Czech Republic

World Bank income group: High income

Legal

Legal framework: Yes
The vigilance system and post-marketing surveillance for medical devices including the monitoring of adverse incidents and the system for their reporting in the Czech Republic, ZP-20 http://www.sukl.eu/file/69142_1_2
Guidelines: N/A

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Ministry of Health - State Institute for Drug Control http://www.sukl.eu/
Responsibilities of the NRA: The Ministry of Health. Act on Medical Devices, Sec. 8. The State Institute for Drug Control. Act on Medical Devices, Sec. 9

Medical device definition

Medical device defined: Yes
Text: A medical device shall mean any instrument, apparatus, appliance, software, including software intended by the manufacturer for specific use for diagnostic or therapeutic purposes and necessary for the correct use of the medical device, material or other article, intended by the manufacturer to be used for human beings for the purposes of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of an anatomical structure or of a physiological process; or
- control of conception;
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
(2) Upon compliance with the general definition referred to by paragraph 1, a medical device shall mean, in particular:
- an active implantable medical device;
- an in vitro diagnostic medical device;
- a custom-made medical device;
- a product intended for the administration of a pharmaceutical, except for products placed on the market in a manner safeguarding that the medical device and the pharmaceutical form a single integral product intended solely for single use in this combination; such product shall be considered a non-official translation medicinal product;
- a product containing as its integral part a substance which, when used independently, may be considered a medicinal product, if its effect provides only an add-on effect to the effect of the medical device; and
- a product containing as its integral part a substance which, when used independently, may be considered an ingredient of a medicinal product or a medicinal product derived from human blood or plasma, if its effect provides only an add-on effect to the effect of the medical device.
Act on Medical Devices, Sec. 2.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined Separately.

Medical device classification

Classification: Yes
Categories: Medical devices are classified by risk into classes I, IIa, IIb, and III. Act on Medical Devices, Sec. 6.
Classification rules: Yes
Classification rules details: N/A

Essential principles

Essential principles: Yes
Details: N/A

Conformity assessment

Conformity assessment bodies: Yes
Details: A person established within the territory of the Czech Republic, who acts as a notified body, must notify its operation to the Institute. Act on Medical Devices, Sec. 26.
Pre-marketing / procedure: A conformity assessment will always include a clinical evaluation or performance evaluation. Act on Medical Devices, Sec. 10.
WHO European Region

Czech Republic

Reliance

Reliance: Yes
Details: As a member of the EU, the Act on Medical Devices incorporates relevant EC provisions into Czech law.
Jurisdictions: EU

Clinical investigation

Clinical investigation controls: Yes
Details: Under the Act on Medical Devices, clinical trials are regulated and must comport with detailed guidelines, ranging from eligible trial participants to the duration of the trial. Sec. 13-25.

Registration and listing

Registration of establishment: Yes
Details: One who intends to place a medical device on the Czech market (whether a manufacturer or its representative) must notify the Institute. Importers and distributors must also notify the Institute. Further, a clinical trial sponsor must notify its activity prior to the commencement of an investigation to the Institute. Act on Medical Devices, Sec. 26. Sections 27-30 of the Act on Medical Devices detail the registration process. Act on Medical Devices, Sec. 77.
Listing of medical devices: Yes

Import controls

Import controls: Yes
Details: A medical device may only be imported by an importer registered by the Institute. It may only supply that device to a distributor, healthcare provider, or seller. Act on Medical Devices, Sec. 44. Further, only a medical device that has a CE marking may be imported, unless it is a custom-made device. Sec. 45.

Post market controls

Post Market Surveillance: Yes
Details: The Czech Republic adopts a Medical Devices Vigilance System, named by the EU, that seeks to protect the health and safety of patients, users, and third parties. ZP-20, Sec. 1.1.
Inspection (QMS): Yes
Details: Act on medical devices, Act. No. 268/2014 Coll. Section 80
Enforcement: Yes
Details: The Act on Medical Devices, Sec. 81-92 provides penalties for noncompliance with various provisions of the act.
Adverse event reporting: Yes
Details: A manufacturer or its representative or an importer must report in writing any adverse incident associated with its medical device to the Institute. If the Institute identifies an adverse incident, then it shall report that information to the manufacturer or its authorized representative. Act on Medical Devices, Sec. 70, Sec. 71.
Field safety corrective action monitoring: Yes
Details: The Institute publishes a list of Field Safety NOtices it receives from device manufacturers on its website. http://www.sukl.eu/medical-devices/bezpecNOstni-napravna-opatreni-v-roce-2015
Implementing legislation, Decree No. 62/2015 Coll. (2015), Sec. 5, instructs importers and distributors to provide and document the internal process control system for distribution and import activities as well as adopt corrective actions.
Advertising: N/A
Details: N/A
Labelling: Yes
Details: Decree of Act on Medical Devices, Decree No. 62/2015 Coll. (2015), Sec. 10.

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.