EUROPEAN SOCIAL INSURANCE PLATFORM

Towards safer medical devices and in vitro diagnostics in Europe

Today the European Parliament finally **adopted the new EU Regulations on medical devices and in vitro diagnostics** after five years of difficult negotiations. As medical devices are of particular importance for ESIP, we have continuously worked to provide the input of payers. Therefore **we welcome this achievement**, in particular those elements outlined below.

At its inception, the revision of the EU legislation on medical devices proved to be justified in the light of several public health scandals at the time such as the PIP scandal. **Stricter rules were necessary** as regards the **market access and testing** of medical devices, adequate **market surveillance** as well as **increased transparency and information**.

Under the newly adopted Regulation on medical devices, market access for **high risk devices will be significantly strengthened** while not going as far as introducing a central authorisation procedure as for medicinal products as proposed by ESIP. Now high-risk devices will be **required to undergo clinical investigations** except in some specific cases. The intended purpose of medical devices will have to be proved by the manufacturer based on clinical assessment evidence of patient related benefit.

Market surveillance of medical devices will also been improved. In particular, the **creation of a Unique Device Identification** (UDI) **system should enhance the traceability of devices**. In addition, **the notified bodies will be empowered** to instruct manufacturers on carrying out market surveillance. Their role will be further strengthened thanks to the establishment of the Medical Device Coordination Group. Finally, **a European implant register will be established** allowing **long-term data on safety and durability of implanted medical devices** to be collected.

Finally, the **extension of the European database on Medical devices** (Eudamed) **is a major step forward for transparency** and providing information on medical devices available in the European Union as well as on the clinical assessment of implantable devices and Class III devices.

Respectively three years and five years after their publication in the Official Journal, the new Regulations on medical devices and in vitro diagnostics will come into force and will provide the basis for improved safety of the devices available in Europe.

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