

ESIP Position

On the Proposal for a Regulation amending the EU Medical Devices Regulation (EU)2017/745

European Social Insurance Platform (ESIP)

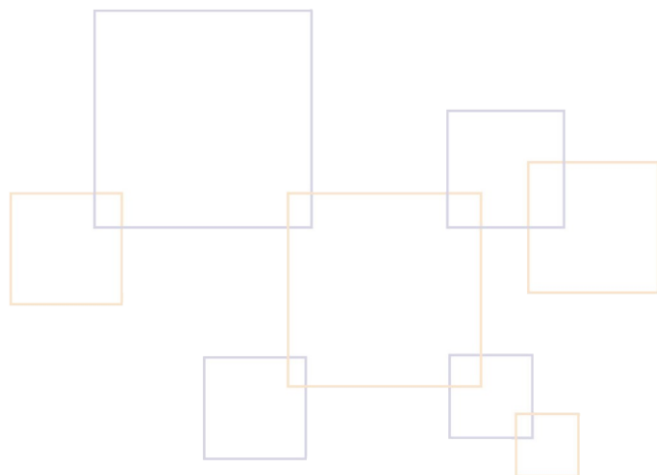
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ESIP aisbl

Maison Européenne de la Protection Sociale

Rue Montoyer 40 • 1000 Bruxelles • ☎ +32 2 315 15 02

✉ esip@esip.eu • 🌐 www.esip.eu • 🐦 @ESIP_EU • VAT: BE 0808.072.950



Executive summary

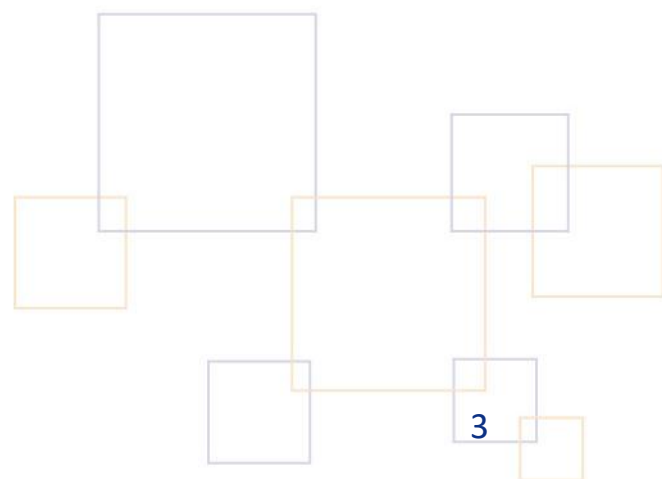
The proposed revision of Regulation (EU)2017/745 (the Medical Devices Regulation-MDR) and Regulation (EU)2017/746 (the In-Vitro Diagnostic Medical Devices Regulation-IVDR) aims to simplify the EU regulatory framework for medical devices and in-vitro diagnostics, reduce unnecessary administrative burden and support timely access to products.

The European Social Insurance Platform (ESIP), representing statutory health insurers across the EU, acknowledges these objectives and the importance of maintaining a competitive and predictable regulatory environment. At the same time, **ESIP stresses that efforts to deliver on simplification must remain fully compatible with robust safeguards for patient and product safety**, ensuring that streamlined procedures do not weaken the level of patient protection or compromise evidence and trust in the safety and performance of medical devices.

In this context, ESIP calls for:

- Support early involvement of independent expert panels to help manufacturers generate stronger and more relevant clinical evidence.
- Allow certification based on non-clinical data only in strictly limited and clearly defined case.
- Maintain clinical investigation requirements for all high-risk devices used outside their original approved and intended purpose, including for devices already on the market.
- Prevent outdated products from being used indefinitely as the basis for assessing new devices.
- Extend the Clinical Evaluation Consultation Procedure (CECP) to Class IIb and Class III Breakthrough Devices (BTDs).
- Require Orphan Devices (ODs) and BTDs to demonstrate a favourable benefit-risk profile and to generate further evidence through structured post-market clinical follow-up (PMCF).
- Reduce the interval for reconfirming OD status from ten years to five years.
- Limit the initial certificate for ODs, BTDs and products developed through regulatory sandboxes to five years.
- Limit regulatory sandboxes to exceptional cases where standard certification routes are not suitable, with mandatory independent expert panel advice for all sandboxes.
- Revise and narrow the list of Well-Established Technologies (WET) to ensure that only clearly defined, low-risk and well-understood devices are included.

