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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
N° prev. doc.:	ST 7255/26
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Subject:	Regulation to simplify rules on medical and in vitro diagnostic devices - Commission presentation on cluster 5 - Placing on the market and market surveillance

Delegations will find in annex the presentation by the Commission services at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 28 May 2026.

MDR/IVDR revision
Commission Proposal

DG SANTE Unit D3, Medical devices



European Commission

#HealthUnion

Agenda – Cluster 5

PUBLIC

1. Placing on the market, economic operators' obligations

- Topics: placing/making available on the market and related obligations (general safety and performance requirements, in-house devices, distance sales, claims, CS, general obligations of manufacturers, shortage monitoring, authorised representatives, general obligations of distributors, person responsible for regulatory compliance, persons assuming the obligations of a manufacturer, relabelling and repackaging, single-use devices, implant card, EU declaration of conformity, systems and procedure packs) (Legal references: MDR+IVDR : Chapter II, Annex I)

2. Market surveillance

- Topics: market surveillance (Legal references: MDR+IVDR: Chapter VII, Section 3)

Revision of the medical devices regulations

PUBLIC



Overall objective of the MDR / IVDR revision:

Simplify the rules to **reduce administrative burden,** increase **predictability, shorten processes, improve cost-efficiency and effectiveness**, while keeping the **high level of patient safety** and **ensuring the availability** of devices.



- Revision proposal (covering MDR/IVDR, their annexes)
- supported by two Staff Working Documents: targeted evaluation and cost-savings analysis

The revision will make the sector **more competitive,** in the internal market and globally, **by supporting innovation for better patient care.**



Placing on the market, economic operators' obligations

European Commission

Agenda – Chapter II

PUBLIC

Article 5: Placing on the market and putting into service
Article 6: Distance sales
Article 7: Claims
Article 9: Common specifications
Article 10: General obligations of manufacturers
Article 10a: Obligations in case of interruption or discontinuation of supply of certain devices
Article 11: Authorised representative
Article 14: General obligations of distributors
Article 15: Person responsible for regulatory compliance
Article 16: Cases in which obligations of manufacturers apply to importers, distributors or other persons
Article 17: Single-use devices and reprocessing of devices that are not for single use
Article 18: Implant card and information to be supplied to the patient with an implanted device
Article 19: EU declaration of conformity
Article 22: Systems and procedure pack

European Commission

In-house devices

PUBLIC

WHAT is the issue?

Feedback from health institutions shows that the current Article 5(5) framework is not functioning effectively in practice, undermining patient care and resilience of healthcare systems

- Obligation to switch to the first available equivalent CE-marked device
- Administrative burden, notably with documentation for IVD accredited health institutions
- Not possible to transfer devices to another Healthcare institution (different approaches)

WHY is it important?

- indispensable for patients with rare diseases, complex conditions or highly specific clinical needs
- essential for healthcare systems to respond rapidly and flexibly to emerging health threats and urgent clinical situations
- help safeguard the EU's clinical and scientific excellence, foster innovation and strategic autonomy

HOW will it be tackled?

- Provide the necessary tools and flexibility to healthcare institutions and reference laboratories to develop and retain expertise to address specific patient and public health needs
- Provide the necessary safeguards to ensure that in-house devices are used in very specific circumstances by accredited healthcare institutions and expert laboratories

In-house devices

PUBLIC

Current challenges

No incentive to maintain or innovate with in-house devices due to obligation to switch to CE-marked device

High cost and admin burden for health institutions

Loss of expertise in health institutions

Negative impact on patient care (unmet/specialised needs)

Vulnerability to crises

Proposal

Remove barriers to innovation with in-house devices and promote collaboration with industry

Reduce administrative burden where it is appropriate (e.g. accredited laboratories)

More tailored patient care

Strong resilience of the system

In-house devices [1/6]

PUBLIC

Aim: flexibility with appropriate safeguards for (1) better crisis preparedness and response and (2) more equitable patient care

[In house device use is possible provided that:]

Current text

(a) the devices are not transferred to another legal entity,

[none]

[none]

Proposed text

(a) the devices are not transferred to another legal entity, **except to another health institution in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency,**

…

[…] the transferring and receiving health institutions shall ensure traceability of the device.

[…] For the purposes of … point (h) … the receiving health institution shall report any incident related to the device to the transferring health institution.

In-house devices [2/6] – IVDs only

PUBLIC

Aim: better specify the scope of the applicable national requirements, and simplify / reduce duplication of documentation for accredited laboratories

Current text

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation

(f) (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor

Proposed text

(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or, where applicable, national provisions **for quality and competence in medical laboratories**, including national provisions regarding accreditation

(f) (iii) a declaration **either that the health institution is accredited to the standard referred to in point (c) or** that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor

In-house devices [3/6]

PUBLIC

Aim: remove overlap with requirement for QMS (letter (b)) and simplify / remove duplication of documentation for accredited IVD labs

Current text

MD : (f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f),

IVD: (g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII

(h) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g);

Proposed text

(f) the health institution draws up documentation that is sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met

(g) as regards class D devices in accordance with the rules set out in Annex VIII, **where the health institution is not accredited to the standard referred to in point (c)**, the health institution 14 draws up documentation sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met

In-house devices [4/6]

PUBLIC

Aim: Remove barriers to innovation with in-house devices and promote collaboration with industry, promote good use of (public) funds, ensure that good CE-marked devices are available to health institutions, preserve and develop expertise in the labs, better patient care

Current text

IVD: (d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

MD: (c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

Proposed text

IVD: [none]

MD: (c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

For the purposes of the first subparagraph, point (c), from the date that the health institution becomes aware that the target patient group's specific needs can be met by a device available on the market, it may continue to manufacture and use its device for a maximum period of 10 years

In-house devices [5/6] – IVDs only

PUBLIC

Aim: facilitate use of devices in clinical trials of medicinal products and promote innovation

Current text

[none]

