Association of the European Self-Care Industry

AESGP Position to the European Commission's Proposal on *simplifying and reducing the burden of the rules on medical devices*

AESGP, the Association of the European Self-Care Industry, represents manufacturers of self-care medical devices[1], non-prescription medicines, and food supplements in Europe, an area also referred to as "self-care" or "consumer healthcare" products.

EXECUTIVE SUMMARY

AESGP generally welcomes the European Commission's proposal to simplify and reduce the burden of the rules on medical devices. We support targeted simplification that improves predictability, transparency and cost-efficiency while maintaining a high level of patient and user safety and a well-functioning Single Market. At the same time, we recommend focused amendments to ensure proportionality and to avoid carrying forward known weaknesses of existing coordination procedures into EU law.

1) Clear and fair decisions on whether a product is a medical device.

The proposed revised coordination mechanism on regulatory status can improve legal certainty, but only if it is limited, transparent, time-bound and includes affected stakeholders. For challenges to the status of CE-marked products, such challenges must remain exceptional, based on substantiated scientific and technical evidence, and must involve the manufacturer and (where applicable) the notified body (**Article 4** and **Article 94**). For early clarification of products *under development*, the new mechanism should be clearly separated from market challenges and should not be usable to target products already on the market (**Article 4a**).

2) Predictable classification and protection against destabilising re-interpretations.

AESGP supports mechanisms that resolve classification questions efficiently, but these must not create new uncertainty for CE-marked devices. Where manufacturers and notified bodies disagree on classification, implementing rules should be mandatory (not optional), the steps should be clear, and an expert panel should be involved as a default safeguard to strengthen legitimacy (**Article 51a** and **Article 106**). Where competent authorities challenge the classification of CE-marked devices, the procedure must be efficient, evidence-based, and stakeholder-inclusive so that such challenges remain the exception and do not undermine free movement of goods (**Article 51b**, linked to **Article 94**).

3) Keep scrutiny proportionate and focused on high-risk devices.

The existing scrutiny mechanism is linked to specific high-risk devices and procedures. Extending the scrutiny mechanism to all medical devices would be disproportionate, would increase administrative burden, and would run counter to the stated goal of simplification. AESGP therefore recommends keeping the current, risk-targeted approach and leaving Article 55 unchanged (**Article 55**).

[1] Self-care medical devices are generally available without medical prescription and are self-administered. Examples include plasters, condoms, salt water nasal sprays, lubricating eye drops, dermal creams or gels.

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4) Strengthen governance with independent expertise and clear roles.

Where the system relies on expert opinion, it must be impartial, balanced and informed by all relevant perspectives. Expert panels should be explicitly required to take into account information from notified bodies' organisations and manufacturers' associations, alongside other stakeholders (**Article 106**). In terms of governance, EMA's role should be clearly limited to administrative support unless and until medical device expertise is demonstrably in place; scientific and technical opinions should remain with independent expert panels (**Article 106b**).

5) Proportionate rules for substance-based devices and clearer criteria for "ancillary medicinal substances".

For devices incorporating a substance, the law should clearly distinguish between substances that are clinically relevant to achieving the device's intended medical purpose and substances present only for technical functions (e.g., preservatives). We therefore propose clarifying that "ancillary medicinal substances" must have a clinically relevant ancillary action in order to achieve the intended medical purpose (**Article 1(8)**), and aligning this approach in the classification rule for devices incorporating such substances (**Annex VIII, Rule 14**). In addition, the MDR should avoid structurally importing medicinal product requirements into medical device conformity assessment: the cross-references to Directive 2001/83/EC should be removed while keeping equivalent safety endpoints within the MDR framework (**Annex I, Section 12.2** and **Annex IX, Section 5.4(a)**).

6) Digitalisation should benefit patients and lay users, not only professionals.

AESGP supports further digitalisation of the regulatory system and device documentation, including electronic instructions for use. However, the MDR should be updated to reflect modern home-use and remote-care realities: electronic instructions should be possible for lay users under appropriate usability and accessibility safeguards, while preserving the right to receive paper instructions on request (**Annex I, Section 23.1(f)**).

7) A risk-based approach for software must be workable in practice.