- Ensure that all safety requirements for high-risk AI remain applicable to medical devices integrating AI components, under the AI Act and through their full incorporation into sector-specific medical device legislation.
- Keep standalone medical software under Notified Body oversight where it performs clinically relevant functions.
- Introduce an EU-wide obligation for medical device manufacturers and other relevant economic operators to hold liability insurance.
- Maintain the current safeguards on unannounced audits, regular surveillance audits, product sampling and sterilisation processes.
- Provide public and regularly updated information on products withdrawn from the market or affected by production interruptions.
- Ensure that corrective and preventive actions linked to post-market surveillance continue to be reported routinely to competent authorities.
- Maintain the mandatory Summary of Safety and Clinical Performance (SSCP), including information that is accessible and understandable for patients where relevant.



General remarks

The proposal amending the EU Medical Devices Regulation (EU)2017/745 and the In-Vitro Diagnostics Regulation (EU)2017/746 undertakes a detailed and far-reaching revision of the two EU regulations, beyond reforming redundancies and unnecessary bureaucratic requirements. These interventions are justified by the results of an evaluation performed in 2025, which relied mainly on stakeholder questionnaires rather than independent data. Regretfully, reliable data on products withdrawn from the European market, discontinued manufacturing or national derogations remain unavailable, at least publicly. In parallel, surveys led by GÖG GmbH confirmed delayed Notified Body (NB) certification processes and longer transition periods than originally foreseen, although NBs have now developed sufficient capacity to meet manufacturers' needs.

The following remarks refer in particular to the planned amendments to the EU Medical Devices Regulation (EU MDR). The large extent of the proposed revision becomes evident from the fact that more than 75% of the articles have undergone changes in wording. Several articles have been deleted entirely (e.g., Art. 79 "Review of coordinated assessment procedure," Art. 82 "Other clinical investigations"), and multiple new articles have been introduced (e.g., Art. 51a: Decision on product classification in cases of dispute between the NB and the manufacturer; Art. 51b: Reclassification of medical devices: process description among Member States; Art. 52a: Orphan and Breakthrough Devices).

The European Social Insurance Platform (ESIP) supports the objective of simplifying the existing rules, but stresses that efforts to strengthen market competitiveness must not come at the expense of patient safety. In this context, ESIP welcomes the clarification that conformity assessment procedures are to be carried out in the public interest. At the same time, although many of the amendments are editorial in nature and aim to simplify and harmonise the legal text, **some of the changes are substantial and raise important concerns.** ESIP considers that several exemptions from the EU MDR rules for conformity assessment and clinical evaluation risk having a detrimental impact for patient and product safety. Particularly, new conformity assessment and clinical evaluation rules have been defined for orphan devices (OD), breakthrough devices (BTD), and well-established technologies (WET). The plan is to allow marketing of BTDs on limited clinical data, without clear evidence of their safety and clinical performance. ESIP acknowledges that early access to innovative treatment might have advantages for the affected patients. However, many examples in the past have shown that marketing of BTDs without structured collection of missing clinical data might lead to severe patient harm, and ultimately to the medical devices in question being withdrawn from the market. **ESIP calls for measures to ensure that patient and product safety remain prioritised in the EU MDR, even for products with specific market access pathways.**

Clinical evaluations, investigations, consultations and associated rules

ESIP is critical of the provisions allowing manufacturers to specify and justify the level of clinical evidence necessary to demonstrate safety and performance, particularly of the prominent emphasis placed on demonstrating conformity through non-clinical data (Article

61(1)). While the EU MDR already allows this in exceptional cases, ESIP considers **clinical evaluation based solely on non-clinical data** as inherently contradictory. In ESIP's view, this **should remain a very limited exception**, at most for specific low-risk well-established technologies (WETs). By contrast, ESIP sees **merit in the expert panel early consultation process** introduced by Article 61(2) for manufacturers of Class IIb and III devices. Early involvement of independent expert panels could support better clinical development strategies and lead to more meaningful clinical data.

