

HOPE Position Paper

on the Medical Devices Regulation

Regulation (EU) 2017/745

HOPE would like by the present position to express its extreme worries about the situation of the supply of medical devices.

Surveys carried out in European hospitals revealed that several hundred products are no longer available today and more will be in the coming months. All over Europe, hospitals are describing delivery delays, bottlenecks, streamlining of product ranges and/or discontinuation of products.

There are reports of patients acutely in danger. Deliveries of medical devices have been discontinued at short notice endangering operating processes. In some areas, only inferior quality substitutes are available, or sometimes there are no alternatives at all. Other products are only available in certain sizes, which means they are often unsuitable. The situation is even worse in 'niche products', by essence only required by relatively small groups of patients. In medical terms, this represents a backward step of several decades.

There are several reasons for such a situation Covid-19 pandemic, Brexit, inflation and increasing costs of raw materials must be considered. They cannot be much influenced. But a root-cause analysis showed that the medical devices regulation is taking an important share of the responsibility of the present situation with an insufficient implementation and a lack of efficient certification infrastructure.

The medical device regulation was initiated with the aim of improving patient safety. As a paradox the MDR is now in force and has been subject to more intense criticism because it has put some patients at risk. The proposal of the Medical Devices Coordination Group is welcomed but will not be enough.

Therefore, HOPE urges the European Commission to exercise its right of initiative and to present a legislative proposal as soon as possible that provides for appropriate solutions.

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 as observer members. 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.