正本

檔　　號：
保存年限：

衛生福利部食品藥物管理署　函

機關地址：11561 臺北市南港區昆陽街161-2號
傳　　真：
聯絡人及電話：江宛真02-2787-7514
電子郵件信箱：joannajiang@fda.gov.tw

241
新北市三重區重新路五段609巷6號3樓之3

受文者：台灣醫療暨生技器材工業同業公會

台灣醫療暨生技器材工業同業公會
收 110. 10. 27 文
檔號： 110753

發文日期：中華民國110年10月25日
發文字號：FDA器字第1109043233號
速別：普通件
密等及解密條件或保密期限：
附件：Publichealth: Commission proposes a progressive roll-out of the new In VitroDiagnostic Medical Devices Regulation新聞資料1份

主旨：檢送歐盟執委會提議逐步實施新體外診斷醫療器材法規（In Vitro Diagnostic Medical Devices Regulation，下稱歐盟IVDR）之新聞資料1份，請轉知所屬會員知悉，請查照。

說明：

一、依據駐歐盟兼駐比利時代表處經濟組110年10月14日比貿字第1100000684號函副本辦理。

二、為預防基本醫療產品供應中斷，歐盟執委會於10月14日提議逐步實施歐盟IVDR，並於同日發布新聞及相關資料供各界參考了解，該資料可於歐盟官網下載，網址：https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5209。

正本：台灣醫療暨生技器材工業同業公會
副本：經濟部國際貿易局

署長 吳秀梅

Public health: Commission proposes a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation

Brussels, 14 October 2021

Today, the European Commission has proposed a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation to prevent disruption in the supply of these essential healthcare products. The unprecedented challenges of the COVID-19 pandemic have diverted resources from Member States, health institutions and economic operators towards addressing the crisis, thereby hampering the capacity to comply on time with the changes introduced.

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: *"The COVID-19 pandemic has shown how essential it is to have accurate diagnostics and a robust regulatory framework for in vitro medical devices. Shortages at this point in time are unthinkable. The pandemic has imposed unprecedented challenges also for our medical devices industry. With more time to prepare for the application of the EU new rules, we will ensure there is a continuous supply of essential in vitro diagnostic medical devices on the market, while not compromising on safety. I call on all manufacturers to prepare for certification under the new Regulation as soon as possible and not wait until the end of the transition period."*

The proposal does not change any requirements of the In Vitro Diagnostic (IVD) Regulation in substance but only changes the transitional provisions to allow the Regulation's progressive rollout. The length of the proposed transition periods depends on the type of device: higher risk devices such as HIV or hepatitis tests (class D) and certain influenza tests (class C), have a transition period until May 2025 and 2026, whilst lower risk ones such as class B and A sterile devices, have a transition period until May 2027.

The IVD Regulation introduces substantial changes in the regulatory framework for in vitro diagnostic medical devices, such as HIV tests, pregnancy tests or SARS-CoV-2 tests. Conformity assessment bodies ('notified bodies') will play a more important role: they will independently monitor whether devices comply with the safety and performance requirements before they reach the EU market.

The IVD Regulation was planned to apply as from 26 May 2022. However, there is a serious shortage of notified body capacity, making it impossible for manufacturers to conduct the legally required conformity assessment procedures in time. Without any legislative action, there is a risk of significant disruption in the supply of various essential in vitro diagnostic medical devices on the market, affecting the diagnosis of patients and their access to relevant health care. Hence today's proposal to ensure a progressive roll-out of the IVDR.

No change is proposed for CE-marked devices that do not require notified body involvement under the IVD Regulation or for devices that are 'new', i.e. devices that have neither a notified body certificate nor a declaration of conformity under the current Directive 98/79/EC. For those types of devices, the IVD Regulation will therefore apply from 26 May 2022 as planned.

The Commission also proposes a deferred application of the requirements for devices manufactured and used within the same health institution ('in-house devices').

The Proposal will now go to the European Parliament and Council for adoption.

Background

Medical devices have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

The In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) establishes a new regulatory framework for in vitro diagnostic medical devices, such as HIV tests, pregnancy tests or SARS-CoV-2 tests. It is estimated that around 70% of clinical decisions are made using in vitro diagnostic medical devices.

The IVDR will replace the current Directive 98/79/EC on in vitro diagnostic medical devices from 26 May 2022, and introduce substantial changes in the sector. The Regulation aims to ensure a high

level of protection of public health, patients and users and the smooth functioning of the internal market taking into account the high number of small and medium-sized enterprises (SMEs) active in this sector.

One of the main changes is to increase the involvement of independent conformity assessment bodies ('notified bodies'). Currently, under Directive 98/79/EC, only a relatively small number of high-risk devices (about 8% of all in vitro diagnostics on the market) is subject to notified body control. Under the IVD Regulation, around 80% of in vitro diagnostic medical devices will be under the control of notified bodies, the vast majority of them for the first time.

The IVD Regulation also introduces a set of common rules for in-house devices, i.e. those that are manufactured and used in the same health institution. The new rules include requirements for justification for the use of these devices and rules to ensure their safety and performance, such as an appropriate quality management system.

The European Parliament, in a letter of 11 May 2021 called on the Commission to submit a legislative proposal to ensure a smooth transition to the new regulatory framework and thereby the availability of in vitro diagnostic medical devices on the EU market. Stakeholders representing the medical device industry, notified bodies, healthcare professionals, clinical laboratories, and not-for-profit blood establishments also called for urgent action.

For More Information

Questions and Answers

Proposal for a Regulation amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices

In Vitro Diagnostic Medical Devices Regulation

Overview | Public Health (europa.eu)

IP/21/5209

Press contacts:

Stefan DE KEERSMAECKER (+32 2 298 46 80)
Darragh CASSIDY (+32 2 298 39 78)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email