With a view to equivalence requirements, the current legislation allows manufacturers to forgo clinical investigations for Class III devices only if these are further developments of their own products, for which sufficient clinical data already exist, or if they have unrestricted access to the technical documentation of another product to which equivalence is to be demonstrated. By no longer demanding full access to a competitor's technical documentation (Article 61(5)), which in practice is rarely available, the new rules provide that it will be sufficient to demonstrate that the original clinical evaluation was conducted under MDR requirements. While ESIP understands the intention to make the equivalence pathway more workable, it emphasises that the provision must still prevent the development of an "ancestry of clinical data,"¹ whereby outdated products continue to serve indefinitely as the basis for new evaluations. ESIP therefore proposes clarifying that **the original clinical evaluation of the equivalent device must be based on a clinical investigation conducted on that specific device**, in compliance with the current MDR requirements, so that **only the most recent clinical standards and state-of-the-art products can serve as benchmarks**.

Furthermore, ESIP is concerned that limiting MDR clinical investigations exclusively to investigational devices not yet placed on the market (Article 62) would narrow the scope of the current rules and create loopholes for the certification of new intended purposes. ESIP therefore insists that **all clinical trials assessing marketed devices outside their existing intended purpose should also fall under Article 62**.

Regarding the clinical evaluation consultation procedure (CECP) for high-risk devices (Article 54), ESIP is concerned by the proposal to restrict the procedure to Class III implantable devices only, thereby excluding Class IIb devices that administer or remove medicinal substances, which are currently covered. ESIP recalls that the consultation procedure was introduced to ensure that the clinical evaluation of certain high-risk medical devices is reviewed by an independent expert panel. Although only a limited number of assessments have so far been published,² the publicly available opinions already demonstrate its importance; for example, one expert panel review found that the clinical evaluation assessment report for a mechanical ventilator did not provide sufficient clinical data to assess the safety and performance of the device.³ **ESIP therefore strongly opposes any narrowing of the scope of Article 54**. This is all the more important because only devices subject to the consultation procedure under Article 54 may currently enter the EU health technology assessment (HTA) process pursuant to

¹ Ardaugh BM et al. (2014): The 510(k) Ancestry of a Metal-on-Metal Hip Implant. N Engl J Med 368, 97-100.

² https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

³ https://health.ec.europa.eu/document/download/80f2432d-a9da-48ae-8ebb-0054b4922033_en?filename=cecp-2025-0000232089_opinion_en.pdf

Article 7(c) of Regulation (EU) 2021/2282. Any restriction of Article 54 would therefore risk weakening the practical effectiveness of the EU HTA framework. Rather than limiting the procedure, **ESIP calls for its extension to all breakthrough devices (BTDs) in Class IIb and Class III.**

Breakthrough devices, Orphan devices

Breakthrough Devices (BTDs) and Orphan Devices (ODs) are now clearly defined under Article 52a, in line with the respective MDCG guidance. ESIP welcomes the inclusion of ODs and BTDs in the Regulation. Particularly, the definition of ODs intended for the treatment of diseases or conditions that affect no more than 12,000 people per year in the EU is a positive clarification, consistent with ESIP's former position.⁴

In addition, the Regulation clarifies the procedure for determining OD and BTD status, including the requirement that findings adopted by the expert panel under Article 106 be made public. It also provides several regulatory advantages for manufacturers of ODs and BTDs: NBs must give priority to the conformity assessment procedure, a rolling review may be used to shorten assessment timelines and certification may be granted on the basis of limited clinical data where certain conditions are fulfilled.

ESIP is **critical about the criteria for issuing certificates based on limited clinical data** (Article 52a(7)): the notion that “the benefit of immediate availability on the market outweighs the risk” remains insufficiently clear if the benefit is not already reflected in the overall benefit–risk assessment. In ESIP's view, this wording risks weakening clinical evidence requirements for ODs and BTDs too far, and priority must remain with the product-specific, patient-centered benefit-risk balance.

