MD REGULATORY DIGEST

FOCUS ON

MANUFACTURER

The manufacturer is an economic operator that will be greatly impacted by the MDR. A few points are critical for the manufacturer's compliance:

NEW CLASSIFICATION RULES

5 new classification rules have been introduced (Annex VIII), and some definitions have been modified (Art. 2). This implies that some medical devices will change class. In addition, Annex XVI lists **non-medical products** that now require compliance with the MDR. Manufacturers of those products will need to meet all MDR requirements to keep their devices on the market.

MORE CLINICAL EVALUATION

The MDR gives a special importance to enhancing the safety of MDs. **Clinical evaluation** becomes mandatory (Art. 10.3), with a very limited use of equivalence. For certain devices, a clinical evaluation consultation procedure by a group of **independent experts** will be involved in the device evaluation (Art. 54).

EUDAMED

The registration of economic operators and of devices mentioned above will go through **Eudamed** (European Database on Medical Devices). **18 months** after the day this database becomes functional (scheduled for 25 May 2020), economic operators shall enter all information required on it and verify information on their devices is complete and correct. As it represents a massive amount of work, they have to make sure they have all the necessary human resources available.

LESS NOTIFIED BODIES

Another important point to consider is that regulatory requirements have been significantly strengthened for **Notified Bodies** as well: this means certain MDD NBs won't be notified for MDR (about 33 expected to be MDR notified, versus 54 MDD today). With a decreasing number of NBs and a high amount of work for the remaining NBs, **increased time and cost** is expected for manufacturers. Be aware of NB shortage!

EARLY OBLIGATIONS

One important point for manufacturers is the obligation to meet MDR requirements relating to **PMS, market surveillance, vigilance, and registration of economic operators & of devices** at the Date of Application: 26 May 2020. This is one of the earliest obligations that will apply.

EU REPRESENTATIVE

Manufacturers based outside the EU shall have a mandate with an **authorised representative inside the EU** to put their device on the European market (Art. 11).

PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

Every manufacturer shall have a **named person responsible for regulatory compliance**, who possesses a requisite and demonstrated expertise in the field of medical devices (Art.15).

LATEST NEWS

European Commission

European Commission:

MDCG 2019-2 Guidance on application of UDI rules to device-part of products referred to in Article 1(8), 1(9) and 1(10) of MDR published

19/02/2019

Version 2 of MDCG 2018-1 Draft guidance on basic UDI-DI and changes to UDI-DI published

19/02/2019

Medical Devices Nomenclature published. "The CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed."

04/03/2019

[BREXIT]

UK Government publishes "Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal".

27/02/2019