

HOPE Position on In-Vitro Diagnostics Regulation

Hospitals and other healthcare facilities are busy preparing for the implementation of the Medical Device Regulation (MDR), which is already quite a challenge.

In parallel, the introduction of the adjoining European regulation in the field of in vitro diagnostics (the IvDR), from May 2022, is of great concern to hospitals, healthcare services and laboratories. This date, in particular, is of great concern for all of us.

Ensuring the quality and continuity of the supply of in vitro diagnostics (IvDs) is an immense task. 34,000 products must be Notified Bodies (NoBo) certified and laboratories must demonstrate hundreds of Lab Developed Tests (LDTs) that they meet IvDR requirements. In addition, we see several bottlenecks that hinder proper implementation:

- The entire chain, from manufacturers and NoBo to healthcare institutions and laboratories, currently lacks guidance documents;
- The necessary expert panels and reference laboratories are not yet operational to guarantee safety;
- Only four NoBo are currently designated for IvDs certification.

The current Covid-19 pandemic hampers progress on the above and has also shown vulnerability to the availability of medical devices and IvDs in emergency situations. We want to prevent patient safety and continuity of care from being endangered.

In order to tackle the aforementioned problems, we see a number of possibilities:

- Extend the new EU-wide emergency marketing authorization scheme for IvDs;
- Determining a grace period of four years for products that do require NoBo for certification under the IvDR, but not under the old legislation. This treats IvDs in the same way as medical devices;
- Establishing a new real time frame for the introduction of the IvDR, taking into account the consequences of the corona pandemic.

HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 36 organisations coming from the 27 Member States of the European Union, as well as from the United Kingdom, Switzerland and Serbia. HOPE mission is to promote improvements in the

health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.