Given that these device categories are intended to address particularly urgent healthcare needs, ESIP calls for safeguards. Importantly, **the device must be shown to have a favourable benefit-risk profile, combined with a binding manufacturer commitment to generate further evidence through structured post-market clinical follow-up (PMCF)**, with clear targets and timelines. Where substantial data is still lacking at the time of market access, the manufacturer should be required to conduct a market-entry clinical trial ensuring that missing clinical data is generated as early as possible. Finally, **ODs and BTDs should be included in the EU health technology assessment (HTA) process**, to ensure structured market access linked to appropriate PMCF obligations.

Systematic assessment of the available evidence is essential for health insurance systems to take timely reimbursement decisions, including the relevant patient groups, the applicable state of the art, the remaining evidence gaps, the studies needed to address them and whether the planned post-market clinical follow-up (PMCF) is sufficient. Such an assessment would also be in the interest of manufacturers, as it would support more timely access to national reimbursement systems across the Member States.

⁴ ESIP Position Paper on Implementing the European Medical Device Regulation and a New Regulatory Framework for Orphan Medical Devices. (2025).

Regulatory sandboxes

ESIP takes a cautious and critical view regarding the proposal to establish regulatory sandboxes (Article 59b and 59c). Under the proposal, Member States and the European Commission could, either on their own initiative or following a justified request from a manufacturer, create frameworks allowing certain MDR requirements to be temporarily suspended or adapted, where a product is expected to address an unmet medical need or deliver a particular clinical benefit, and/or where the ordinary regulatory pathway might otherwise delay development or access.

While ESIP welcomes the requirement for a detailed sandbox plan, as well as the possibility to request an expert panel advice, the current provisions are drafted too broadly and leave the practical consequences of sandboxes insufficiently clear, particularly as regards whether the mechanism is intended primarily for BTDs or ODs. In its current form, Union regulatory sandboxes are not restricted to devices addressing an unmet medical need or providing a significant benefit to patients or healthcare systems (Article 59c). ESIP is concerned that the mechanism could be misused to selectively relax core MDR requirements for other high-risk devices, thereby undermining patient safety and weakening the coherence of the regulatory framework.

ESIP therefore calls for a narrower and more clearly defined scope. In particular, **regulatory sandboxes should be limited to exceptional cases where it is duly demonstrated that the standardised regulatory pathways are not suitable for certification**. Their possible use could be justified, for example, for BTDs, for devices used 'only in research' settings, for coverage with evidence development (CED) programmes, or for cross-country registries linked to devices subject to Article 52a. ESIP also considers that the objectives of regulatory sandboxes should be expressly confined to such situations and that consideration should be given to limiting the validity of certificates granted on the basis of a sandbox, in order to ensure that any derogation remains temporary, proportionate and subject to strict oversight. Furthermore, ESIP requests that **expert panel scientific advice be made mandatory not only for Union regulatory sandboxes, but also for national sandboxes**.

Validity of certificates

Under Article 5 of the proposal, **in-house manufactured devices** may continue to be used for up to 10 years after the responsible healthcare institution becomes aware that a CE-certified product exists. ESIP acknowledges the objective to grant hospitals and other institutions a longer transition and operational period for using in-house developments, thereby encouraging innovative developments. Under the current rules, however, such applications are no longer allowed once a product with the same intended purpose has been placed on the market. ESIP considers a 10-year period disproportionate and argues that, in the interest of patient protection, **the continued use period should not exceed five years**, in line with the validity period of certificates under the old directives.

