AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

WHITE PAPER

Simplifying EU Healthcare Legislation to enhance Self-Care benefits

Process, Objectives, and Expected Outcomes

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INTRODUCTION

The European healthcare landscape is a cornerstone of public well-being, yet its regulatory framework has grown increasingly complex.

Self-care saves €36.72 billion annually in Europe by reducing medical service costs and productivity losses. **Expansion of self-care could save an additional €17.6 billion per year**, freeing up financial and human resources for more serious health conditions. Self-care reduces the burden on healthcare systems, saves time for healthcare professionals and individuals, and improves access to health services.[1]

Following a meeting with the Cabinet of Commissioner for Health, Oliver Varhelyi, on behalf of AESGP, we felt encouraged to identify opportunities for simplifying EU health legislation and guidelines.

Although we acknowledge that the General Pharmaceutical Legislation is still ongoing legislative procedure and that a Medical Devices Regulation review is underway, we see many opportunities to improve, by reiterating some of the points and by adding new simplification proposals. We believe these measures can make regulatory frameworks more consistent across legislative files and guidelines.

The decision to include guidelines in this proposal is because they are many times used as by-law or soft-law and are enforced by regulatory agency officials with the same strength as legislation, with little flexibility or the openness to do a case-by-case analysis and consider exceptional conditions.

This white paper outlines our process, objectives, and proposed outcomes, structured around four key areas of focus derived from our discussions with AESGP members and encapsulated in the concrete proposals of the Annexes.

We have divided the proposal into four main areas, reflecting the priorities of the European Union in the current situation:

[1] May U et al. Self-Medication in Europe: Economic and Social Impact on Individuals and Society. Gesundh ökon Qual manag. https://aesgp.eu/content/uploads/2023/05/Self-Medication-in-Europe-Economic-and-Social-Impact-on-Individuals-and-Society-Thieme-Gesundheit-okon-Quality-management-2023.pdf

RECOMMENDATIONS

Competitiveness in a Global Market

Global competitiveness is a critical concern for the European self-care industry. Regulatory complexity often acts as a barrier to innovation, hindering the ability of companies to adapt to international market demands. Our members have identified specific legislative bottlenecks that limit the growth potential of non-prescription medicines, medical devices, and food supplements, particularly in comparison to markets outside the EU.

Proposed Measures:

- Streamlining the approval process for non-prescription medicines to reduce time-to-market.
- Reducing administrative burden and eliminating unnecessary costs or obsolete services.
- Facilitating mutual recognition agreements with non-EU countries to enable cross-border trade.

Expected Outcomes:

- Enhanced global positioning of EU-based self-care companies, particularly SMEs and midcaps.
- Increased investment in innovation, driven by a more predictable regulatory environment to the benefit of global consumers.
- Improved accessibility of EU self-care products to consumers in Europe and worldwide.

Updating Legislation to Digital Solutions

The digital transformation of healthcare is reshaping how products and services are developed, marketed, delivered and kept up to date. However, current EU regulations often fail to account for these technological advancements, leading to inefficiencies and missed opportunities. Harnessing digitalisation and technological innovation will simplify and streamline life-cycle changes and allow for a faster pace of innovation.

Proposed Measures:

- Incorporating provisions for electronic product information to ensure availability of the most updated version to patients and users while ensuring wider accessibility to people who struggle with limitations.
- Standardizing the use of digital tools for consumer education, increasing their health literacy and empowering them in responsible self-care.
- Ensuring the regulatory system can benefit from AI and data analytics and that the legislation fosters its safe usage.

Expected Outcomes:

- Greater alignment between regulatory frameworks and digital innovations.
- Reduced compliance costs for businesses adopting digital solutions and free human resources in industry and regulatory authorities for work that needs human intelligence.
- Improved consumer access to accurate, up-to-date product information.

Avoiding Overlapping and Duplication

The coexistence of horizontal legislations introducing conflicting requirements often leads to redundancies and inconsistencies that make implementation highly challenging and further complicate compliance. This is particularly evident in horizontal measures that span across non-prescription medicines, medical devices, and food supplements.

Proposed Measures:

- Ensure coherence across horizontal legislations by aligning regulatory requirements to prevent duplication and conflicting obligations.
- Defining clear roles and responsibilities for EU and national authorities to avoid jurisdictional conflicts.
- Establishing single points of access for regulatory submissions, approvals and appeals.

Expected Outcomes:

- Reduced administrative burden for both Regulators and Stakeholders.
- Enhanced clarity and transparency in regulatory processes.
- Faster adaptation to market changes, benefiting both businesses and consumers.

Consumer Protection and Empowerment

While simplification aims to reduce complexity, it must not compromise consumer safety or rights. On the contrary, a more streamlined regulatory environment should empower consumers by providing greater transparency and accessibility.

Proposed Measures:

- Ensuring that simplified guidelines maintain rigorous safety standards for self-care products.
- Promoting consumer education initiatives to increase awareness of self-care options and appropriate use.
- Enhancing labelling requirements to ensure clarity, comprehensibility and proper derived action for all consumers.

Expected Outcomes:

- Increased consumer confidence in self-care products.
- Greater public understanding of the role of self-care in promoting health and well-being.
- Stronger safeguards against misinformation and unsafe practices.

CONCLUSION

Simplifying the EU healthcare legislation and guidelines is an opportunity to address long-standing inefficiencies, foster innovation, and empower both businesses and consumers.

The measures proposed in this reflection paper, developed in close collaboration with AESGP members, aim to create a regulatory framework that is both robust and adaptable, ensuring that EU self-care products remain competitive, safe, and accessible in a rapidly evolving global market.