The proposal's intention to introduce a default Class I pathway for low-risk software is welcome, but the revised wording must not make Class I unattainable in practice. AESGP therefore proposes targeted refinements so that low-risk software used in non-serious situations can be classified as Class I, while higher-risk contexts remain appropriately classified. The classification should explicitly reflect the clinical context, impact and the time available to intervene before foreseeable harm occurs (**Annex VIII, Rule 11**).

8) Avoid unintended reclassification of low-risk products.

Small textual changes can have large effects on market access. The proposed adjustment to the wording of Rule 21 would unintentionally expand its scope and risk reclassifying established low-risk preparations (e.g., certain gels applied on the skin) from Class I to Class IIa, creating unnecessary notified body involvement, higher costs and delayed availability. To keep requirements proportionate and consistent with current guidance, the wording of Rule 21 should remain unchanged (**Annex VIII, Rule 21**).

The amendments proposed in this paper are designed to be practical and targeted. They aim to reduce unnecessary burdens while safeguarding patient safety, ensuring legal certainty and protecting the Single Market.

INTRODUCTION

AESGP Generally Supports EU Proposal to Simplify and Streamline Medical Device Regulations

AESGP generally welcomes the European Commission's legislative proposal on simplifying and reducing the burden of the rules on medical devices[2] aiming to **improve the functioning of the current regulatory framework**, notably regarding the **smooth functioning of the single market for medical devices**, while ensuring a **high level of health protection for patients and users**.

The envisaged measures in the proposal seek to **address shortcomings and inefficiencies**, as identified in the **targeted evaluations** of the MDR/IVDR[3], and exemplified by complex and, at times, disproportionate requirements as well as **unpredictable, opaque, cumbersome and costly regulatory processes** affecting adversely the competitiveness of business operators and, in particular, small and medium-sized enterprises. In turn, the **current regulatory framework negatively impacts both healthcare systems and patient safety** by hindering quick and affordable market access for medical devices.

As a response, the legislative proposal comprehends **targeted simplification measures** seeking to reduce administrative burden, ensure greater predictability and enhance cost-efficiency of the legislative framework. In other words, the **proposal builds upon and enhances existing provisions** without completely overhauling the current regulatory framework applicable to medical devices.

Against this background, AESGP believes in accordance with its previous recommendations[4] that the legislative proposal marks a step in the right direction of a **more efficient, predictable and transparent regulatory system** without compromising the high level of public health and patient safety.

The proposal's targeted **simplification measures are welcomed** as they aim to alleviate unnecessary burdens, streamline processes, and enhance cost-efficiency for business operators – especially **small and medium-sized enterprises** who often face disproportionate challenges under the current framework. By **improving market access** and **reducing administrative complexity**, the proposal is expected to foster innovation and competition within the medical device sector, ultimately benefiting patients and healthcare providers across Europe.

Need for Further Improvements in the Proposal and Addressing Unresolved Issues in MDR

However, AESGP recognizes that further improvements to the legislative proposal are necessary. Certain elements of the proposal need further improvement, while other structural and interpretation issues in the existing regulatory system remain unaddressed by the proposal. For example, some requirements continue to or will be lacking proportionality, leading to unpredictability and higher costs that can hinder the competitiveness of manufacturers.

Enhancements are essential to fully realize the objectives of the revision, ensuring that the regulatory framework not only protects **public health** and **patient safety** but also **supports innovation**, **accessibility**, and **growth** within the sector.

In the following, the specific topics and elements in the proposal that would benefit from further improvement are detailed.

[2] Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonization legislation referred to in its Annex I.
[3] SWD(2025)1051.
[4] AESGP White Paper: Lessons learned with the MDR Implementation. Recommendations towards a robust, transparent, predictable and sustainable regulatory framework for medical devices ensuring a high level of safety and health whilst supporting innovation. April 2024. https://aesgp.eu/content/uploads/2024/04/AESGP_White-Paper_Future-Regulatory-Framework-MD_2024.pdf

AESGP PROPOSAL

AESGP proposes changes to the following legal provisions in Regulation (EU) 2017/745:

- **Article 1(8) –** Subject matter and scope
- **Article 4 –** Regulatory Status of Products
- **Article 4a –** Opinion on and determination of the regulatory status of a product
- **Article 51a –** Classification in the event of a dispute between manufacturer and notified body
- **Article 51b –** Challenges to the classification of CE marked devices
- **Article 55 –** Mechanism for scrutiny of conformity assessment
- **Article 94 –** Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
- **Article 106 –** Expert panels
- **Article 106b –** Support by the EMA
- **Annex I –** General Safety and Performance Requirements
  - *Section 12.2*
  - *Section 23.1 (f)*
- **Annex VIII –** Classification Rules
  - *Rule 11*
  - *Rule 14*
  - *Rule 21*
- **Annex IX –** Conformity assessment based on a quality management system and on assessment of technical documentation
  - *Section 5.4 (a)*

▪ Subject matter and scope

Article 1(8)

Article 1(8) has not been amended by the Commission proposal.

This provision sets out the concept of **ancillary medicinal substance** and is therefore linked to **Classification Rule 14** that is applicable to medical devices incorporating an ancillary medicinal substance. As also explained further below on the Classification Rule 14, practical **challenges in interpreting** this classification rule persist, notably when it comes to **the determination of an ancillary medicinal substance**.

Many substance-based medical devices contain substances which, if used separately, can be considered to be medicinal products. However, typically those substances present in the amount in medical devices are not clinically relevant to the fulfilment of the intended medical purpose. An example constitutes substances having merely the function to preserve the formulation and are, therefore, used as **preservatives** – consequently, they **do not contribute to the intended medical purpose**.

Nevertheless, these substances are currently sometimes considered as ancillary medicinal substances without considering whether the substances are clinically relevant to achieve the intended medical purpose in the amount present in the product. That is why, it should be clarified in Article 1 (8) that substances to be considered as ancillary medicinal substances must be clinically relevant to the fulfilment of the intended medical purpose of the device.

▪ Regulatory Status of Products

Article 4

The Commission proposal significantly revises current Article 4 by requiring Member States to coordinate their activities whether a given product falls within the scope of the MDR. In particular, a Member State that following an evaluation under Article 94 considers that a CE marked device does not fall within the scope of the MDR, must consult the other Member States regarding its envisaged measure.

If one Member State raises in the subsequent consultation a substantiated disagreement, the matter must be referred to an expert panel. The opinion of the expert panel is not legally binding on the consulting Member State. As clarified in the explanatory memorandum to the proposal, the coordination among Member States regarding the qualification of a product under the so-called **Helsinki procedure** will be codified. Hence, a legally binding coordination mechanism has been introduced into Article 4. The purpose of the revised article is to ensure legal certainty and safeguard the principle of the free movement of goods while the final decision on the regulatory status of a product will remain with the Member States or the Commission respectively.[5]

AESGP acknowledges that this Article, as it is proposed, will be fundamental in the demarcation between the scope of application of the MDR and other regulatory frameworks, such as the medicinal products Directive. In this context, it is essential to avoid narrowing the scope of the MDR and to ensure that a proportionate and pragmatic balance in terms of scope between different regulatory frameworks is maintained.

Challenging the status of CE marked devices as foreseen by this Article (i.e. devices that are on the market and have successfully undergone conformity assessment procedures) must be **subject to well-established and transparent criteria as well as procedures involving stakeholders**, notably those that have been responsible for placing the given product on the market: the manufacturer of the device and the Notified Body that has issued the respective certificate, where applicable[6].

Concretely, **challenging the status of CE marked devices should constitute the exception** rather than the norm so that any challenge raised by competent authorities of Member States must be based on substantiated reasons and justifications, including scientific evidence, that particularly address the mode of action of the device. This takes into account that in accordance with the MDR, medical devices do not achieve their principal mode of action by pharmacological, immunological or metabolic means.[7] In other words, the key criterion to determine whether or not a product qualifies as a medical device is the **principal mode of action** performed by the product to achieve its intended medical purpose.

Additionally, the current experience with **the Helsinki procedure** is that it **lacks legitimacy** because it seldom produces scientifically grounded outcomes. At the same time, it **lacks transparency for stakeholders**, including affected manufacturers, and individual steps of the procedure are not adhered to, creating unpredictability. Therefore, it is important that the Commission will – and not may – **detail the steps of the procedure**, including the specification of associated timelines, and ensures proper involvement and consultation of stakeholders. It is essential that the weaknesses of the existing Helsinki procedure are not carried over into a codified mechanism under Article 4 which would be marked by similar shortcomings or would be even enhanced.