A key change introduced by the revision is the establishment of special market access regimes for ODs or BTDs, WETs and products developed through regulatory sandboxes. A common feature of these regimes is that the clinical evidence requirements to be met before these products are placed on the market are substantially lowered. As this shifts a substantial part of the evidentiary burden to the post-market phase, **the validity of the corresponding initial CE certificates should be limited to a maximum of five years and should be renewed only if the manufacturer provides sufficient clinical evidence in line with pre-defined requirements.**

Furthermore, ESIP views critically that devices placed on the market under the old directives and benefiting from the existing derogations in Article 5, paragraphs 3a and 3b may continue to be placed on the market provided that an expert panel has confirmed their OD status, no significant changes have been made to their design or intended purpose and they do not present an unacceptable risk to patients, users or third parties (Article 120). These devices would not bear a CE marking. In addition, manufacturers would have to obtain an expert panel opinion at least every 10 years in order to reconfirm OD status. ESIP understands that the purpose of this amendment is to ensure that legacy devices intended for small patient populations remain available without undergoing full MDR certification. However, ESIP is concerned that these devices would effectively remain outside the full scope of the MDR and outside NB supervision for their entire lifecycle, with oversight instead left to national competent authorities. ESIP further considers that **the proposed 10-year interval for reconfirming OD status should be reduced to a maximum of five years.**

Well-established technologies

On 20 March 2026, the European Commission published two implementing regulations (C(2026) 1798 and C(2026) 1809), concerning so-called well-established technology (WET) devices, for which certain exemptions from the EU MDR are to apply. The listed device groups are intended to include relatively simple products characterised by a common and stable design with a low level of innovation, well-known safety and clinical performance, and a long history of market use. The listed WET medical device types of Class IIb are intended to be exempt, with immediate effect, from the obligation to undergo an assessment of the technical documentation pursuant to Article 52 of the MDR. The listed WET medical device types of Class III, on the other hand, are exempt with immediate effect, pursuant to Article 61(6), from the obligation to conduct a clinical investigation.

ESIP has important concerns regarding this approach. No individual products are specified; instead, generic product groups are listed without clarification of their characteristics, in particular the materials used, or their intended purpose. There is neither an allocation of the product groups to the European Medical Devices Nomenclature (EMDN) defined in the MDR, nor any reference to existing product-specific requirements that would allow for a reliable interpretation and assessment of the products. Furthermore, the lists include product groups within which certain individual products have previously been subject to market surveillance actions and withdrawn from the market due to safety concerns. For example, atrioseptostomy catheters for cardiac surgical procedures in newborns were withdrawn from

the market by two manufacturers following serious incidents, some of them fatal. In ESIP's views, such products must not be regarded as WET devices.

Bone substitute materials, on the other hand, should also not be listed for the additional reason that they represent a highly heterogeneous product group. They may, for example, be of mineral origin or contain synthetic components. Their use may be envisaged in dentistry as well as in trauma or tumour surgery. They may release medicinal products or contain or consist of biological substances, for which special precautions are required to prevent undesirable contamination, for example by viruses or prions. In the first consultation procedure pursuant to Article 54 of the MDR, a bone substitute material derived from porcine teeth was assessed and classified by the competent expert panel as giving rise to a health concern.⁵

For these reasons, ESIP cannot support the lists in their current form.

Software and artificial intelligence in medical devices

With regard to software and artificial intelligence in medical devices, ESIP is concerned by the proposed reformulation of Rule 11 in Annex VIII, which would substantially lower the classification of certain standalone medical software. Under the proposal, software intended to generate output with a medical purpose – currently Class IIa – would, as a rule, be classified as Class I, unless its output is used in a critical situation (Class III), a serious situation (Class IIb), or a non-serious situation (Class IIa). ESIP considers this approach problematic, in particular because the notion of a “non-serious situation” remains insufficiently clear and could result in medical software being placed in Class I despite having clinically relevant functions. In ESIP's view, **standalone software as a medical device should, as a default, remain subject to NB oversight**, including assessment of the manufacturer's quality management system, which requires to maintain at least Class IIa classification, rather than Class I.