ANNEX 1 - Summary of proposed simplification measures and their benefits

ANNEX 2 – Proposed simplification measures per legislation and justifications

ANNEX 1

Summary of proposed simplification measures and their benefits

Annex 2 Page	Directive Regulation Guideline	Proposed Change	Benefits
	MEDICINES		
1	**Dir. 2001/83/EC** *Article 74a*	*Extend data protection for evidence from 1 year to 3 years, including non-clinical tests, clinical studies, behavioural studies, pharmacy-based studies and validated market research, and other types of real-world studies that translate into real-world evidence*	
2	**Dir. 2001/83/EC** *Art. 24 (1-4)*	*Make marketing authorisations valid for an unlimited period as the general rule, with exceptions for those demanding particular safety monitoring.*	
3	**Dir. 2001/83/EC** *Art. 24 (4-6)*	*Proposed deletion of the sunset clause, which is deemed unnecessary and burdensome and does not serve original intent*	
4	**Dir. 2001/83/EC** *Art. 59*	*Simplify package leaflets and remove certain information that is confusing for patients or neither understood nor needed by patients*	
5	**Dir. 2001/83/EC** *Art. 10d and 104a (1)*	*Addition of Article 10d to release MAHs from submission of RMPs for generic products, products with well-established medicinal use, and reference products*	
6	**Dir. 2001/83/EC** *Art. 107b*	*Exempt products with more than 10 years on the market from submitting periodic safety update reports, except in specific cases*	
7	**Reg. 726/2004** *Art. 57*	*To give an enlarged mission and tasks to EMA on scientific advice on any topic which impacts medicinal products including what comes from other regulatory fields and agencies such as EFSA*	
8	**Reg. 2024/1701** *Art. 8*	*The newly introduced annual update makes the reliance of 3rd countries on EU authorisations more difficult and imposes new constraints on EU MAHs*	
9	**Reg. 2024/1701** *Art. 20*	*Work-sharing should not entail including variations which have already been assessed nor those where work-sharing bears no benefit (e.g., translations).*	
10	**Prop. Dir. 2023/0132(COD)** *Art. 51 (e)*	*AMR risks are already evaluated on ERA prior to a change of legal status request ("switch"). Non-prescription antifungals and antivirals without AMR risks are unfairly affected, reducing patient accessibility and increasing pressure on the health system.*	

Annex 2 Page	Directive Regulation Guideline	Proposed Change	Benefits
11	**Prop. Dir. 2023/0132(COD)** *Art 51 (f)*	*Parameters such as PBT or PMT are hazard-based classifications, which do not necessarily indicate an environmental risk. ERA will already assess these risks and propose mitigation measures*	
12	**Prop. Dir. 2023/0132(COD)** *Art. 13*	*Ensuring that bibliographic application remains a valid legal basis for herbal medicinal products for which generic applications are technically not feasible and would, hence, drastically restrict the market and the availability of medicinal products*	
14	**Prop. Dir. 2023/0132(COD)** *Art. 21*	*Exception medicinal products with well-established active substance(s) and no significant safety concerns, from submitting risk mitigation plans*	
15	**Prop. Dir. 2023/0132(COD)** *Art. 22*	*Prioritise antibiotics, over all antimicrobials, because there is no overall methodology to derive PNECs for resistance for all antimicrobials. Hence, an evaluation is not possible.*	
16	**Prop. Dir. 2023/0132(COD)** *Art. 23*	*For medicinal products authorised prior to October 2005, the assessment should be prioritized on a risk-based approach.*	
17	**Prop. Dir. 2023/0132(COD)** *Art. 24*	*Prioritising and making use of databases to avoid animal testing in ERA*	
18	**GdIn. 2013/C 223/01** *Variations A4 and A5*	*Digitalisation should be applicable to simple administrative changes (i.e., Precedence applied to variations C.I.8 and C.I.9 to be extended to other type IA variations)*	
19	**EMEA/CHMP/SWP/4447/00**	*Eliminate unnecessary animal testing, avoid duplication of ERA studies, use of databases for ERA purposes.*	
20	**EMA/CHMP/287710/2014** *Points 4.1.5 and 4.1.11*	*A common umbrella branding segment may be authorised provided a risk assessment has taken place.*	
21	**EMA/33617/2014** *Point 38*	*Only Member States that have authorised a product should be in scope for translating the CHMP annexes needed for MRP/DCP request.*	
22	**EMA/118465/2012** *Module XV.B.5.1.*	*Only Member States that have authorised the product should be in scope of the translation and dissemination of the DHPC*	
	MEDICAL DEVICES		
23	**Reg. 2017/745** *Art. 1 (8)*	*Classify devices based on clinically relevant ancillary action*	
24	**Reg. 2017/745** *Ann. VIII Rule 14*	*Classify devices based on clinically relevant ancillary action*	
25	**Reg. 2017/745** *Art. 56 (2)*	*Make certificates valid for the lifetime of the device, subject to post-market surveillance.*	