Without defining well-established criteria and procedures, **legal certainty** and the principle of the **free movement of goods** will be undermined rather than safeguarded. Based on the foregoing considerations, AESGP proposes targeted changes to **Article 4** in conjunction with **Article 94** concerning the evaluation of devices suspected of presenting an unacceptable risk or other non-compliance.

[5] Cf. recital 11 of the Commission Proposal.
[6] Class I devices do not require the involvement of a Notified Body.
[7] Article 2(1) MDR.

▪ Opinion on and determination of the regulatory status of a product

Article 4a

Article 4a, concerning an opinion on and determination of the regulatory status of a product, is a new provision that is introduced by the Commission in its proposal. As with Article 4, this provision will be crucial in distinguishing the boundaries between the MDR's scope and other regulatory frameworks, such as the directive on medicinal products. It is vital in this regard to prevent the MDR's scope from becoming too limited and to maintain a practical balance between the scopes of the various regulatory systems.

Pursuant to this provision, any stakeholder – including manufactures, developers, notified bodies – are entitled to request an opinion from an expert panel whether a given products falls within the scope of the MDR. As under Article 4, the **opinion of the expert panel is not legally binding** given that the requestor is obliged to give utmost consideration to the expert panel opinion.

In addition, a Member State may submit a substantiated request to the Commission based on an expert panel opinion delivered in accordance with this Article or Article 4a to determine whether a given product falls within the MDR scope. The Commission on its end must decide on the substantiated request by means of an Implementing Act or may also decide on its own initiative by means of an Implementing Act on the regulatory status of a product for which an expert panel opinion has been sought. In other words, the decision making on regulatory status stays with national authorities or respectively with the Commission through Implementing Acts.

AESGP believes that it is important to **clarify that the envisaged mechanism of seeking an opinion** from an expert panel on the regulatory status of a product should only relate to products that are under development and have not been placed on the market yet and should, therefore, **exclude CE-marked devices**. This ensures that any uncertainties or questions regarding a **product's regulatory status** are **addressed prior to market entry** or further development, thereby supporting compliance and patient safety. At the same time through the proposed changes, the **differences in application between Article 4** (i.e. covering challenges concerning CE marked devices as regards their status) **and Article 4a** (i.e. establishing a mechanism for clarifying the regulatory status of products under development) **would be clarified and streamlined**.

Without limiting the scope of this mechanism to products which are not yet on the market, it would likely give rise to **unfair competitive behaviour** and **market distortion** by giving competitors the opportunity to challenge products on the market directly and proactively, which would also lead to a disproportionate use of the mechanism defeating its overall purpose.

- ## Classification in the event of a dispute between manufacturer and notified body

  Article 51a

Article 51a describes the procedure and defines **timelines concerning the situation, where a Notified Body and manufacturer have a dispute concerning the classification** of a given device under **Annex VIII**. The dispute may be referred to the Member State in which the manufacturer has its registered place of business. Under paragraph 6 of this provision, the Commission has the discretion to lay down further details of this procedure and for the procedure provided for under Article 51b (please see dedicated point).

It is of essence that the **Commission must – rather than may – clearly define the procedural steps** with the purpose of **ensuring transparency** as well as meaningful stakeholder involvement and consultation through the adoption of implementing acts. It is essential that the deficiencies of the current Helsinki procedure in terms of unpredictability and lack of legitimacy are not carried over in any formalised process under Article 51a and, in particular 51b.

Furthermore, it is deemed important that an **expert panel is involved by default** after the coordination activities of the competent authorities of the Member States to enhance the **legitimacy of a decision under this procedure**.

▪ Challenges to the classification of CE marked devices

Article 51b

Article 51b provides that competent authorities of Member States may **challenge the classification of CE marked devices**. Similar to Article 4, challenge **must** be **subject to well-established and transparent criteria** as well as **procedures involving stakeholders**, notably those that have been responsible for placing the given product on the market: the **manufacturer** of the device and the **Notified Body** that has issued the respective certificate.

