KNOW-HOW

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HEALTHCARE AND LIFE SCIENCES

INCREASING TRANSPARENCY ON MEDICAL IMPLANTS: GERMAN LAW ESTABLISHING MEDICAL IMPLANTS REGISTRY IN EFFECT SINCE 1 JANUARY 2020

The German Act Establishing a Medical Implants Registry (Federal Law Gazette I 2019, p. 2494 - *Implantateregister-Errichtungsgesetz* or "EIRD") came into force on 1 January 2020. The act creates a mandatory and detailed registry aimed at protecting patients and improving the collection of data on the quality of implants available on the market. Dr. Enno Burk, counsel at our Berlin office and medical technology market expert, has summarised the features of the registry and the information duties that will apply to product managers, hospitals and surgeons below.

I. Establishment of a mandatory federal medical implants registry

The German Institute of Medical Documentation and Information (DIMDI) has been put in charge of establishing and maintaining the implants registry, for which it will create a dedicated registration office. The following medical devices will require registration:

- Joint endoprostheses (hip, knee, shoulder, elbow and ankle)
- Breast implants
- Heart valve and other cardiac implants
- Implantable defibrillators and pacemakers
- Neurostimulators
- Cochlear implants
- Vertebral body replacement systems and disc prostheses
- Stents

Both custom-made and specially approved implants will not require registration.

II. Reporting duties of manufacturers/product managers with the implants registry

Under the new legislation, product managers must enter the implant identification number, product data and company name as well as the product manager's contact data in the implants registry's product database before placing medical devices on the market for the first time or – in the case of medical devices already on the market – immediately after registration duty has taken effect. This data must be updated in the event of any changes to products.

III. Reporting duties of hospitals and outpatient surgeries

Reporting duties for healthcare facilities responsible for the placement of implants (hospitals, outpatient surgeries, e.g. ambulatory healthcare centres and specialised practices) are more extensive. After every placement or removal of an implant, safety-related or functional change as well as implant-related amputation of an extremity they must submit the following data:

- Technical/organisational and clinical data as well as dates of the treatment process (such as data on patient anamneses, implant-relevant findings, indications, previous operations, size, weight and medical history of

- patients, admission date, date of surgery and discharge date)
- Data that enable identification of the implant and the facility

IV. Protection of patient data

- Data identifying patient and case, including the patient's health insurance number and date of birth, must be reported separately to the notification office to be established by the Robert Koch Institute (RKI). The RKI's notification office pseudonymises these data and can, if necessary, identify the patient, such as e.g. in the case of health risks.
- Such patients must be informed of the purpose of the implants registry and the processing of their data. They shall receive a written or electronic copy of the personal data submitted by the responsible healthcare facility to the registry and notification office. Patients' consent for the collection of their data is not required.
- The data is transferred via the telematics infrastructure pursuant to section 291a German Social Security Code, Book V (*Sozialgesetzbuch V*, SGB V).

V. Additional compensation for notification burden

- In the outpatient sector, the additional burden for data submission will be compensated for via an adjustment of the codes of the "Uniform Value Scale" (*Einheitlicher Bewertungsmaßstab* or EBM) – the catalogue of applicable doctors' fees in Germany – on the basis of the newly introduced section 87(2)l SGB V and in the inpatient sector via a new surcharge pursuant to section 17b(1)a no. 9 Hospital Financing Act (*Krankenhausfinanzierungsgesetz*, KHG).
- Product managers will not be compensated for registering data.

VI. Notification office of the implants registry reports registry data to supervisory authorities, professional societies and product managers

The implants registry's notification office acts as the central administrator for registry data. It can make its data available to the following institutions and persons:

- Reporting healthcare facilities in particular for quality control purposes,
- Authorities (in particular the German Federal Institute for Drugs and Medical Devices, BfArM) for monitoring purposes,
- Research institutions and professional societies involved in the registry,
- The Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA)
- Product managers, in particular for the purpose of carrying out the conformity assessment procedure,
- The Federal Association of SHI-Accredited Physicians (*Kassenärztlichen Bundesvereinigung*)
- Statutory and private health insurance funds for the assessment of indications of implant-related health damage.

There are no plans to give patients a right to information.

VII. Long-term effects to be monitored with the help of report groups

- The DIMDI will create a report group for each implant type. These report groups will assess the statistical evaluation of registry data and use them to compile an assessment report.
- The report groups are to include, in particular, representatives from the BfArM, the Institute for Quality and Efficiency in Health Care (IQWiG) and the respective medical professional societies for the implant type.
- Systematic long-term monitoring is aimed at improving information on the durability and quality of products as well as the quality of medical treatment provided by hospitals.

VIII. Sanctions for violation of reporting duties

- Where healthcare facilities violate their reporting duties or use a manufacturer's product that is not registered in the product database they can be denied compensation for the performed surgery as a whole.
- The German Medical Implants Registry Act (*Implantateregistergesetz*, IRegG) does not provide for any sanctions for product managers for violations of their reporting duties.

IX. When does information on implants have to be collected in the registry?

The Federal Ministry of Health has yet to issue a regulation determining when the reporting duty is to commence for the individual implant types. According to the information available to date, the registry is to take up operations on 1 July 2021.

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LAWYERS

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