Annex 2 Page	Directive Regulation Guideline	Proposed Change	Benefits
26	**Reg. 2017/745** *Art. 86 (1)*	*Update PSURs based on significant changes or serious incidents.*	
27	**Reg. 2017/745** *Art. 61 (11)*	*Update the summary of safety and clinical performance only when necessary.*	
28	**Reg. 2017/745,** *Annex VIII Rule 19*	*Classify devices incorporating nanomaterials based on potential for internal exposure*	
29	**Reg. 2021/2226** *Rec. 4 + Art. 3(2)*	*Restricting eIFU to professional users is outdated in today's digital healthcare environment. Many devices are now used by patients at home or in remote care settings.*	
30	**MDCG 2022 – 5** *1.2.2 Definitions*	*Definitions should be clear and avoid uncertainty regarding whether their products should be classified as medicinal products or medical devices*	
31	**MDCG 2022 – 5** *2. Herbal Products*	*Simplified and legally sound approach to product classification must rely on clear, case-by-case scientific assessments, rather than on generalised assumptions.*	
32	**MDCG 2023-2** *List of Standard Fees*	*It is not justifiable why notified bodies are able to charge an (internal) annual "maintenance fee" that is not part of conformity assessment activities rendered to a manufacturer.*	
33	**EMA/37991/2019** *Q&A 3.2.1.*	*Co-packed medical device's information may be provided within the section 6 of the Product Information Leaflet of the given medicinal product.*	
	FOOD SUPPLEMENTS		
34	**Guidance on nutrition and health claims** *Point III.1.*	*Remove probiotics and prebiotics from the example of groups of substances with a specific functional health claim*	
	HORIZONTAL		
35	**Dir. 2024/3019 (UWWTD)** *Art. 9 + Art. 10*	*Base impact assessment on transparent and realistic data, and follow the Swiss model for financing through wastewater charges*	
36	**Dir. 2024/3019 (UWWTD)** *Art. 33*	*Extend the transposition timeline until the European Commission publishes an impact assessment*	
37	**Reg. 2025/40 (PPWD)** *Art. 6*	*Include food supplements under exemptions for recyclable packaging as other small packaged products are also benefitting from the same exemption.*	

ANNEX 2

Proposed simplification measures per legislation and justifications

MEDICINES	
Community code for medicinal products for human use	
Directive 2001/83/EC	**Article 74a**
2023/0132(COD)	**Article 55**

Original Text	Proposed Change
Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for ~~**one year**~~ after the initial change was authorised.	Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, **behavioural studies, pharmacy and market research and other types of real world studies**, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for **three years** after the initial change was authorised.

Justification

The current provisions only cover "significant pre-clinical tests or clinical trials," ignoring the value of other types of evidence, e.g. RWD/RWE, that can be material in assessing (and reaching a conclusion on a switch's safety, effectiveness and healthcare contribution. These additions are appropriate for confirming whether any incremental risk of non-prescription use is manageable and the benefit/risk remains positive.

Even in cases where 1 year data exclusivity is granted, this is still not sufficient to truly incentivize switches, since several months lie between marketing authorization approval and launch, meaning less exclusivity time on the market.

Switch is a significant form of innovation in the self-care sector and plays an important role in expanding the range of self-care treatments available. Non-prescription status makes it easier and quicker to access treatments that are effective and safe, empowering people to manage their own health, with or without the support of a health worker. By freeing up health workers' time, away from managing ailments that are appropriately self-diagnosed and self-treated, switches allow health workers to focus on conditions that require the support and exercise of their professional judgment. This efficient use of expert qualified resource, in turn, helps ensure the long-term sustainability of EU healthcare systems.

The consumer healthcare environment is also a highly competitive market, with strong competition from generics and the ability of other companies to quickly enter the market after the originator. This rapid market entry can increase the commercial risk of investing in development and being a first mover, particularly when there is a high level of commercial investment involved in switch applications and market launches

MEDICINES	
Community code for medicinal products for human use	
Directive 2001/83/EC	Article 24 (1-4)

Original Text	Proposed Change
1. Without prejudice to paragraphs 4 ~~and 5~~, a marketing authorisation shall be valid for ~~five years~~.	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal product shall be valid **for an unlimited period.**
~~2. The marketing authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the competent authority of the authorising Member State.~~	**By way of derogation from the first subparagraph, a national marketing authorisation granted in accordance with Article 45(1) shall be valid for five years and be subject to renewal in accordance with paragraph 2.**
~~To this end, the marketing authorisation holder shall provide the national competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including the evaluation of data contained in suspected adverse reactions reports and periodic safety update reports submitted in accordance with Title IX, and information on all variations introduced since the marketing authorisation was granted, at least 9 months before the marketing authorisation ceases to be valid in accordance with paragraph 1.~~	**By way of derogation from the first subparagraph, a competent authority of the Member State may decide at the time of granting the national marketing authorisation, on objectively and duly justified grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.**
~~3. Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the national competent authority decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, to proceed with one additional five-year renewal in accordance with paragraph 2.~~	**2. The marketing authorisation holder may submit an application for a renewal of a national marketing authorisation granted under paragraph 1, second or third subparagraph. Such application shall be submitted at least nine months before the national marketing authorisation ceases to be valid.**
~~4. Any authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the authorising Member State shall cease to be valid.~~	**3. Once the application for a renewal has been submitted within the time limit provided for in paragraph 2, the national marketing authorisation shall remain valid until the competent authority of the Member State adopts a decision.**
	4. The competent authority of the Member State may renew the national marketing authorisation on the basis of a re-evaluation of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.

Justification

In a regulatory control system with stringent Pharmacovigilance and Post-Approval Changes requirements, renewals are an unjustified burdensome / administrative procedure for both regulatory authorities and companies, for limited gains in consumer protection.

These changes are already in effect in the Commission proposal for a General Pharmaceutical Legislation 2023/0132(COD).

MEDICINES	
Community code for medicinal products for human use	
Directive 2001/83/EC	Article 24 (4-6)

Original Text	Proposed Change
~~4. Any authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the authorising Member State shall cease to be valid.~~ ~~5. When an authorised product previously placed on the market in the authorising Member State is no longer actually present on the market for a period of three consecutive years, the authorisation for that product shall cease to be valid.~~ ~~6. The competent authority may, in exceptional circumstances and on public health grounds grant exemptions from paragraphs 4 and 5. Such exemptions must be duly justified.~~	**[DELETE]**

Justification

Sunset clause is no longer needed. It does not bring value to combat shortages according to the Pharmaceutical Committee.

https://health.ec.europa.eu/document/download/f853587e-4b2e-4f12-a706-3d92c94236eb_en

This clause was intended to remove administrative burden of maintaining un-marketed licences however, it has not been seen that the implementation of the Sunset Clause indeed had any impact on removing administrative burden as some further administrative burden linked to Sunset Clause's request, evaluation and implementation has been added.