Concretely, challenging the classification of CE marked devices should **constitute the exception rather than the norm** so that any challenge raised by competent authorities of Member States must be **based on substantiated reasons and justifications**, including scientific evidence.

Additionally, the current experience with the **Helsinki procedure** is that it **lacks legitimacy** because it seldom produces scientifically grounded outcomes. At the same time, it **lacks transparency** for stakeholders, including affected manufacturers, and **individual steps of the procedure are not adhered to,** creating unpredictability. It is essential that the **weaknesses of the existing Helsinki procedure are not carried over into a codified mechanism under Article 51b which would be marked by similar shortcomings or even enhances them.**

Without defining well-established criteria and procedures, legal certainty and the principle of the free movement of goods will be undermined rather than safeguarded. Based on the foregoing considerations, AESGP proposes **targeted changes to Article 51b** in **conjunction with Article 94** concerning the evaluation of devices suspected of presenting an **unacceptable risk or other non-compliance**.

▪ Mechanism for scrutiny of conformity assessment

Article 55

Article 55 establishes a **scrutiny mechanism linked to the conformity assessment** process. Under the current MDR legal text, this mechanism is **connected to the procedure in Article 54** and therefore **applies only to certain high-risk devices, notably class IIb and class III** devices subject to the clinical evaluation consultation procedure.

In the Commission proposal, Article 55 has been revamped and broadened so that the **scrutiny mechanism applies to all medical devices**, rather than being limited to high-risk devices. Consequently, this would **significantly expand the scope of the provision by subjecting any device, irrespective of risk class, to the scrutiny mechanism**.

AESGP believes that the amended Article 55 and its widening of scope to all devices is **disproportionate to the actual risks posed by lower risk devices**. Therefore, **Article 55 should be left unchanged** so as to limit its scope to high-risk devices, notably class IIb and III.

- ## Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

  Article 94

Article 94 has been revised by the Commission's proposal. However, given its **linkage to Article 4 and Article 51b** giving the competent authorities of Member States the right to challenge CE marked devices concerning product status and classification, AESGP emphasizes that **further adjustments in this provision are needed to ensure that challenges concerning CE marked devices are an exception subject to well-defined criteria and procedures** in order to safeguard the **free movement of goods** while maintaining a **high level of patient and user safety**.

It must be objective that any challe**nge to a CE marked device is well-founded and justifiable based on technical and scientific information**.

In particular, AESGP sees the need that, in cases where authorities believe a medical device is incorrectly classified according to Annex VIII or falls outside the Regulation's scope, they should **consider in their evaluation all technical and scientific data requested from the relevant manufacturer** and the **Notified Body that issued the certificate.**

▪ Expert panels

Article 106

Article 106 describes the general principles pertaining to the role and tasks of independent expert panels.

The significantly revised provision by the Commission proposal intends to **expand the type of expertise available in expert panels** given the broader range of areas in which expert panels provide advice and their involvement in the regulatory system.[8]

EMA will provide the secretariat for the independent expert panels that are designated under this Article in accordance with the proposed amendments to Regulation (EU) 2022/123.

To meet the **objective of giving impartial and objective opinions**, expert panels shall have access to **information provided by all relevant stakeholders, including Notified Bodies' organisations and manufacturer's associations**.

[8] Cf. recital 45 of the Commission Proposal.

▪ Support by the EMA

Article 106b

Given the **decentralized nature of the medical devices' regulatory system** and pursuant to the legislative proposal, an **effective coordination between national authorities** is needed to ensure the smooth functioning of the internal market and a coherent application of the requirements for a uniform high level of patient and user safety. For this reason, the new provision of Article 106b mandates EMA, on behalf of the Commission, to provide scientific, technical and administrative support for the coordination between national competent authorities.

In accordance with the medical technology's Joint Discussion Paper on governance[9], co-signed by AESGP, it has been emphasized that **certain roles and responsibilities of the governance of the regulatory system need to become centralised under a single structure at EU level** so as to end the splitting of tasks across different players.

While the proposal does not include specific measures centralizing certain roles and responsibilities under one single structure at EU level, it aims at improving the coordination between national competent authorities to address the existing fragmentation in the regulatory system. In this context, **the proposal falls short of achieving the level of governance reform** outlined in the Joint Discussion Paper. However, according to AESGP, the increased coordination among competent authorities is a positive interim measure that will arguably help promote the necessary consistency in the application and interpretation of requirements.

