DZP
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Legal alert

New obligation relating to medical devices supplied on instruction

On 6 February 2026, a draft act was published amending certain acts in connection with the development of e-health services in which a number of changes to the healthcare information system were proposed. **Given the new information obligations, the draft of the new regulations may be of particular interest to manufacturers, importers and distributors whose medical devices are reimbursed in the instruction procedure.**

Creation of a Home Healthcare System

The draft act introduces a number of changes related to digitisation in healthcare, including the exchange of information about patients' health. Among other things, a new module is to be created for the Medical Information System – the Home Healthcare System.

The new system is to enable the remote collection of personal data and individual medical data from **medical devices** and **wellbeing applications** used by patients, and the monitoring of patients' health based on these data.

Why is the draft important for the sector of medical devices issued on instruction?

The draft act introduces a new obligation for manufacturers, importers and distributors that have placed on the market or put into service a medical device reimbursed in the instruction procedure.

Which devices are covered by the obligation?

A detailed list of devices has not yet been published. According to the draft, the obligation to provide data will be based on the granting criteria specified in the Minister of Health regulation on the list of medical devices issued on instruction. This obligation is expected to apply to medical devices that connect to the internet ("IoMT" – Internet of Medical Things).

What data are to be provided?

Individual patient medical data are to be entered into the system, particularly test results, physicians' recommendations and orders, and also measurements and observations relevant to the assessment of a patient's health, made by the patients themselves. Data identifying healthcare providers are also to be entered into the system.

For what purposes are data collected?

Data will be provided for the purpose of monitoring the health of patients using the indicated medical devices and to carry out analyses of the demand for medical devices, including frequency of use and an assessment of treatment efficacy in conjunction with information on medicinal products used by the patients.

Furthermore, data collected in the Home Healthcare System may be passed on by the Minister of Health to other entities, e.g. the National Health Fund, the Medical Research Agency, the Agency for Health Technology Assessment and the Tariff System and also the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Subsequent steps

The draft is currently at the consultation stage, so it is worth preparing now for the upcoming changes, particularly in terms of adapting IT processes and systems to comply with the obligation to submit data to the Medical Information System.

Our experts in the Life Sciences Practice are monitoring the legislative process so that they can keep you informed of any significant changes.

How can we help?

- We provide day-to-day advice on legal aspects of operating on the medical devices market – from the design stage to bringing the product to market.
- We advise on the registration of entities and the modification of data in IT systems used in healthcare.
- We support the process of reviewing and amending the terms and conditions of patient services and information clauses on the processing and sharing of patients' personal data.
- We represent entities in all their dealings with public administrative authorities, including the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Minister of Health.

Key advisers

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