These changes are already in effect in the Commission proposal for a General Pharmaceutical Legislation 2023/0132(COD).

MEDICINES	
Community code for medicinal products for human use	
Directive 2001/83/EC	Article 59

Original Text	Proposed Change
1. The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order: [...] (f) a reference to the expiry date indicated on the label, with: [...] ~~**(vii) the name and address of the manufacturer;**~~ [...] ~~**(g) "where the medicinal product is authorised in accordance with Articles 28 to 39 under different names in the Member States concerned, a list of the names authorised in each Member State"**~~	1. The **content of the** package leaflet shall be drawn up **in lay language** in accordance with the **content of the** summary of the product characteristics; it shall include, in the following order: [...] (f) a reference to the expiry date indicated on the label, with: [...] (vii) **[DELETE]**; [...] (g) **[DELETE]**;

Justification

The wording of the PIL is still considered too complex. In addition, a lot of PILs include information which cannot be assessed by patients on their own, such as e.g. low blood levels of Kalium. Package leaflets should be written in a clear and understandable way, avoiding HCP-terminology and providing clear guidance for patients what to do, e.g. in case of skin reactions. A patient is likely not able to differentiate on its own whether the kind reaction is SJS, TEN, DRESS or others. So, patients should be clearly advised: if you observe a severe skin reaction after taking x, please immediately see a doctor.

Remove point vii as patients and users are confused as to who to contact in case of issues. This was the feedback from patients, carers and user testing companies.

Remove point G as this is information is of no use for patients and carers and makes the leaflet extremely long.

MEDICINES	
Community code for medicinal products for human use	
Directive 2001/83/EC	Article 10d and 104a

Original Text	Proposed Change
[NEW]	**Article 10d** **By derogation, marketing authorisation holders shall be released from submission of risk management plans for generic products, products with well-established medicinal use and reference products if marketed (regardless of the type of market authorisation procedure) within the Community for at least 10 years (Article 10(1)(a)(ii)), where conditions of recognized efficacy and an acceptable level of safety in terms of the conditions set out in Annex 1 are met.**

Justification

The blanket requirement for RMP for medicinal products with well-established on the market active substance(s) and where there is no existing or new significant safety concerns should be removed; there is no additional pharmacovigilance plan or risk minimization in place beyond the routine ones; and the active substance is not a subjects of Article 23 (1cd) of Regulation (EC) No 726/2004 requirements for additional monitoring.

Moreover, the CMDh HaRP (Harmonization of RMP) project has recently resulted in removing of non-important identified/potential risks from the existing RMPs for many NPM products.

Good Pharmacovigilance Practice (GvP) Module V (V.C.1.1) permits submission of the simplified RMP for generic, hybrid, well established products and fixed combinations with no new substance but further steps are required to eliminate redundancies.

Directive EU 2001/83/EC as amended by Directive 2010/84/EU in Title IX article 104a (1) by derogation from article 104 (3c) does not require to operate a risk management system for each product where the authorization was granted before 21 July 2012 in situations where the benefit/risk of the product remain unchanged. It is not fully clear why a new market authorization of such well-established API would require a risk management plan if no safety concerns are present. In particular, that the CA, by means of the Article 104a (2,3,4), were given rights to impose an obligation on MAH to operate a risk management system for any product if safety concerns are present. RMP should be triggered by a safety reason but not routinely required.

Also, **Article 104a (1)** should be amended to lift the obligation for submission of risk management system description for generic products, well-established medicinal use products and reference products (regardless of the type of market authorisation procedure).

MEDICINES	
Community code for medicinal products for human use	
Directive 2001/83/EC	Article 107b

Original Text	Proposed Change
3. By way of derogation from paragraph 1 of this Article, the holders of marketing authorisations for medicinal products referred to in Article 10(1), or Article 10a, and the holders of registrations for medicinal products referred to in Articles 14 or 16a, shall submit periodic safety update reports for such medicinal products in the following cases: (a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Article 21a or Article 22; or (b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted. The assessment reports of the requested periodic safety update reports shall be communicated to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment report for all marketing authorisations for medicinal products containing the same active substance and inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Article 107c(4) and Article 107e.	3. By way of derogation from paragraph 1 of this Article, the holders of marketing authorisations for medicinal products referred to in Article 10(1), or Article 10a, and the holders of registrations for medicinal products referred to in Articles 14 or 16a, **and all products containing APIs with more than 10 years on the market and sufficient pharmacovigilance data,** shall **not** submit periodic safety update reports for such medicinal products **except** in the following cases: (a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Article 21a or Article 22; or (b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted. The assessment reports of the requested periodic safety update reports shall be communicated to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment report for all marketing authorisations for medicinal products containing the same active substance and inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Article 107c(4) and Article 107e. **The EURD list should be updated accordingly**

Justification

The request to continue requesting PSURs for medicinal products where the active substance(s) has been marketed in the EC beyond 10 years and where there is no existing or new significant safety concerns serves no scientific purposes but adds a significant work constraints to authorities and companies; there is no additional pharmacovigilance plan or risk minimization in place beyond the routine ones; and the active substance is not a subjects of Article 23 (1c,d) of Regulation (EC) No 726/2004 requirements for additional monitoring. The EURD list needs to be update accordingly.

