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台灣醫療暨生技器材工業同業公會
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主旨：有關駐歐盟兼駐比利時代表處經濟組函報歐盟將實施體外診斷醫療器材法(IVDR)事，請查照。

說明：依據駐歐盟兼駐比利時代表處經濟組111年5月25日比貿字第1110000294號函辦理（如附件）。

正本：台灣醫療暨生技器材工業同業公會、社團法人國家生技醫療產業策進會
副本：駐歐盟兼駐比利時代表處經濟組

局長 江文若

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主旨：有關歐盟將實施體外診斷醫療器材法(IVDR)事，敬請卓參。說明：

說明：

一、依據歐盟執委會本(111)年5月25日新聞資料辦理；本組110年5月27日比貿字第1100000332號函諒察。

訂

二、根據前揭新聞資料指出，歐盟將自明(26)日起適用新的體外診斷醫療器材法(Regulation (EU) 2017/746)，所涉產品包括HIV檢測、驗孕或新冠篩檢等。旨揭規範將確保公共健康與患者安全，使歐盟法令與技術及醫學進步一致。另透過調整不同會員國市場進入要求，亦能保障製造商公平進入歐盟市場之機會。

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線

三、歐盟IVDR法規具3項特點如下：

(一)透過新的基於風險之器材分類系統、更詳細與嚴格之器材性能評估規則，及更多獨立符合性評估機構之參與，提升體外診斷醫療器材質量、安全性與可靠性。新的科學機構，如：專家小組及歐盟參考實驗室等，可參與對最高風險設備之評估。

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(二)加強對患者之資訊透明度：歐洲醫療器材資料庫(Eudamed)將包含市場所有體外診斷醫療器材資料，包括業者及驗證機構所簽發證書等。另每項產品均須具備單一醫療器材識別碼，以便於 Eudamed搜尋。對於中高風險設備，亦將公布安全與性能摘要資訊。

(三)加強警示與市場監督：醫療器材一旦上市，製造商須收集相關性能數據，歐盟國家亦將密切協調其警示及市場監督活動。

四、檢送本案歐盟執委會新聞及問答集等資料(如附件)，併請卓參。

正本：經濟部國際貿易局
副本：衛生福利部食品藥物管理署、經濟部工業局、經濟部技術處(以上均含附件)

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駐歐盟兼駐比利時代表處經濟組

部國際騎縫章

Public health: Stronger rules for placing medical tests on the market

Brussels, 25 May 2022

As of tomorrow, new rules on in vitro diagnostic medical devices (IVDR) such as HIV tests, pregnancy tests or COVID-19 tests, will be applicable. The rules will better protect public health and patient safety in respect to these devices, bringing EU law in line with technological advances and progress in medical science. By aligning market access requirements in the different EU Member States, it also safeguards fair market access for manufacturers.

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: *"Diagnostic medical devices are key for lifesaving and innovative healthcare solutions. Today we are marking a big step forward for the patients and the diagnostics industry in the EU. The COVID-19 pandemic has underlined the importance of accurate and safe diagnostics, and having stronger rules in place is a key element in ensuring this is the case for EU patients."*

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

In summary, the Regulation on in vitro diagnostic medical devices introduces three important advances:

- **Improves the quality, safety and reliability of in vitro diagnostic medical devices with** a new risk-based device classification system, more detailed and stringent rules on the evaluation of device performance, and greater involvement of independent conformity assessment bodies ('notified bodies'). New scientific bodies such as a panel of experts and EU reference laboratories can be involved in the assessment of the highest-risk devices.
- **Strengthens transparency and information for patients,** so that vital information is easier to find. The European database of medical devices (Eudamed) will contain information about all in vitro diagnostic medical devices on the market, including economic operators and certificates issued by notified bodies. A unique device identifier will be mandatory for every product so that it can be found in Eudamed. For medium- and high-risk devices a summary of safety and performance will be made publicly available.
- **Enhances vigilance and market surveillance:**Once devices are available on the market, manufacturers have to collect data about their performance and EU countries will closely coordinate their vigilance and market surveillance activities.

Background

The Regulation on in vitro diagnostic medical devices replaces an earlier Directive and significantly reinforces the regulatory framework for medical tests. It is estimated that around 70% of clinical decisions are made using in vitro diagnostic medical devices.

In January 2022, the European Parliament and the Council amended the transitional provisions of the Regulation on in vitro diagnostic medical devices for those devices already on the market. The amendment allows for a progressive roll-out of the Regulation with the length of the transition periods depending on the risk class of the device. However, the date of application of the Regulation on in vitro diagnostic medical devices remained unchanged.

The Regulation on in vitro diagnostic medical devices is complemented by the Regulation on medical devices, which has been applicable since 26 May 2021. Examples of medical devices are contact lenses, x-ray machines, ventilators, pacemakers, software, breast implants, hip replacements and sticking plasters.

