliged, at the request of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, to make available to them the names and addresses of businesses or individuals placing paid advertisements or announcements, as well as any other materials related to advertising in their possesion. Media service providers or publishers are obliged to store advertising materials for medical devices for a period of not less than one year. This is to allow the enforcement of the new stricter rules on medical device advertising. Under the new law, the advertising of medical devices will be regulated in a similar way to the advertising of medical products.

Failure to comply with the obligation to store advertising records is punishable by an administrative penalty of up to PLN 50,000. The penalty is imposed by administrative decision.

The new law came into force in principle on 26 May 2022. However, the provision introducing the new obligation will take effect later and will come into force on 1 January 2023. The postponement of the introduction of the new obligation is intended to allow for preparation for the new regulations.

Komunikat Prezesa Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych z dnia 11 maja 2022 roku w sprawie ogłoszenia ustawy o wyrobach medycznych

https://urpl.gov.pl/pl/komunikat-prezesa-urz%C4%99du-z-dnia-11-maja-2022-roku-

w-sprawie-og%C5%82oszenia-ustawy-o-wyrobach-medycznych

Statement of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of 11 May 2022 on the promulgation of the Law on Medical Devices

Dziennik Ustaw: Dz.U. 2022 poz. 974 oraz ISAP Internetowy System Aktów Prawnych Sejmu Rzeczypospolitej Polskiej

https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20220000974

Journal of Laws: Dz.U. 2022 item 974 and ISAP Internet System of Legal Acts of the Parliament of the Republic of Poland