There are requirements concerning MAH responsibilities laid out in Article 104 (3c,e), to operate a risk management system for each medical product, update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit risk. Therefore, there are other mechanisms to monitor and if needed to communicate and implement risk mitigation.

The EMA is in charge of maintaining the EURD list, which is a living document. Any changes to the list, following a request for amendment, are approved, or denied by the CHMP and the CMDh following consultation with the PRAC. The CHMP and the CMDh in consultation with the PRAC and CAs in case of NAPs should be able to waive the requirement for submission of a PSUR. The article 107b (3) should be amended to allow such flexibility

MEDICINES	
Regulation laying down Union procedures for authorisation and supervision of medicinal products for human use and establishing EMA	
Regulation (EC) No 726/2004 (amended)	**Article 57**

Original Text	Proposed Change
1. The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use or veterinary medicinal products which is referred to it in accordance with the Union legislation relating to medicinal products for human use or veterinary medicinal products.	1. The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use or veterinary medicinal products which is referred to it in accordance with the Union legislation relating to medicinal products for human use or veterinary medicinal products. **The Agency shall also provide scientific advice and scientific and technical support for the Union's legislation and policies in all fields which have a direct or indirect impact on of medicinal products for human use or veterinary medicinal products.**
To that end, the Agency, acting particularly through its committees, shall carry out the following tasks:	To that end, the Agency, acting particularly through its committees, shall carry out the following tasks: **(aa) providing the Union institutions and the Member States with the best possible scientific opinions in all cases provided for by Union legislation and on any question within its mission stated in the first paragraph of this article;** **(ab) promoting and coordinating the development of uniform risk assessment methodologies in the fields falling within its mission stated in the first paragraph of this article;** **(ac) providing scientific and technical support to the Commission in the areas within its mission stated in the first paragraph of this article, and, when so requested, in the interpretation and consideration of risk assessment opinions;**
(a) coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products for human use and of veterinary medicinal products which are subject to Union marketing authoris ation procedures; (...)	(a) coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products for human use and of veterinary medicinal products which are subject to Union marketing authoris ation procedures; (...)

Justification

To give enlarged mission and tasks to the EMA to be seized for scientific advice on any topic which impacts medicinal products including what comes from other regulatory fields and regulatory agencies such as EFSA or ECHA.

MEDICINES	
Regulation concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use	
Regulation (EC) No 1234/2008 (amended)	**Article 8 (1)**

Original Text	Proposed Change
1. Where a minor variation of type IA is made, the holder shall submit simultaneously to all relevant authorities a notification containing the elements listed in Annex IV. ~~**That**~~ notification shall be submitted within 12 months following the implementation of the variation ~~**as an annual update for all minor variations of type IA or be submitted as part of grouping of variations in accordance with Article 7(2), first subparagraph, points (b) and (c), or as part of super-grouping of variations in accordance with Article 7a**~~	1. Where a minor variation of type IA is made, the holder shall submit simultaneously to all relevant authorities a notification containing the elements listed in Annex IV. **This** notification shall be submitted within 12 months following the implementation of the variation. **However, the notification shall be submitted immediately after the implementation of the variation in the case of minor variations requiring immediate notification for the continuous supervision of the medicinal product concerned.**

Justification

The newly introduced annual update makes the reliance of 3rd countries more difficult with EU MAs; the benefit of this measure is unclear, but it is more resources intensive.

MEDICINES	
Regulation concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use	
Regulation (EC) No 1234/2008 (amended)	**Article 20**

Original Text	Proposed Change
By way of derogation from Articles 7(1) and Articles 9, 10, 13b, 13c, 13d, 15 and 16 the holder ~~**shall**~~ follow the worksharing procedure laid down in paragraphs 3 to 9 of this Article in the following cases:	1. By way of derogation from Articles 7(1), 9, 10, 13b, 13c, 13d, 15 and 16 the holder **of a marketing authorisation** ~~shall~~ **may choose to** follow the worksharing procedure laid down in paragraphs 3 to 9 in the following cases:
Justification Worksharing should not entail including variations which have already been assessed and cases where the variation consists in implementing a wording which has already been assessed and harmonised (e.g., PRAC recommendation).	

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 51 (e)**

Original Text	Proposed Change
1. A medicinal product shall be subject to medical prescription where it: [...] (e) is an ~~**antimicrobial; or**~~	1. A medicinal product shall be subject to medical prescription where it: [...] (e) is an **antibiotic with an identified antimicrobial resistance risk.**

Justification

The risk of antimicrobial resistance is already part of the first prescription criteria (as indirect danger) and companies already assess the risk of antimicrobial resistance when considering changing legal status from prescription to non-prescription (switch).

A few antivirals and antifungals are available without prescription in well-defined conditions when speed of treatment is key to avoid aggravation (e.g., athletes' foot, labial herpes, dandruff, sore throat and vaginal thrush). Antivirals and antifungals containing non-prescription medicines are usually available at a lower dosage than their prescription (Rx) equivalent or for shorter time treatments. These products have less units per packaging and treatment is stopped if not exerting a positive effect within a short time frame.

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 51 (f)**

Original Text	Proposed Change
1. A medicinal product shall be subject to medical prescription where it: [...] ~~**(f) contains an active substance which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.**~~	1. A medicinal product shall be subject to medical prescription where it: [...] (f) **[DELETE]**

Justification

Parameters such as PBT or PMT are hazard-based classifications, which do not necessarily indicate an environmental risk. Since a risk assessment is required by law for all new APIs, the risk can be determined through the established environmental testing and assessment procedures. Therefore, automatic restrictions for compounds with PBT/vPvB or PMT/vPvM are not in line with the environmental risk assessment goals.