For More Information

Questions and Answers

In Vitro Diagnostic Medical Devices Regulation

Overview | Public Health (europa.eu)

IP/22/3288

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Questions and Answers: Stronger rules for placing medical tests on the market

Brussels, 25 May 2022

1. What are in vitro diagnostic medical devices?

In vitro diagnostic medical devices are tests used on biological samples to determine the status of a person's health. There is a broad range of in vitro diagnostics (IVDs), from self-tests for pregnancy and blood glucose tests for diabetics, to sophisticated tests performed in clinical laboratories, for example to screen blood donations for various infections or to match up the donor and recipient for a transfusion. SARS-CoV-2 tests are also IVDs.

2. Why do we need new rules on in vitro medical devices?

The first EU-level rules for placing IVDs on the market were created in 1998. To reflect the substantial technological and scientific progress in this sector over the last 20 years, the EU lawmakers updated the rules to improve the safety of medical devices, modernise the sector and consolidate the EU's role as a global leader in this area.

The Regulation on *in vitro* diagnostic medical devices (IVD Regulation) entered into force in May 2017 and becomes applicable on 26 May 2022. The IVD Regulation seeks to ensure a high level of public health and patient safety, taking into account scientific progress, as well as a smooth operation of the single market for these products. It was adopted together with the Regulation on medical devices that is applicable since 26 May 2021.

3. What are the main benefits of the new regulation?

The new rules on in vitro medical devices contain a number of improvements, including:

- clear **obligations for economic operators** (manufacturers, importers, distributors);
- introduction of a **risk-based classification system with 4 risk classes** of IVDs: class A (low individual risk and low public health risk), class B (moderate individual risk and/or low public health risk), class C (high individual risk and/or moderate public health risk) and class D (high individual risk and high public health risk);
- **stricter control for high-risk in vitro diagnostic devices**via a new pre-market scrutiny mechanism with a pool of experts at EU level;
- reinforcement of the criteria for the designation and **oversight of notified bodies** (a 'notified body' is an independent third party conformity assessment body) – more information below;
- **improved transparency**through a comprehensive EU database on medical devices (Eudamed), parts of which will be publicly accessible – more information below;
- a **traceability system** based on a unique device identifier (UDI);
- **reinforced rules on clinical evidence and performance evaluation**, including an EU-wide coordinated procedure for authorising multi-centre performance studies;
- **strengthened post-market surveillance**requirements for manufacturers;
- **improved coordination** mechanisms between EU countries on vigilance and market surveillance;
- a specific regime for **devices manufactured and used in the same health institution** ('in-house devices').

4. What does the application of the Regulation mean in practice?

New devices being placed on the EU market from 26 May 2022, regardless of their risk class, must follow the rules of the Regulation. Existing devices for which the manufacturer **significantly changes** either the intended purpose or the design must also follow the Regulation, as opposed to the old Directive.

All class A non-sterile devices (such as laboratory instruments), regardless whether new or already on the market, must comply with the Regulation from 26 May 2022.

According to the Regulation's transitional provisions, **existing devices other than class A non-sterile** that comply with Directive 98/79/EC may still be placed on the market during transitional periods under certain conditions. Several requirements of the Regulation already apply also to those devices, such as the registration of devices and economic operators, market surveillance and vigilance.

5. Why were the transitional provisions of the IVD Regulation amended?

Due to resources being diverted to addressing the COVID-19 pandemic and the substantial changes introduced by the IVD Regulation, Member States' authorities, health institutions, notified bodies and economic operators were not ready to fully meet the requirements of the IVD Regulation at the date of application on 26 May 2022.

In particular, with only seven notified bodies designated so far under the IVD Regulation, there is a grave shortage of notified body capacity, making it difficult for manufacturers to conduct the legally required conformity assessment procedures in time. As the currently designated notified bodies are established in only four countries (Germany, France, the Netherlands and Slovakia), the situation is particularly problematic for SMEs established in other Member States, which have a tendency to apply to notified bodies in their own or neighbouring Member States.

If not addressed, this situation would have led to a significant disruption in the supply of a multitude of in vitro diagnostic medical devices on the market both for health institutions and for the public. This is why the European Parliament and Council adopted Regulation (EU) 2022/112, on the basis of a proposal from the European Commission.

6. Which transitional periods will apply?

For in vitro diagnostic medical devices with a certificate issued by a notified body in accordance with the previous Directive before 26 May 2022, there is now a transitional period until May 2025.. However, only devices that require a notified body certificate already under the previous Directive (around 8%) will benefit from this existing transitional provision.

In order to address the shortage of notified body capacity more broadly, additional transitional periods were introduced for IVDs that have to undergo a conformity assessment involving notified bodies for the first time under the IVD Regulation.

The transitional provisions differentiate between risk classes:

- for high risk devices (class D) there is a transition period until May 2025,
- for class C devices the transition period lasts until May 2026
- for lower risk devices (class B and A sterile) it lasts until May 2027.

Devices that are concerned by the additional transitional periods may make use of them only provided they satisfy certain conditions, notably they continue to comply with the Directive and there are no significant changes in their design and intended purpose. This approach aims to balance the available notified body capacity with a high level of public health protection.

As mentioned above, there is no transitional period for the lowest-risk devices, class A non-sterile.

7. What is the role of notified bodies?

Unlike medicinal products, medical devices, including in vitro diagnostic medical devices, are not subject to a pre-market authorisation by a regulatory authority. Instead, medium and high-risk devices are subject to a conformity assessment procedure involving an independent third party known as a 'notified body'.