Proposed text

This paragraph shall also apply to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a clinical trial subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council*. Where, in this paragraph, reference is made to a health institution, such reference shall also be understood as reference to a laboratory referred to in the first sentence of this subparagraph

In-house devices [6/6]

PUBLIC

Aim: proportionate oversight by the competent authority – remove requirement for additional justification, reduce possibility of additional documentation, harmonise documentation requirements

Current text

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture or the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

Proposed text

(d) **upon request by a competent authority,** the health institution provides information on the use of such devices, which **includes the justification referred to in points (a)** ***[transfer]*** **and (c)** ***[MD only – no CE-marked equivalent]*****,**

Member States shall retain the right to restrict the manufacture or the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

Emerging risks & technologies

PUBLIC

Aim: ensure a future-proof and agile framework capable of rapidly adapting to scientific, technological and international developments

Current text

[none]

Proposed text

7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the general safety and performance requirements set out in Annex I in order to adapt them to scientific or technical progress or to international developments or to add requirements in relation to emerging risks or technologies

e.g. 2020: how to deal with/streamline information to be provided by manufacturers for co-packaged products.

e.g. Novel manufacturing methods such as 3D printing/additive manufacturing (medical device production systems)

e.g. Requirements for management of risks linked to adaptive or continuously learning AI systems

Distance sales

Aim: improve transparency and competent authority oversight for distance sales while ensuring harmonised and proportionate information requirements

PUBLIC

Current text

2a. **[none]**

3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.

4. A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity.

Proposed text

2a. **Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Annex I, section 23.2, points (a) to (d) and (m), and access to the instructions for use.**

3. […] a copy of the EU declaration of conformity drawn up in accordance with Article 19 or the statement drawn up in accordance with Article 21(2) for the device concerned and cooperate with the competent authorities of the Member State where the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service […] or a provider of a service in accordance with paragraph 2, to cease its activity.

Claims

PUBLIC

Aim: improve transparency, coherence and legal certainty

Current text

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties […]

(b) creating a false impression […]

(c) failing to inform the user or the patient […]

(d) suggesting uses for the device […]

[none]

Proposed text

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trade marks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties […]

(b) creating a false impression […]

(c) failing to inform the user or the patient […]

(d) suggesting uses for the device […]

Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).

Common Specifications

Aim: reinforce the New Legislative Framework logic by maintaining essential requirements at legislative level and addressing technical details through Common Specifications

PUBLIC

Current text

1. ~~**Without prejudice to Article 1(2) and 17(5) and the deadline laid down in those provisions**~~, where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV.

Proposed text

1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out **in this Regulation, in particular the reports and plans to be drawn up by manufacturers,** the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, **the conformity assessment procedures set out in Annexes IX to XI and the procedure for custom-made devices set out in Annex XIII**, the clinical evaluation and post-market clinical follow-up […].

General obligations of manufacturers

PUBLIC

Four types of proposed changes:

Type A: removing non-exhaustive list and incomprehensive cross references across the legislation

Type B: introduction of regulatory flexibility related to languages

Type C: ensuring coherence with horizontal legislation (e.g. product liability)

Type D: ‘Own Brand Labelling’/’Original Equipment Manufacturer’

Legal reference: Chapter II, Article 10 (3), (7), (9), (10), (13)

General obligations of manufacturers

PUBLIC

Aim: simplify the legal framework and improve consistency by removing redundant and non-exhaustive references

Current text

3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.

7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.

9. Manufacturers shall ensure that procedures are in place to keep series production […] The quality management system shall address at least the following aspects: (a)-(m)

10. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.

13. Manufacturers shall have a system for recording and reporting of incidents […]

Proposed text

~~3. Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.~~

~~7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.~~

~~9. Manufacturers shall ensure that procedures are in place to keep series production […] The quality management system shall address at least the following aspects: (a)-(m)~~

~~10. Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.~~

~~13. Manufacturers shall have a system for recording and reporting of incidents […]~~

General obligations of manufacturers

PUBLIC

Aim: provide greater flexibility for Member States when determining language requirements based on the intended users without compromising safety

Current text

11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

[none]

Proposed text

11. Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).

General obligations of manufacturers

PUBLIC

Aim: improve coherence of the Regulation by ensuring obligations are assigned to the appropriate actors (this article is aimed at manufacturers)

Current text

14. […] ~~If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, [..]~~

16. ~~Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.~~

Proposed text

14. […]

[none]

16. **[none]**

General obligations of manufacturers

PUBLIC

Aim: preserve viable OBL/OEM business models while ensuring regulatory oversight and protection of confidential technical information

Current text

15. Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4)

Proposed text

15. Where manufacturers have their devices designed and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4).

In those cases, the manufacturer shall ensure that the relevant parts of the technical documentation are drawn up, kept up to date and, upon request, made available to the competent authorities in accordance with paragraphs 4 and 8 of this Article by the legal or natural person that has designed and manufactured the device. In addition, the manufacturer shall draw up, keep up to date and, upon request, make available to the competent authorities the remaining parts of the technical documentation, in particular those referred to in Section 2 of Annex II and in Annex III.

Obligations in case of interruption or discontinuation of supply of certain devices [1/2]

PUBLIC

Aim: strengthen predictability, regulatory oversight and coherent enforcement of supply interruption notification requirements

Current text

1. Where a manufacturer anticipates an interruption or a discontinuation […]

The information referred to in the first subparagraph shall, ~~**other than in exceptional circumstances,**~~ be provided at least 6 months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority

Proposed text

1. Where a manufacturer anticipates an interruption or a discontinuation […]

The information referred to in the first subparagraph shall be provided at least six months before the anticipated interruption or discontinuation or, **if this is not possible, without undue delay after the manufacturer becomes aware of the anticipated interruption or discontinuation**. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority

Legal reference: Chapter II, Article 10(a)

Obligations in case of interruption or discontinuation of supply of certain devices [2/2]

PUBLIC

Current text

[none]

Proposed text

4. The COM, where needed in cooperation with the EMA, shall set up, maintain, and manage an IT system to facilitate the reporting and information […] 1, 2 and 3. That IT system shall be integrated in or interoperable with Eudamed. It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity.