Should an environmental risk be assessed and identified that requires risk mitigation, the medical prescription is not appropriate to mitigate such an environmental risk, because the individual assessment would be out of the qualifications scope of the healthcare professional who prescribes. The prescription status of medicines containing an active substance which is PBT, vPvB, PMT, vPvM, is, therefore, not an appropriate risk mitigation measure to reduce the environmental exposure.

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 13**

Original Text	Proposed Change
Applications based on bibliographic data In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature.	Applications based on bibliographic data In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned **or in case of herbal medicinal products**, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature.

Justification

Simplification in this case means avoiding complexity for the specific case of herbal medicinal products for which generic applications are technically not feasible and hence would impose a competitive disadvantage. When looking at the specific case of herbal medicinal products, well-established medicinal use is a fundamental legal basis in addition to full applications and traditional use. Figures from the MRI Product Index show that more than half of European procedures for herbal medicinal products are WEU applications of which more than 85 % conform to HMPC (EMA) monographs.

There are, in principle, no generic products for herbal medicinal products. This is because the API (herbal preparation) is characterized not only by its specification and fingerprint but also by the manufacturing process. The extracted components can vary significantly depending on factors in manufacturing such as the solvent used, the Drug Extract Ratio (DER), the extraction temperature, pressure and time, the extraction method, the purification steps, just to name a few. The extract as a whole acts as the Active Pharmaceutical Ingredient (API) with documented efficacy and safety as reported in the bibliographic data.

Bioequivalence studies are technically not feasible for herbal medicines. This difficulty arises because herbal preparations, such as extracts, contain many different components. Additionally, the key constituents in standardized or quantified extracts are usually present in very low amounts, close to the detection limit. This makes it mostly impossible to measure their pharmacokinetics, thus rendering bioequivalence studies impossible.

The request for bioequivalence studies would decrease competitiveness.

For herbal medicinal products, the authorities' concern about the resources required for the evaluation of the bibliographic applications is already addressed and resolved. Applying well-established medicinal use applications or herbal medicinal products will reduce red tape because when done according to the WEU HMPC monographs no further resource is needed. This is because scientific evaluation and assessment were completed during the creation of the WEU monograph by the Herbal Medicinal Product Committee and its adoption by the 27 Member States.

The harmonisation exercise achieved across the EU and the efficiency gains from this completed scientific work should be leveraged.

The publicly available HMPC (EMA) monographs capture and document the well-established medicinal use and provide already a harmonized SmPC based on the review and assessment of the EMA HMPC experts. These monographs crystallise the scientific state of knowledge and are used by both companies and authorities. Applicants must justify the relevance of the specific WEU monograph for their application at the time of the submission, already in line with the additional parliament proposal for Art. 13 for justification of relevance of the literature.

Thus, the Applications based on bibliographic data for herbal medicinal products in the EU are a fit-for-purpose and regulatory simplified and harmonized way for market access. They have proven to work with efficient resources use by National Competent Authorities in EU procedures for the last years thus reducing red tape. Consequently, Applications based on bibliographic data (Art.13) should be explicitly allowed in case of herbal medicinal products.

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 21**

Original Text	Proposed Change
The applicant of a marketing authorisation for a medicinal product referred to in Articles 9 ~~and~~ 11 shall not be required to submit a risk management plan and a summary thereof, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.	1. The applicant of a marketing authorisation for a medicinal product referred to in Articles 9, 11 **and 13** shall not be required to submit a risk management plan and a summary thereof, provided that no additional risk minimisation measures exist for the reference medicinal product. 2. **Paragraph 1 applies to medicinal products referred to in Article 9 and 11 provided that no additional risk minimisation measures exist for the reference medicinal product** and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.

Justification

Developing an RMP for medicinal products with well-established active substance(s) and no significant safety concerns, particularly for MAHs of non-prescription medicines, is an unnecessary burden, especially when no additional pharmacovigilance plan or risk minimization measures are required beyond routine ones.

Even in the absence of a reference product, the safety profile of medicinal products of well-established use are monitored in a risk-proportionate basis through the PSUR process.

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 22**

Original Text	Proposed Change
4. The ERA for ~~**antimicrobials**~~ shall include an evaluation of the risk for ~~**antimicrobial**~~ resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal of the ~~**antimicrobial**~~ taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	4. The ERA for **antibiotics** shall include an evaluation of the risk for **antibiotic** resistance selection in the environment due to the manufacturing of the active substance or medicinal product within the European Union, use and disposal of the **antibiotic** taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.
Justification There is no overall methodology to derive PNECs for resistance for ALL antimicrobials. Hence, an evaluation is not possible.	

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 23**

Original Text	Proposed Change
1. By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, ~~**after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA)**~~, establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified ~~**as potentially harmful to the environment**~~ in accordance with paragraph 2 This programme shall be made publicly available by the Agency.	1.By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified **to potentially cause a risk to the environment by risk-based prioritisation** in accordance with paragraph 2. This programme shall be made publicly available by the Agency.
2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially ~~**harmful**~~ to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information. [...]	2. The Agency shall set the scientific criteria for the identification of the medicinal products that potentially **cause risk** to the environment and for the prioritisation of their ERA, using a risk-based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information. [...]
4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals.	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals, **specifically to avoid unnecessary testing of vertebrate species and to follow the 3Rs rule.**

Justification

For medicinal products authorised prior to October 2005, the assessment should be risk-based prioritized, with a focus on pharmaceuticals which are the most likely to present a risk to the environment.

The IMI iPiE and PREMIER projects are developing a prioritisation framework to help identify APIs contained in medicinal products authorised before 2006 that are most likely to present a risk to the environment.