ESIP is likewise concerned by the proposed amendment in Article 4 to Regulation (EU) 2024/1689 (the AI Act), which would move the MDR and IVDR from Section A to Section B of Annex I. At present, inclusion in Section A means that AI systems which are safety components of regulated products, or are integrated into them, are automatically treated as high-risk AI. Relocating MDR and IVDR to Section B would remove that automatic classification and could mean that many AI Act requirements no longer apply in the same way. While acknowledging the objective of avoiding unnecessary regulatory duplication between the AI Act and the MDR/IVDR, ESIP stresses that this must not lead to a lowering of safeguards. In particular, the MDR and IVDR do not currently address all AI-specific risks adequately, including issues such as fundamental rights protection, robustness, data quality, the use of general-purpose AI, or the presence of open and self-learning systems. ESIP therefore insists that any **AI Act requirements relating to product and patient safety, as well as to the protection of the fundamental rights of AI users, should continue to apply. Requirements that would no**

⁵ https://health.ec.europa.eu/document/download/9a24a908-7cb1-4664-aca9-66074afd6324_en?filename=cepc-2021-000201_opinion_en.pdf

longer automatically apply as a result of this relocation must be substantively integrated into the MDR and IVDR, so that the current level of patient and product safety is fully preserved.

In addition, ESIP calls for **AI-related risks to be expressly reflected in the risk classification systems of the MDR and IVDR** through a dedicated classification rule in Annex VIII. In particular, it must be avoided that devices incorporating AI components may be placed on the market as Class I medical devices or Class A IVDs. Open, self-learning AI models embedded in medical devices should in all cases be classified as Class IIb if not Class III, regardless of their classification under Rule 11.

Product liability and liability insurance

ESIP views critically the deletion, without replacement, of key provisions designed to protect patients and those bearing the costs of harm caused by defective medical devices. The removal of the obligation for authorities to inform patients, insurers and other affected third parties of damage caused by a device (Article 10(14) in the current legislation) limit access for health insurers to essential information needed to support insured persons in product liability proceedings and should therefore be reversed. Even more concerning is the deletion of the compensation-related provisions in current Article 10(16), including the requirement for manufacturers to maintain adequate financial coverage proportionate to the risk and type of device. ESIP recalls that this provision, introduced by the EU MDR, represented the first EU-wide step towards ensuring that injured patients could actually obtain compensation. Removing the provision without explanation runs counter to the lessons learned from the PIP breast implant scandal, which showed the consequences of inadequate financial safeguards: in practice, only France, where liability insurance is required, has ensured compensation, while affected patients and cost bearers in other Member States have often received nothing. ESIP therefore views this deletion as a serious setback for patient rights and for the protection of social security systems. ESIP is equally concerned by the proposed deletion in current Article 11 of the rule making authorised representatives jointly and severally liable with manufacturers for defective products and maintains that this safeguard should also be preserved for the same reasons.

Rather than deleting these provisions, ESIP considers that the legislation should now be strengthened by **introducing an EU-wide obligation for medical device manufacturers and other relevant economic operators to take out liability insurance**, similarly to what the European Parliament and ESIP had already called for during the original MDR negotiations. Only such a harmonised EU-wide insurance requirement can prevent the unfair transfer of insolvency and liability risks to patients and social security institutions, while also avoiding distortions of competition arising from divergent national liability regimes.

On a positive note, **ESIP welcomes the proposed reform of the rules on single-use devices and their reprocessing** (Article 17), as it provides much **clearer allocation of responsibilities and accountability**, while seeking to encourage manufacturers to develop reusable products. Under the revised framework, manufacturers would be required to justify why a product is

intended for single use only, and such a designation would be permitted only where they cannot ensure that repeated use would still comply with the relevant safety and performance requirements. Manufacturers would also have to include in the instructions for use information on an appropriate reprocessing procedure. Where a single-use product is refurbished for reuse, the refurbisher would assume the role and responsibilities of the manufacturer. While ESIP sees these changes as a positive step, it is still uncertain whether these changes will deliver a meaningful benefit from a sustainability perspective.

