OCT. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Guidance Document from the Medical Devices Coordination Group

In June 2022, at one of the annual meetings of the Employment, Social Policy, Health and Consumer Affairs ("EPSCO") Council, health ministers expressed their concerns regarding the legislative transition to Regulation (EU) No 2017/745 of the European Parliament and of the European Council of 5 April 2017 on medical devices ("MDR") and to Regulation 2017/746 of the European Parliament and of the European Council of 5 April 2017 on in vitro diagnostic medical devices ("IVDR").

Health ministers expressed their concerns regarding the legislative transition to the medical devices and in vitro diagnostic medical devices regulations.

As a result, the MDCG was asked to make an urgent proposal for solutions to assist in the legislative transition to the legal framework established by the regulations described above.

These regulations have imposed new obligations with only a short transition period. This is not compatible with the adjustment capacity of notified bodies and manufacturers to adapt their medical devices and in vitro devices in accordance with those obligations.

If not properly addressed, the difficulties identified could lead to disruption of the supply of devices for healthcare systems and patients. They could also hinder access to innovative medical devices.

Eduardo Nogueira Pinto
Ricardo Rocha
Rita Antunes da Cunha
Healthcare, Life Sciences & Pharmaceuticals team

The MDCG has drafted a guidance document to facilitate the implementation of the new regulatory requirements provided for in European legislation.

In this context, the MDCG has drafted a guidance document to facilitate the implementation of the new regulatory requirements provided for in European legislation. The document is subdivided into the following topics:

i) Increased capacity for notified bodies

ii) Access to the notified bodies

iii) Increased preparation of manufacturers

iv) Other actions to facilitate transition and/or prevent device shortages

The progress and impact of these measures will be assessed by the MDCG to ascertain the need for further action.

For additional background on the MDR and the IVDR, please see our earlier Informative Notes: (i) the Informative Notes of June 2021 and August 2022 , both on the new regulation on medical devices, and the Informative Note of May 2022 on the new regulation applicable to in vitro diagnostic medical devices. ■