5. The EMA, in collaboration with MDSSG shall develop a methodology to identify the devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the EMA in collaboration w/ MDSSG & with the COM's agreement draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. The MDCG and stakeholders [..] may be consulted as necessary.

6. The NCAs & COM may request MNF in the list in para 5 to provide all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including production capacity and volume of sales.

Authorised representatives

PUBLIC

Aim: ensure a clearer and more proportionate allocation of obligations and liabilities between manufacturers and authorised representatives

Current text

~~***4. The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).***~~

~~**5. Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.**~~

Proposed text

[none]

Distributors

PUBLIC

Aim: improve readability and coherence through simplified cross-referencing

Current text

2. Before making a device available on the market, distributors shall verify […]

(a) the device has been CE marked and the EU DoC;

(b) the device is accompanied by the information supplied by the MNF […]

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer

In order to meet the requirements referred to in points ~~**(a), (b) and (d) of the first subparagraph**~~ the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Proposed text

2. Before making a device available on the market, distributors shall verify […]

(a) the device has been CE marked and the EU DoC;

(b) the device is accompanied by the information supplied by the MNF […]

(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) that, where applicable, a UDI has been assigned by the manufacturer **in accordance with Article 27(3)**

In order to meet the requirements referred to in **the first subparagraph,** the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Person responsible for regulatory compliance

Aim: introduce a more flexible framework for PRRC qualification and more proportionate requirements for micro and small companies

Current text

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. ~~**[…] expertise shall be demonstrated by either of : (a) […] (b) […]**~~

2. Micro and small enterprises […] shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person ~~**permanently**~~ and continuously at their disposal

3. The PRRC shall at least be responsible for ensuring that: (c) the post-market surveillance obligations are complied with in accordance with ~~**Article 10(10);**~~

6. ARs shall have permanently and continuously at their disposal at least one […] with xx expertise (same as point 1)

Proposed text

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

2. Micro and small enterprises shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

3. The PRRC shall at least be responsible for ensuring that: (c) the post-market surveillance obligations are complied with in accordance **with Article 83;**

6. ARs shall have permanently and continuously at their disposal at least one PRRC who possesses the requisite expertise […] (same as point 1)

Legal reference: Chapter II, Article 16(1)

Cases in which obligations of manufacturers apply to importers, distributors or other persons [1/2]

Aim: provide greater legal certainty for healthcare professionals and other persons adapting devices for individual patients or relabeling

Current text

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following: (a)-(c) […]

The first subparagraph shall not apply to any person who, while not considered a manufacturer ~~**as defined in point (30) of Article 2**~~, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

Proposed text

1. A distributor, an importer or another natural or legal person **who places a product on the market or puts it into service** shall assume the obligations incumbent on manufacturers if it does any of the following: (a)-(c) […]

The first subparagraph shall not apply to any **healthcare professional or any** other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

Legal reference: Chapter II, Article 16(4)

Cases in which obligations of manufacturers apply to importers, distributors or other persons [2/2]

Aim: simplify regulatory procedures and reduce duplicative administrative requirements for relabelling and repackaging activities

Current text

~~4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.~~

Proposed text

[none]

Legal reference: Chapter II, Article 17

Single-use devices and reprocessing of devices that are not for single use

Aim: ensure single-use labeling is justified, simplify and harmonise reprocessing

PUBLIC

Current text

~~1. Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.~~

Proposed text

1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing. The manufacturer's justification of an indication of single use shall be part of the technical documentation referred to in Annex II.

Single-use devices and reprocessing of devices that are not for single use

PUBLIC

Current text

~~2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.~~

ALL current provisions of Article 17 have been replaced.

Proposed text

2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n).

3. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device.

4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single-use devices.

Implant card and information to be supplied to the patient with an implanted device

Aim: modernise patient information obligations by enabling digital access and clarifying exemptions for well-established technologies

Current text

1. The manufacturer of an implantable device shall provide together with the device the following: (a) – (d)

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the ~~**particular**~~ patient who has been implanted with the device, by any means that allow rapid access to that information […].

~~**3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings […] .**~~

~~**The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.**~~

Proposed text

1. The manufacturer of an implantable device shall provide together with the device the following: (a) – (d)

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the patient who has been implanted with the device, by any means, **including in electronic or digital format,** that allow rapid access to that information […].

3. Implants that are well-established technology devices shall be exempted from the obligations laid down in this Article.

Legal reference: Chapter II, Article 19

EU declaration of conformity

PUBLIC

Aim: modernise essential manufacturer obligations by enabling digital access

Current text

[none]

Proposed text

2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.

Systems and procedure packs

PUBLIC

Aim: strengthen traceability, transparency and legal clarity for systems and procedure packs

Current text

1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products […]

2. In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that:

(a) they verified the mutual compatibility of the devices and, if applicable other products, […]

(b) they packaged the system or procedure pack and supplied relevant information to users[…]

(c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Proposed text

1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products […]

2. The statement made pursuant to paragraph 1 shall contain at least the following information:

(a) an identification of the devices and, where applicable, other products included in the system or procedure pack, including where applicable their Basic UDI-DI; *

(b) where applicable, an identification of the notified body involved in the sterilisation activities referred to in paragraph 3;

(c) a declaration by the natural or legal person that: (i) - (iii) = to (a) - (c)

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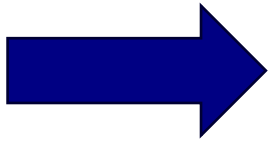
Annex I – General Safety and Performance Requirements

The EU “New Legislative Framework” Approach

PUBLIC

Legislation sets:

- High-level legal requirements
- Safety and performance objectives
- Obligations for economic operators
- Conformity assessment framework
- […]



Technical implementation tools:

- Common Specifications
- Harmonised standards
- MDCG guidance
- International standards/guidance (e.g. IMDRF)
- […]

Manufacturers retain flexibility regarding: *technical design solutions, scientific and engineering approaches, and demonstration methods in* ***accordance with the state of the art***

Annex I: General Safety and Performance Requirements (GSPRs)

PUBLIC

CHAPTER I GENERAL REQUIREMENTS (Points 1-9) : Total: 2 pages

CHAPTER II REQUIREMENTS REGARDING DESIGN AND MANUFACTURE (points 10-22) Total: 11 pages

CHAPTER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE (point 23): Total: 7 pages



Chapter II: Requirements regarding design and manufacturer

Legal reference: Annex I, Chapter II, 10.6

Nanomaterials

PUBLIC

Aim: ensuring coherence with scientific developments and legal clarity

Current text

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.