MEDICINES	
Proposal for a DIRECTIVE on the Union code relating to medicinal products for human use	
2023/0132(COD)	**Article 24**

Original Text	Proposed Change
2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2.The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances **and relevant data requirements, particularly considering vertebrate studies.**

Justification

The data requirements of active substances should also permit some prioritisation to allow for prioritisation of data generation based on risk. For example, where risk is demonstrably insignificant with existing or new non-vertebrate data, in vivo vertebrate data may not be required.

MEDICINES	
Guidelines on the details of the various categories of variations	
Guideline 2013/C 223/01	**ANNEX** A – Administrative Changes **Variations A.4 and A.5**

Original Text	Proposed Change
A.4 [NEW NOTE]	**A.4** **Note: Once the Article 57 database is functional, changes, including contact details (telephone and fax numbers, postal address and e-mail address) may be updated through the PMS database only (without the need for a variation). Where the MAH makes use of the possibility to update this information through the PMS database, the MAH must indicate in the marketing authorisation that the updated information of those particulars is included in the database.**
A.5 [NEW NOTE]	**A.5** **Note: Once the Article 57 database is functional, changes, including contact details (telephone and fax numbers, postal address and e-mail address) may be updated through the PMS database only (without the need for a variation). Where the MAH makes use of the possibility to update this information through the PMS database, the MAH must indicate in the marketing authorisation that the updated information of those particulars is included in the database.**

Justification

The principle of automation and leveraging the OMS/PMS database should be enshrined in the variation framework as it would allow a huge gain of resources. The successful precedence created by article 57 database for PSMF location and QPPV contact details change in the current system, already applied for Variations C.I.8 and C.I.9, should be extended to other pure administrative changes like in variations A4 and A5 having no impact on quality, efficacy and safety.

The variation guideline should provide the option to use the SPOR database, and this should be reflected with an asterisk and the Footnote.

MEDICINES	
EMA guideline on environmental risk assessment of medicinal products	
EMEA/CHMP/SWP/4447/00 Rev. 1- Corr.	**General**

Recommendations

- Reduce the reliance on vertebrate testing in the ERA by actively recommending the use of validated non-vertebrate approaches.
- Implement and have EMA manage and maintain the database that is being developed under IHI Premier to ensure elimination of duplication of studies.
- Update of the ERA guidance to incorporate acknowledgement of the special situation for extension of well established actives present in the EU to tailor requirements for submission.

Justification

The previous version guidance was supported by a Q&A document that specifically addressed special considerations for generics primarily covering well-established actives, generics/ hybrid applications. This guidance was broadly applicable to non-prescription medicinal products and essentially acknowledged that a full Environmental Risk Assessment (ERA) was not required when environmental exposure was not expected to significantly increase. In the recent update of the guidance and the responses to the public consultation, the EMA acknowledged that "the special situation for generics is recognized; however, this is a legal restriction related to the current version of Directive 2001/83, which cannot be resolved through guideline revision." Historically, authorities have adhered to this guidance and the accompanying Q&A.

The recent updates to the guidance will necessitate significant investment for new submissions with the same APIs already on the market and may inadvertently hinder innovation in the sector disproportionately. Additionally, there are ongoing initiatives within the EU aimed at addressing pharmaceuticals in the environment, such as the 'PREMIER' project. In light of these considerations, we propose that a Q&A to clarify the guidance in the special case of generics is issued and/or a direct update to the guidance is expedited to better align with the realities of the market and to foster innovation while ensuring environmental safety.

The 2024 ERA guidance introduces requirements that will significantly increase the number of vertebrates required to complete a large number of ERA assessments. The guidance currently only allows the use of vertebrate studies to meet the data requirements for bioaccumulation (for PBT and/or secondary poisoning assessments). Alternative methodologies (e.g. OECD 321) have now been validated and harmonised by OECD, accepted within other regulatory frameworks and generate the required data faster, cheaper and without the use of vertebrates.

MEDICINES	
Guideline on the acceptability of names for human medicinal products processed through the centralised procedure	
EMA/CHMP/287710/2014 - Rev. 7	**Points 4.1.5 and 4.1.11**

Original Text	Proposed Change
~~4.1.5. The invented name of a medicinal product should not include the full invented name of another medicinal product. Exceptions may apply on a case-by-case basis depending on the potential for confusion and the level of similarity identified.~~ [...] ~~4.1.11 As a general principle, the inclusion of a common umbrella segment (e.g. part of the name of the sponsor) within the invented names of different medicinal products is not acceptable as it creates a link which may lead to confusion and medication errors (see section 4.1.5). Other forms of umbrella branding, such as those related to the composition of active substances, may be accepted on a case-by-case basis.~~	**[DELETE]**

Justification:

A common umbrella segment may be authorised provided a risk assessment has taken place. This is routinely the case in companies before the proposal of a brand name.

In addition, the brand name needs to be considered together with the packaging dress; the latter is an important component to help differentiate between products.

