

Ter info:

Eudamed Decision Adopted by the EU Commission

The EU Commission has adopted the decision on the implementation of Eudamed, the European databank for medical devices, from 1 May 2011. This decision will not only oblige member states to use Eudamed as a central data repository on information for registration of devices, vigilance incidents and ultimately clinical data but will it also means that **notifications of IVDs under article 10.6 will come to an end in the near future**. The [EU Commission has issued a press release](#) explaining the key points of their decision, and the decision itself will be published in the Official Journal of the EU in the coming days. For more information, please click [here](#).

Patient safety: EU-wide databank for medical devices to boost market surveillance

A European Commission decision adopted today will oblige all EU countries to use, as of May 2011, a

European databank for medical devices (Eudamed). Medical devices range from life-supporting devices such as pacemakers through hip implants or X-ray machines, down to products used daily such as syringes or blood tests. Even though these devices are traded on the European single market, data which are key to their safety – such as conformity certificates, data on clinical investigations – are for the time being collected only at the national level. The Eudamed databank is a secure IT tool which will ensure rapid access to such data by market surveillance authorities. The databank will also streamline the rules for manufacturers placing in vitro diagnostic (IVD) devices on the market.

Commissioner in charge of Health and Consumer Policy John Dalli said: "Today's decision means good news for patients across the EU. It will lead to increased patients' safety thanks to rapid access to critical data by national authorities".

The decision

The European Commission has adopted today a Decision which will oblige EU Member States to use a European databank for medical devices (Eudamed) as of 1st May 2011. Eudamed is a secure web-based portal for rapid information exchange between national authorities. It is already used on a voluntary basis by a number of EU countries.

Why is a databank for medical devices needed?

Under EU law, medical devices cover thousands of product types used in **diagnostics, prevention and therapy**. They range from life-supporting devices such as pacemakers, through implants, complex diagnostic devices such as X-ray machines, to devices such as blood pressure meters, syringes or blood and urine tests.

Medical devices that conform to the European legislation may be **traded on the EU single market**. But important data (for example – data on **conformity certificates, including those withdrawn or refused, on clinical investigations, or reports on malfunctioning or incidents**) on their safety is currently collected at national level.– . This comprises reports on **600 known incidents** involving medical devices in 2009. Today, such data are only shared manually.

The Eudamed databank will **boost market surveillance**, as national authorities will be able rapidly to access crucial safety data for medical devices on the EU market, and to respond to risks, for example by ordering a withdrawal.

In addition, Eudamed will **eliminate administrative hurdles** for manufacturers of in vitro diagnostic (IVD) devices. At present, they must notify every EU country concerned separately when placing certain IVD devices on the market. Eudamed will allow them streamlined registration.

How will patients benefit?

Thanks to rapid communication channels between market surveillance authorities, the **risk for patients of a safety incident or malfunctioning** will be **reduced**. In particular, rapidly sharing information on any known incidents will diminish the risk of recurring incidents elsewhere in the EU.

More information on Eudamed:

<http://ec.europa.eu/enterprise/sectors/medical-devices/market-surveillance-vigilance/eudamed/>

Met vriendelijke groeten – Sincères salutations – Best regards

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