Proposed text

Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials **as defined in Commission Recommendation C/2022/3689 [Commission Recommendation of 10 June 2022 on the definition of nanomaterial (OJ C 229, 14.6.2022, pp. 1)]**

Legal reference: Annex I, Chapter II, 13.1

Devices incorporating materials of biological origin – **Human origin**

Aim: ensuring coherence with horizontal and sectoral legislation

PUBLIC

Current text

13.1. For devices manufactured utilising derivatives ~~**of tissues or cells**~~ of human origin which are non-viable or are rendered non-viable covered by this Regulation […], the following shall apply:

(a) ~~**donation, procurement and testing of the tissues and cells**~~ shall be done in accordance with Directive 2004/23/EC;

(b) processing, preservation and any other handling of those ~~**tissues and cells**~~ or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. […]

(c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in ~~**Directive 2004/23/EC and in Directive 2002/98/EC**~~

Proposed text

13.1. For devices manufactured utilising derivatives **of substances** of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with Article 1(6), point (g), the following shall apply:

(a) **donor registration, donor review, collection and testing […]** in accordance with Regulation (EU) 2024/1938;

(b) processing, preservation and any other handling of those **substances of human origin** or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. […]

(c) the traceability system for those devices shall be complementary to and compatible with the traceability and data protection requirements laid down in **Regulation (EU) 2024/1938**.

Legal reference: Annex I, Chapter II, 13.1

Devices incorporating materials of biological origin – **animal origin**

PUBLIC

Aim: ensuring coherence with horizontal and sectoral legislation

Current text

13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:

(a) […]

(b) […]

(c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply

Proposed text

13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:

(a) […]

(b) […]

(c) in the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, as referred to in Regulation (EU) No 722/2012, the particular requirements laid down in that Regulation, **or in any subsequent implementing rules adopted pursuant to this Regulation, shall apply.**

Legal reference: Annex I, Chapter II, 17.4

Minimum requirements concerning hardware and IT […]

PUBLIC

Aim: clarify that cybersecurity forms part of existing general safety and performance requirements while maintaining the principle-based NLF approach

Current text

17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

Proposed text

17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics, IT security measures **and cybersecurity**, including protection against unauthorised access, necessary to run the software as intended.



Chapter III: Requirements regarding the information supplied with the device

Legal reference: Annex I, Chapter III, 23.1

General requirements regarding the information supplied by the manufacturer

Aim: align digital information requirements with the existing eIFU framework while avoiding unnecessary obligations

PUBLIC

Current text

Each device shall be accompanied by the information […]. Such information may appear on the device itself, on the packaging or in the instructions for use, ~~**and shall, if the manufacturer has a website, be made available and kept up to date on the website**~~, taking into account the following:

(a),(b),(d),(e),(g),(h)

(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, […].

(f) IFU may be provided […] (e.g. electronic) to the extent, and only under the conditions, set out in ~~**Regulation (EU) No 207/2012**~~ […]

Proposed text

Each device shall be accompanied by the information […]. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:

(a),(b),(d),(e),(g),(h)

(c) labels shall be provided in a human-readable format and may be supplemented by machine-readable […]. **Labels may be provided in digital form to the extent, and only under the conditions, set out in any implementing rules adopted pursuant to this Regulation.**

(f) IFU may be provided […] (e.g. electronic) to the extent, and only under the conditions, set out in **Commission Implementing Regulation (EU) 2021/2226.**

Legal reference: Annex I, Chapter III, 23.1

General requirements regarding the information supplied by the manufacturer

Aim: ensuring coherence with other sectoral legislation and legal clarity for medical devices co-packaged with medicinal products

PUBLIC

Current text

(i) **[none]**

Proposed text

(i) For a device that is exclusively in use with a medicinal product […] and packaged together with a medicinal product, the IFU may be included, where needed, as part of the co-packaging of the medicinal product with the device. Moreover, the information on the label of the device may be limited to the particulars referred to in Section 23.2, points (a) and (c), where, following agreement of the competent authority responsible for the authorisation of the medicinal product, the following conditions are met:

– the information necessary for safe use and correct functioning of the device is provided to the user with the summary of product characteristics and/or package leaflet of the medicinal product under the responsibility of the marketing authorisation holder set out in […]

– the traceability and identification of the device is ensured by the marketing authorisation holder.

Legal reference: Annex I, Chapter III, 23.2

Information on the label

PUBLIC

Aim: ensuring coherence with other sectoral legislation

Current text

The label shall bear all of the following particulars: (a)-(d)

(e) where applicable, an indication that the device contains or incorporates:

– a medicinal substance, including a human blood or plasma derivative, or

– tissues or cells, or their derivatives, of human origin, or

– tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;

Proposed text

The label shall bear all of the following particulars: (a)-(d)

(e) where applicable, an indication that the device contains or incorporates:

– a medicinal substance, including a human blood or plasma derivative, or

– substances of human origin or their derivatives, or

– tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 or in any subsequent implementing rules adopted pursuant to this Regulation

Legal reference: Annex I, Chapter III, 23.2

Information on the label

PUBLIC

Aim: align with proposed Article 17 and simplify the labelling.

Equivalent information is already included in the instructions for use (Section 23.4(n) of Annex I).