At the same time, **it must be questioned whether EMA should be equipped with a broad mandate**, particularly with regard to **providing scientific and technical support to national competent authorities**. Without a doubt, **EMA as it currently stands has only very limited expertise in the field of medical devices**. It is therefore important that any scientific, regulatory, clinical and technical opinions or **advice is given by independent expert panels** as long as EMA's main expertise lies with medicinal products and without EMA's expansion of its expertise to medical devices.

Consequently, at this point in time, AESGP proposes to **limit EMA's mandate explicitly to administrative support** to national competent authorities and, thereby, **remove references to scientific and technical support**. This helps clarifying that EMA should not be involved in scientific and technical support to **avoid affecting the assessment by national competent authorities of medical devices**, for example when it comes to questions related to regulatory status or classification.

[9] Joint discussion paper on Future governance of medical technologies in Europe, 19 March 2025. Joint discussion paper on Future governance of medical technologies in Europe | AESGP

▪ Annex I – General Safety and Performance Requirements

Section 12.2 Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

Annex I, Section 12.2 requires that **substance-based medical devices** (i.e. medical devices composed of substances, or combinations of substances, intended to be introduced into the human body and absorbed or locally dispersed) comply – for aspects not covered by the MDR – with the relevant requirements of Annex I to Directive 2001/83/EC relating to medicinal products, notably with regard to the **evaluation of absorption, distribution, metabolism and excretion (ADME), local tolerance, toxicity, interactions and potential adverse reactions**.

This has been left **unchanged by the Commission proposal**. While the underlying safety objectives are fully supported, the **cross-reference to Directive 2001/83/EC should be removed**, while maintaining equivalent safety endpoints within the medical device framework.

By definition, a **medical device does not achieve its principal intended action through pharmacological, immunological or metabolic mechanisms**. Directive 2001/83/EC is specifically designed for medicinal products and is **based on a benefit–risk assessment model** tailored to substances with a pharmacological, immunological or metabolic mode of action.

Furthermore, the Commission proposal clarifies, under **Recital 53**, that **substance-based medical devices that are systemically absorbed by the human body are medical devices** and that the **consultation of a medicinal products authority for such substance-based medical devices are not appropriate**. By analogy and for consistency purposes, the **reference to Directive 2001/83/EC should also be removed** in this particular section of Annex I to the MDR.

Automatically importing the medicinal product framework into the conformity assessment of medical devices introduces a **structural inconsistency**. It risks **imposing evidence requirements** that **are not scientifically proportionate, not appropriately tailored** to the nature of medical devices, and in many cases methodologically unsuitable for complex substance-based medical devices, including those containing natural substances.

The same issue is mirrored in **Annex IX, Section 5.4(a)**, where a similar cross-reference leads to comparable concerns regarding regulatory coherence, scientific appropriateness and proportionality. **Addressing this inconsistency would improve legal clarity**, reduce unnecessary regulatory burden and better align the requirements with the intrinsic characteristics of substance-based medical devices, **without compromising patient safety**.

▪ Annex I – General Safety and Performance Requirements

Section 23.1. (f) Electronic Instructions for Use

AESGP welcomes the proposed measures in the Commission proposal enabling **further digitalization** of the regulatory system, including the digitalization of conformity assessment procedures.

However, AESGP believes additional measures towards digitalization are necessary to **ensure that also lay-users of medical devices can benefit from digital advancements** while taking into account the skills and needs of the intended user group.

The current **restriction of eIFU to professional users is no longer appropriate** in a digital healthcare environment. Many devices are today used by patients and laypersons in home settings or in the context of digital and remote care. Allowing eIFU for these user groups – under **clear usability and accessibility safeguards** – would **modernize the regulatio**n and align it with the EU's **Digital Health Strategy** and **Green Deal** objectives.

Opening the eIFU framework to patients **improves accessibility, reduces packaging waste, supports multilingual information management without compromising safety**, provided **user-appropriate design** is ensured. Of course, users shall retain the right to request and receive the instructions for use in paper format at any time.

In this context, the developments in the pharmaceutical regulatory framework, notably with regard the introduction of electronic product information for all medicinal products should be taken into account.