Conformity assessment quality and involvement of Notified Bodies

Several amendments proposed by the Commission seek to reduce administrative burden on manufacturers by limiting the role of NBs. ESIP considers that some of these reductions are disproportionate and potentially detrimental to patient safety, particularly as they would lower oversight even below the standards established under the former medical device directives. **ESIP therefore calls for the following changes to be withdrawn:**

- **Unannounced audits:** Their purpose and frequency should remain unchanged, as they are essential for ensuring the quality of manufacturing processes.
- **Surveillance audits:** Regular audits are necessary to maintain consistently high product quality and should be retained at the original frequency.
- **Product sampling:** The proposed reduction of sampling and monitoring frequency creates a risk that, for manufacturers with a large product portfolio or with many products covered by a single quality management system, the technical documentation of certain products might not be reviewed throughout their life cycle.
- **Sterilisation processes:** High-quality, validated cleaning and sterilisation processes are essential and can only be ensured if Class I reusable devices remain subject to certification and oversight by NBs. ESIP therefore does not support the proposed deletions in the MDR and IVDR.

Transparency and foresight

ESIP welcomes the proposed amendments to strengthen the early warning system for medical device shortages by allowing not only manufacturers, but also users and healthcare institutions, to report anticipated supply shortages and procurement difficulties (Article 10a). ESIP also supports the plan for the Commission and the European Medicines Agency (EMA) to establish an electronic reporting system interoperable with EUDAMED, as well as the EMA's role in developing a methodology to forecast supply problems and publishing a list of products or product groups for which the reporting obligations are especially relevant. These measures should make it possible to **systematically capture information on products withdrawn from the market or affected by production interruptions that have a negative impact on patient care**. ESIP stresses that these data should be made **publicly available and updated regularly**.

More generally, ESIP welcomes the general move toward the digitalisation of technical documentation, the electronic exchange of data and documents between manufacturers,



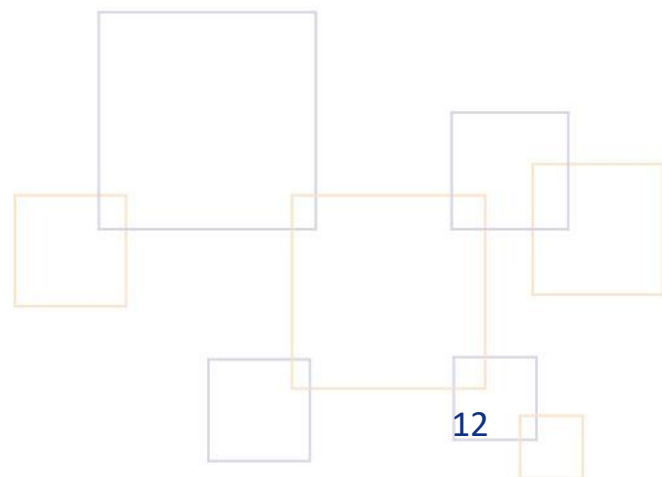
notified bodies, authorities, the Commission and expert groups, as well as the possibility to provide certain product information electronically. This information should remain available in human-readable formats in addition to machine-readable formats.

By contrast, ESIP is concerned by the proposed amendment to Article 83, under which manufacturers would only notify competent authorities of **corrective or preventive actions** related to post-market surveillance upon request. In ESIP's view, this would reduce the information available to authorities, potentially undermine effective market oversight. ESIP therefore calls for **such information to continue to be provided routinely, without the need for a request**.

Similarly, ESIP regrets the limitation of **Summary of Safety and Clinical Performance (SSCP)** requirements to Class III and implantable devices, and the removal of the obligation to prepare a **patient-understandable version of the SSCP** (Article 32). Such information should remain **mandatory for all products** used directly by patients, or where patients must make an informed treatment choice together with their doctor.

Instead, **ESIP supports measures to enhance the transparency of clinical data**. Clinical evidence is derived from data generated thanks to the voluntary participation of patients in clinical trials with the aim of advancing medical knowledge. Therefore, this data should be made publicly available whenever possible.

Finally, ESIP welcomes the new requirement that Member State derogations from conformity assessment procedures under Article 59 be both time-limited and made public, as this reflects an important transparency measure.



About the European Social Insurance Platform (ESIP)

The [European Social Insurance Platform \(ESIP\)](#) represents 46 national statutory social insurance organisations in 19 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

ESIP members support this position insofar as the subject matter lies within their field of competence.

Contact: Yannis.natsis@esip.eu , Benedetta.baldini@esip.eu