Current text

The label shall bear all of the following particulars:

~~**(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;**~~

(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';

Proposed text

The label shall bear all of the following particulars:

(o) [none]

(q) an indication that the device is a medical device **or an accessory for a medical device.** If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';

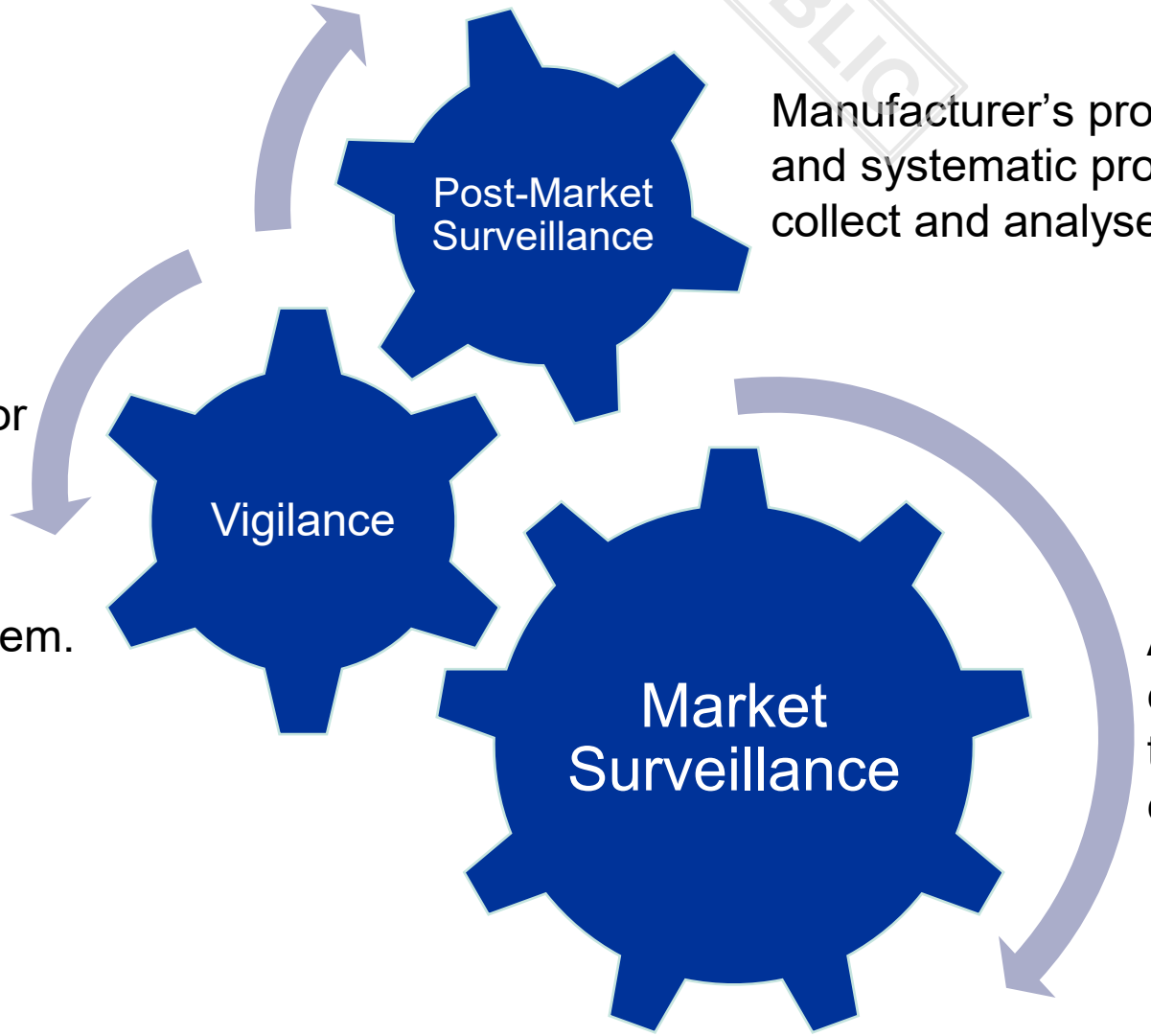


Market surveillance

European Commission

Post-Market Surveillance, Vigilance and Market Surveillance

PUBLIC



Manufacturer's proactive and systematic process to collect and analyse data.

Manufacturer's system for reporting and managing safety issues, and for national competent authorities to evaluate them.

Activities by national competent authorities to ensure that devices comply and are safe.

Market Surveillance Activities

PUBLIC

'Market surveillance' means the **activities** carried out and **measures** taken by competent authorities to **check** and **ensure** that **devices comply** with the requirements set out in the relevant Union harmonisation legislation and do **not endanger** health, safety or any other aspect of **public interest protection**.[1]

Current challenges

Limited legal clarity on checks and enforcement related to economic operator compliance.

Uneven resourcing and infrastructure across competent authorities.

Lack of support for conducting evaluations and access to relevant documentation.

Unharmonised application and understanding of market surveillance measures.

Proposed effects

Clarify the scope of the compliance checks.

Strengthen authority resources.