▪ Annex VIII - Classification Rules

Rule 11

The Commission proposal revises the wording on **Rule 11 concerning software**. In particular, the introduction of a **default class I classification** is supported as it **provides for greater proportionality** when it comes to the classification of software.

However, **a fundamental inconsistency exists** within the revised Rule 11. While the opening part of the rule allows for a class I classification, the **final indent effectively makes it almost impossible for software to be classified as class I in practice**. In particular, the final indent referring to **software intended "to inform clinical management in a critical or serious situation"** renders the identification of class I software ineffective.

In practice, **virtually all software outputs relate to situations beyond "non-serious"**, thereby triggering a **default classification as class IIa**.

AESGP proposes, therefore, to adjust the wording of this classification rule.

▪ Annex VIII - Classification Rules

Rule 14

Classification **Rule 14 has not been amended by the Commission proposal**. Nonetheless, practical challenges in interpreting this classification rule persist, which could be addressed by refining and clarifying its wording.

Many **substance-based medical devices** contain substances which, **if used separately, can be considered to be medicinal products**. However, those substances present in the amount in medical devices are not clinically relevant to the fulfilment of the intended medical purpose. An example constitutes substances having merely the function to preserve the formulation and are therefore used as preservatives - but do not contribute to the intended medical purpose. However, these substances are currently sometimes considered as ancillary medicinal substances without considering whether the substances are clinically relevant to achieve the intended medical purpose with the effects that products containing them are **incorrectly classified as Class III** products due to the wording of Classification Rule 14. As a result, this **classification requires a disproportionate amount of resources**, bureaucracy and costs for manufacturers and Notified Bodies.

Specifically, the classification rule should take into account if the respective substance has an impact on the intended purpose of the device. If this is not the case, it is **not justifiable to classify those products under the highest risk class**.

▪ Annex VIII - Classification Rules

Rule 21

Per the Commission proposal, **Rule 21 has been slightly modified** with regard to its wording. In particular, the terms "on or" have been added to the introductory sentence of this classification rule. Despite the fact that this modification is minimal, it will have an **impact on the current interpretation of the Rule 21** as it exte**nds the scope of its application** and would **apply to products that are currently subject to other classification rules**.

The proposed change would have the **effect of bringing certain devices within the scope of Rule 21 that are currently classified under other rules**, in particular Rule 1, as class I devices. In particular, this affects devices that are locally dispersed on the human body, such as **electrode gel, ultrasound gel and ultrasound cream**. Currently, these devices are consistently classified as class I devices according to MDCG Guidance 2021-24 on classification.

Without a doubt, these devices are **low-risk preparations**. **Reclassifying them** from class I (Rule 1) to class IIa (Rule 21) **would be disproportionate** to their actual risk posed. In addition, such products would have to undergo a **conformity assessment involving a Notified Body entailing significant additional time and cost** for manufacturers. In other words, the proposed change concerning Rule 21 would increase administrative burden, including costs, for manufacturers of these products rather than reducing them.

To avoid undermining the objectives of the Commission's revision proposal, notably with regard to ensure requirements that are proportionate to the actual risks posed by the devices as well as the reduction of administrative burden for manufacturers, AESGP believes that the **wording of classification Rule 21 should be left unchanged**.

- ## Annex IX – Conformity assessment based on a quality management system and on assessment of technical documentation
  Section 5.4 (a)

The issue identified for Annex I, Section 12.2 is also mirrored in Annex IX, Section 5.4 (a), where a similar cross-reference leads to **comparable concerns regarding regulatory coherence, scientific appropriateness and proportionality**.

While the underlying safety objectives are fully supported, the **cross-reference to Directive 2001/83/EC should be removed**, while maintaining equivalent safety endpoints within the medical device framework.

Automatically importing this medicinal product framework into the conformity assessment of medical devices introduces a **structural inconsistency**. It risks imposing evidence requirements that are not scientifically proportionate, not appropriately tailored to the nature of medical devices, and in many cases methodologically unsuitable for complex substance-based medical devices, including those containing natural substances.

Addressing this inconsistency would improve legal clarity, reduce unnecessary regulatory burden and better align the requirements with the intrinsic characteristics of substance-based medical devices, without compromising patient safety.