Notified bodies are designated and monitored by the Member States and act under the control of the national authorities. Since 2013, assessments of notified bodies are performed by a joint team of

members from other Member States and the Commission. Under the new framework, the successful experience of these joint assessments for the designation of notified bodies is reinforced.

Under the previous Directive on in vitro diagnostics, only a relatively small number of high-risk in vitro diagnostic medical devices is subject to notified body control (about 8% of all in vitro diagnostics on the market). 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 (MedTech Europe Survey Report, 8 September 2021, page 4).

Under the new IVD Regulation, the notified bodies must also consult an independent panel of experts on certain high-risk devices before the final decision on the certification of the product is taken. This will help a notified body to make more informed decisions, drive innovation while preserving a high level of safety and performance of products.

8. Why are there so few notified bodies?

Notified bodies are in most cases private for-profit entities. Their establishment is therefore market-driven. Under the current Directive 98/79/EC on in vitro diagnostic medical devices, 18 notified bodies are designated (22 before the UK's withdrawal from the EU). So far, only 7 notified bodies have been designated under the IVD Regulation. 11 applications for designation are pending (May 2022).

The IVD Regulation, like the Regulation on medical devices, has reinforced the criteria for the designation and oversight of notified bodies. While this is necessary for a high level of safety and performance of devices, it also makes it more challenging for a candidate notified body to apply. Moreover, it may be a challenge to identify and recruit personnel with specific qualifications required for notified body staff in the in vitro diagnostics sector.

Together with Member States' authorities and relevant stakeholders, the Commission is closely monitoring the situation on the market, including notified body capacity and preparedness of manufacturers to submit applications for certification, and is considering measures to address the shortage of notified body capacity.

9. Besides notified bodies, is the other necessary infrastructure in place to ensure application of the Regulation from May 2022?

Besides limited notified body capacity, all the other legal prerequisites for placing devices on the market are in place. The expert panels are the only legally obligatory component of the conformity assessment system of the highest risk (class D) IVDs in addition to the notified bodies. They are already operating, have started receiving submissions and issued scientific opinions.

The IVD Regulation provides the possibility for other optional elements, for example to designate EU reference laboratories and to adopt common specifications. However, neither the EU reference laboratories nor common specifications for IVDs are a pre-condition for the application of the IVD Regulation. It is possible to place devices on the market without them, after the assessment by the notified body and in some cases an expert panel.

For some less common class D devices it could be the case that there will be no EU reference laboratory as there may be no candidate laboratories. It may also be that there is insufficient scientific consensus in the field to produce common specifications for those less common class D devices. Such devices can nevertheless be legally placed on the market and made available to patients.

Even though they are not obligatory, it would be very helpful for the sector to have EU reference laboratories designated and common specifications available. The Commission is working on establishing the EU reference laboratories and adopting common specifications for 16 types of IVDs.

10. What is the state of play of the medical devices database, Eudamed?

Eudamed will provide an overview of all medical devices available in the European Union. It will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance. It will integrate different electronic systems with information about medical devices and related companies (e.g. manufacturers).

The development of Eudamed is progressing, with the first Eudamed module on actor registration

made available in December 2020. Since the beginning of October 2021, the second and third modules are available, namely the module on UDI/device registration and the module on certificates and notified bodies, except for the mechanism for scrutiny and the clinical evaluation consultation procedure functionalities (CECP) (the latter relevant only to medical devices such as implants and not in vitro diagnostics). The remaining modules as well as the functionalities for the mechanism for scrutiny and the CECP will be released when Eudamed is fully functional.

The Commission will continue to work in close cooperation with the Member States on this highly complex project.

11. What are the rules for 'in-house devices'?

'In-house devices', also referred to as 'laboratory-developed tests' are manufactured and used within the same health institution. They are not marketed or transferred to other legal entities and do not bear the CE marking. In-house devices developed in laboratories can be essential for the diagnosis and treatment, especially for rare diseases.

With the exception of the general safety and performance requirements laid down in Annex I of the IVD Regulation, in-house devices are exempted from the IVD Regulation requirements, provided the health institution meets a number of conditions set out in Article 5(5) of the Regulation.

Among other things, health institutions must have an appropriate quality management system, comply with the international standard setting out the quality and competence requirements for medical laboratories (EN ISO 15189) or other national provisions, and must justify that the target patient group's specific needs cannot appropriately be met by an equivalent in vitro diagnostic medical device available on the market.

Since the outbreak of the pandemic, many health institutions, in particular hospitals, have had to focus their efforts on dealing with COVID-19. Therefore Regulation (EU) 2022/112 postpones the application of most of the conditions to be met by health institutions making in-house devices by 2 years until 26 May 2024. The requirement for the justification that there is no equivalent CE marked device available to meet the target patient group's specific needs is postponed even further, until 26 May 2028, as the health institutions will need an overview of CE-marked in vitro diagnostic medical devices available on the market to comply with this requirement.

For more information:

Press release

Medical Devices - New regulations

QANDA/22/3289

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