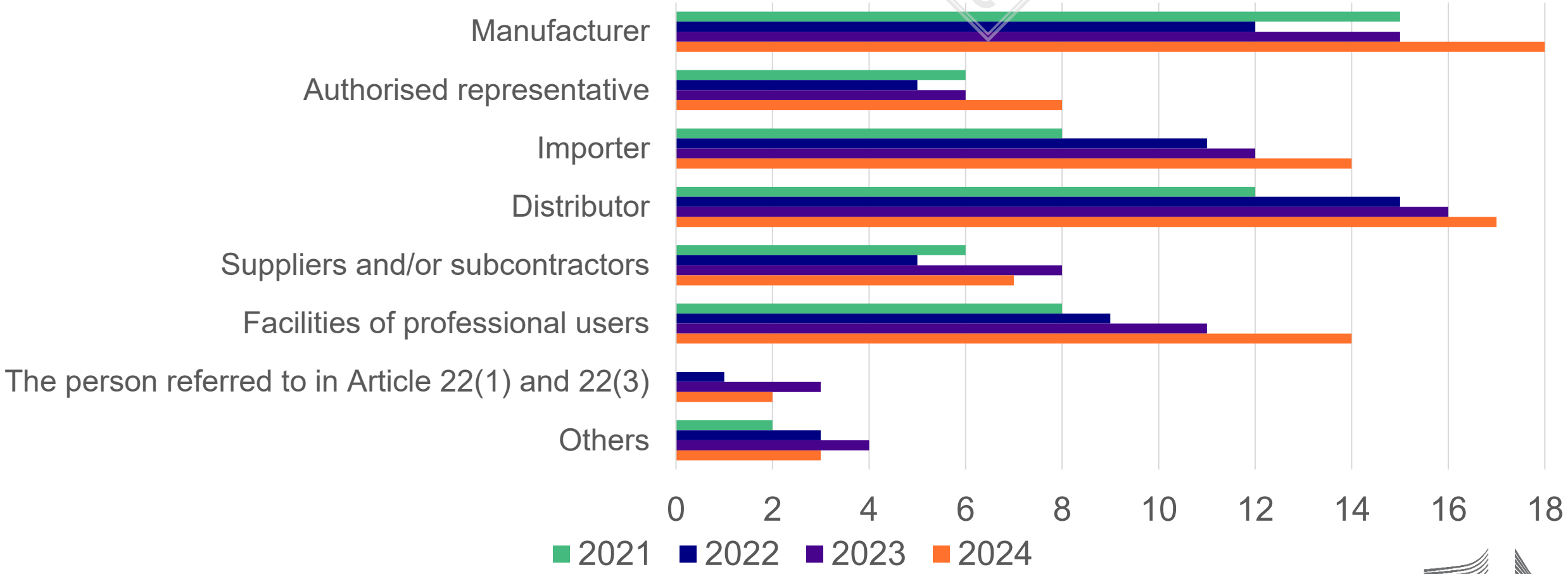
Strengthen cooperation and access to documents resulting in more robust evaluations.

Harmonise the applicability and scope of the market surveillance measures.

[1] Definition of 'market surveillance' under Article 2(61) MDR/ 2(64) IVDR.

Market Surveillance Data [1/4]

Inspections: Economic operators and actors inspected

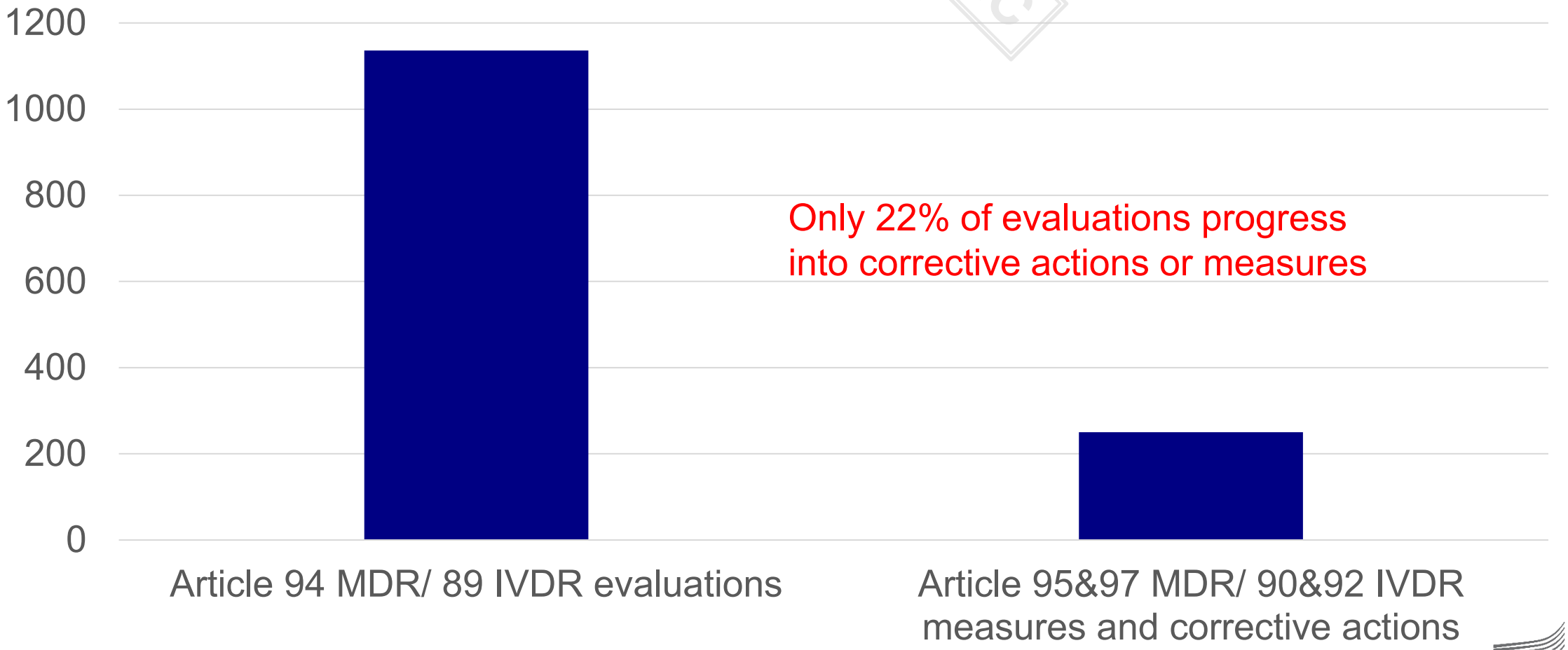


Types of economic operators and actors inspected by national competent authorities in 2021-2024.
Data from the targeted national competent authority survey (16 EU Member States + NO + TR) and the annual market surveillance reports, collected as part of the Targeted Evaluation.

Market Surveillance Data [2/4]

Enforcement: Market Surveillance measures

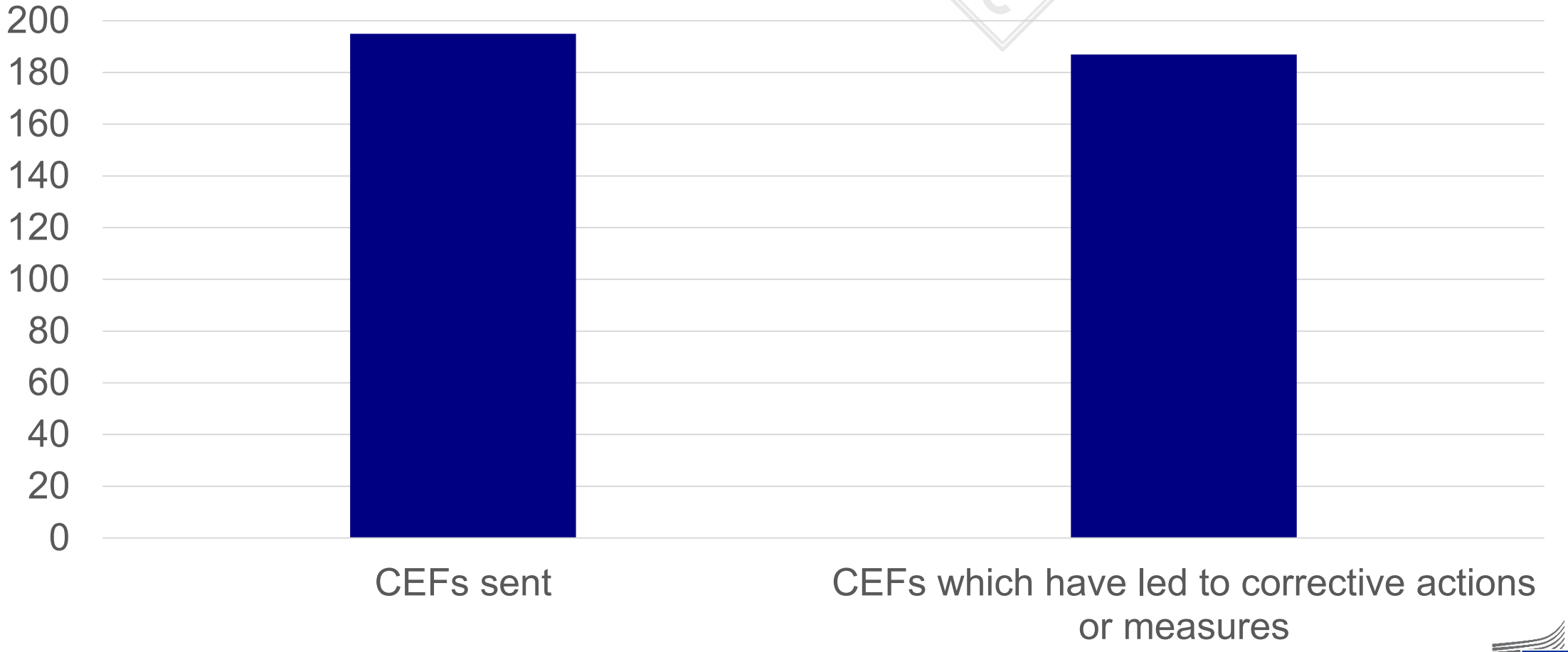
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Number of evaluations under Article 94 MDR/ 89 IVDR, and corresponding corrective actions and measures taken under Article 95&97 MDR/ 90&92 IVDR in 2024.
Data from the targeted national competent authority survey (16 EU Member States + NO + TR) and the annual market surveillance reports, collected as part of the Targeted Evaluation.

Market Surveillance Data [3/4]

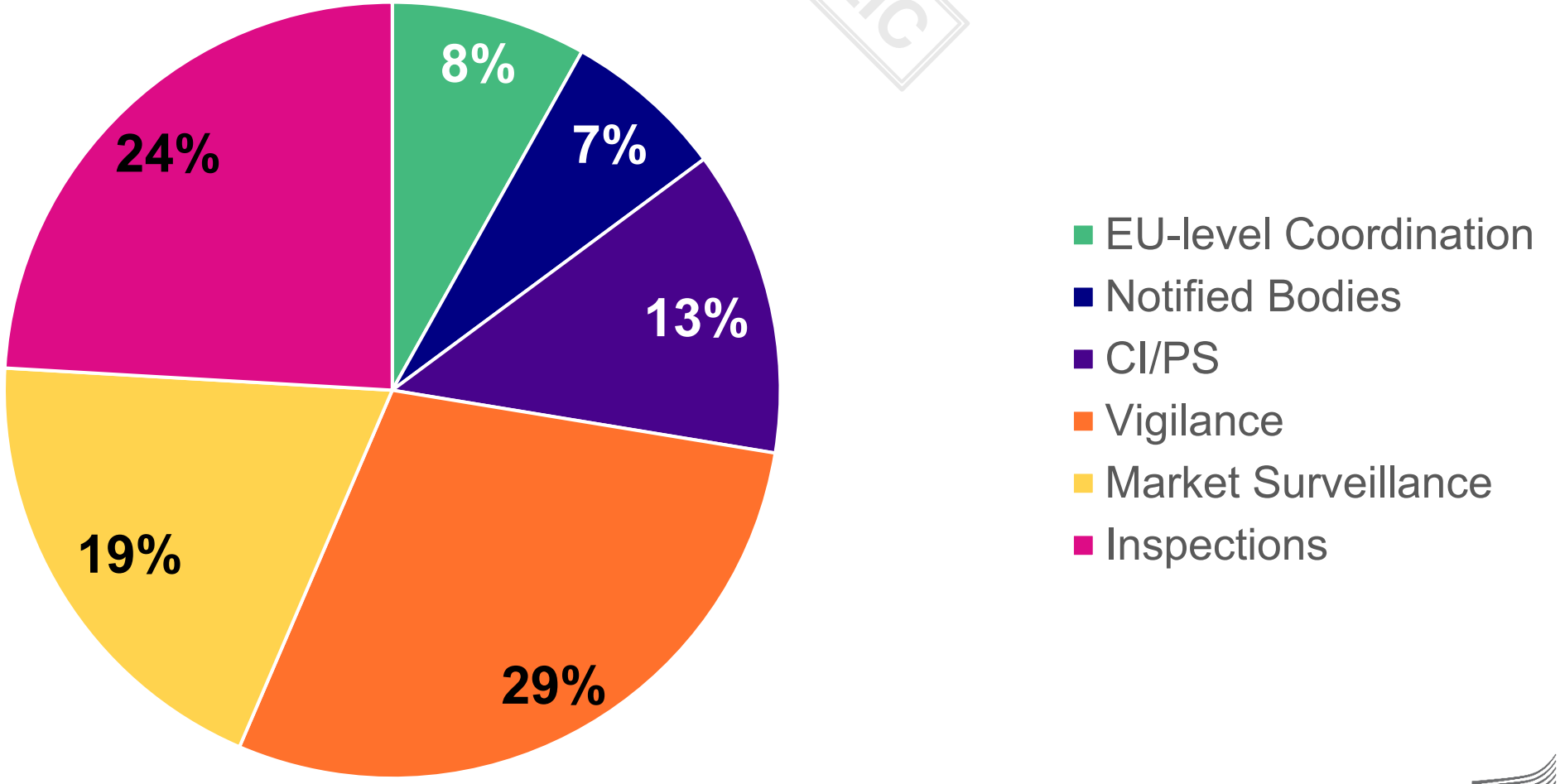
Collaboration: Compliance Exchange Forms (CEFs)



Number of compliance exchange forms (CEFs) sent by national competent authorities and number that has led to corrective actions or measures in 2024.
Data from the targeted national competent authority survey (16 EU Member States + NO + TR) and the annual market surveillance reports, collected as part of the Targeted Evaluation.

Market Surveillance Data [4/4]

Resources: Full-Time Equivalents (FTEs) & Budget



Percentage of full-time equivalents (FTEs) per activity. There is no double counting.
Data from the targeted national competent authority survey (16 EU Member States + NO + TR) and the annual market surveillance reports, collected as part of the Targeted Evaluation.

Legal reference: Chapter VII, Article 93 MDR/88 IVDR

Market Surveillance Activities

Aim: Clarify that compliance checks are not limited to devices and reinforce requirements on competent authority resources and infrastructure.

Current text

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices […].

2. The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities […].

Proposed text

1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices **and on the compliance of economic operators with the obligations set out in this Regulation** […].

1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.

2. The competent authorities shall draw up annual surveillance activity plans […].

Legal reference: Chapter VII, Article 94 MDR/89 IVDR

Evaluation of devices suspected of presenting an unacceptable risk or other noncompliance

PUBLIC

***Aim:** strengthen cooperation in evaluations and extend the scope to economic operators.*

Current text

Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

a) may present an unacceptable risk […];

b)otherwise does not comply with the requirements laid down in this Regulation,

they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device.

Proposed text

The competent authorities of a Member State shall, **alone or in cooperation with the competent authorities of other Member States,** carry out an evaluation of a device **or of an economic operator** covering all the relevant requirements laid down in this Regulation […], where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

a) the device may present an unacceptable risk […];

b) the device **or the economic operator concerned** otherwise does not comply with the requirements […].

Evaluation of devices suspected of presenting an unacceptable risk or other noncompliance

PUBLIC

Current text

The relevant economic operators shall cooperate with the competent authorities.

[none]

Proposed text

The relevant economic operators **and, where applicable and requested, the notified body that issued a certificate for the device in question** shall cooperate with the competent authorities.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.

Procedure for devices presenting an unacceptable risk

PUBLIC

Aim: Streamline, simplify and harmonise the procedures for addressing devices presenting an unacceptable risk.

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities find that the device presents an unacceptable risk […] , they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements […] within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2. The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued […], the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take […].

Current text

3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

Proposed text

3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken, **within the period referred to in paragraph 1**, throughout the Union in respect of all the devices concerned that they have made available on the market.

Legal reference: Chapter VII, Article 93 MDR/90 IVDR

Procedure for dealing with devices presenting an unacceptable risk

PUBLIC

4. *Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.*

The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system […].

Current text

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate […] measures […] on their national market, are taken without delay in respect of the device concerned.

Proposed text

7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of **the notified measures** taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate […] measures, […]. on their national market are taken […]. **Paragraph 4 shall not apply to such measures adopted by the Member States.**

Legal reference: Chapter VII, Article 96 MDR/91 IVDR

Procedure for evaluating national measures at Union level

PUBLIC

1. Where, within two months of receipt of the notification referred to in Article 95(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned […]*, evaluate that national measure.*

Current text

2. Where the Commission considers the national measure to be justified as referred to in paragraph 1 […]., the second subparagraph of Article 95(7) shall apply.

If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Proposed text

2. Where the Commission considers the national measure to be justified as referred to in paragraph 1 […]., the second subparagraph of Article 95(7) shall apply.

If the Commission considers that the national measure is unjustified, the Member State concerned, **as well as any Member State that has taken corresponding restrictive or prohibitive measures**, shall withdraw the measure.

Other non-compliances

PUBLIC

Aim: clarify the application and Union-wide effect of national measures and ensure coherent enforcement.

Current text

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk […], they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator […].

Proposed text

1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device **or an economic operator** does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk […], they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator […].

Legal reference: Chapter VII, Article 97 MDR/92 IVDR

Other non-compliances

PUBLIC

Current text

2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 […], the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market.

That Member State shall inform the Commission and the other Member States, without delay, of those measures […].

[none]

Proposed text

2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available **on the national market** or to ensure that it is recalled or withdrawn from **the national market.** That Member State shall inform the Commission and the other Member States, without delay, of those measures […].

2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 or 2 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.

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PUBLIC

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