MEDICINES	
EMA Questions & answers on Article 31 pharmacovigilance referral procedures	
EMA/33617/2014 - Rev.3	**Point 38**

Original Text	Proposed Change
The marketing authorisation holder(s) (MAHs) of medicinal products authorised nationally (including via the mutual recognition or decentralised procedures) will have to provide translations in all EU languages (including Icelandic and Norwegian, if applicable) of the following annexes to the Committee for Medicinal Products for Human Use (CHMP) opinion or Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) position: • listing of nationally authorised products (including via mutual recognition/decentralised procedures) concerned by the procedure; • wording to be included in the relevant sections of the summary of product characteristics, labelling and/or package leaflet, if applicable. Only one translation per EU language is required, therefore the MAHs actively involved in the procedure will be presented with a proposal for worksharing for the translation process. Not all MAHs may be involved in the translation process. MAHs that have not been contacted to participate in the worksharing process will be provided the set of translations at a later stage. The Agency will contact the MAHs as early as possible to ensure the smooth running of the worksharing process. The translations will have to be provided to ~~**the Member States**~~ contact points for linguistic check by Day +5 (i.e. 5 days after adoption of the opinion or the position) and copied to the Agency. Member States may send linguistic comments until Day +19. [...]	The marketing authorisation holder(s) (MAHs) of medicinal products authorised nationally (including via the mutual recognition or decentralised procedures) will have to provide translations in all EU languages (including Icelandic and Norwegian, if applicable) **where the product is authorised** of the following annexes to the Committee for Medicinal Products for Human Use (CHMP) opinion or Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) position: • listing of nationally authorised products (including via mutual recognition/decentralised procedures) concerned by the procedure; • wording to be included in the relevant sections of the summary of product characteristics, labelling and/or package leaflet, if applicable. Only one translation per EU language **of the countries where the product is authorised** is required, therefore the MAHs actively involved in the procedure will be presented with a proposal for worksharing for the translation process. Not all MAHs may be involved in the translation process. MAHs that have not been contacted to participate in the worksharing process will be provided the set of translations at a later stage. The Agency will contact the MAHs as early as possible to ensure the smooth running of the worksharing process. The translations will have to be provided to contact points **of those Member States which have authorised the product** for linguistic check by Day +5 (i.e. 5 days after adoption of the opinion or the position) and copied to the Agency. Member States may send linguistic comments until Day +19. [...]

Justification:

To ensure adequate use of resources only those Member States that have authorised the product should be in scope of the translations of the annexes.

MEDICINES	
Guideline on good pharmacovigilance practices (GVP) Module XV – Safety communication (Rev 1)	
EMA/118465/2012 Rev 1	**Point XV.B.5.1.**

Recommendations
• Regarding Direct Healthcare Professional Communication (DHPC) the text mentions competent authorities without differentiating between those that have authorised the product at play and the others. • The guideline text should make clear that DHCP should be translated and communicated only in Member States that have authorised the medicinal products.
Justification: To ensure adequate use of resources only those Member States that have authorised the product should be in scope of the translation and dissemination of the DHPC.

MEDICAL DEVICES	
Regulation on medical devices	
Regulation (EU) 2017/745	Article 1 (8)

Original Text	Proposed Change
8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has a**n** ~~**action**~~ ancillary ~~**to that of the device**~~, shall be assessed and authorised in accordance with this Regulation.	8. Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has a **clinically relevant** ancillary **action in order to achieve the intended medical** shall be assessed and authorised in accordance with this Regulation.

Justification

Article 1(8) subparagraph 2 MDR stipulates that the overall product should be a medicinal product if the integral component has a main action and not just an ancillary action. It is clear from this that the ancillary action must contribute to the fulfilment of the medical intended purpose and no other (e.g. conservative) action is meant.

MEDICAL DEVICES	
Regulation on medical devices	
Regulation (EU) 2017/745	Annex VIII – 7.1. Rule 14

Original Text	Proposed Change
All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has ~~**an action**~~ ancillary ~~**to that of the devices**~~, are classified as class III."	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that **has a clinically relevant** ancillary **action in order to achieve the intended medical purpose**, are classified as class III."

Justification

According to Recital (59) of the MDR, the objective of the regulation is to obtain a suitable risk-based classification of devices. This should also be the case for products falling under Rule 14. The classification rule should take into account if the medicinal substance has an impact on the intended purpose of the device. If this is not the case, then it is not justifiable to classify those products under the highest risk class.

Many substance-based medical devices and dental medical devices (i.e. dental filling materials) contain substances which, if used separately, can be considered to be medicinal products and that have an action ancillary to that of the devices, but which are not clinically relevant to the fulfilment of the intended medical purpose. However, these products are currently sometimes 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 both manufacturers and Notified Bodies and is in no way justified or intended for relatively low-risk devices.

Rule 14 applies to medical devices that are given an action ancillary in the fulfilment of the medical intended purpose by a contained substance which, if used separately, can be considered to be a medicinal product.

MEDICAL DEVICES	
Regulation on medical devices	
Regulation (EU) 2017/745	Article 56 (2)

Original Text	Proposed Change
The certificates shall be valid for the ~~**period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures**~~. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.	The certificates shall be valid for the **lifetime of the device, subject to the manufacturer's post-market surveillance system supporting the quality, safety and performance over the lifetime of the device in accordance with Chapter VII, Section 1 and Part B of Annex XIV**. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

Justification:

Certificates issued as part of certification according to the MDR or IVDR should have an indefinite validity. Manufacturers' quality management systems are regularly monitored and audited. Furthermore, the MDR and IVDR require the creation and regular updating of reports and documents (PMS report, PSUR, SSCP, CER, QMS, RMS, trend report, vigilance reports, etc.), which are also regularly reviewed as part of the lifecycle approach. Substantial changes to medical devices and in vitro diagnostics are evaluated when the technical documentation is updated. This ensures continuous monitoring of manufacturers by Notified Bodies.

Continuous validity of the certificates, provided the manufacturer fulfils the requirements specified in MDR and IVDR, can avoid gaps in supply in the event that the new certificate cannot be issued in time before its validity date expires through no fault of the manufacturer. A complete recertification of all processes and documents every five years, in addition to the mentioned measures and reviews, does not provide added value in terms of ensuring or increasing patient safety and product quality but leads to unnecessary and avoidable personnel and financial burdens.

MEDICAL DEVICES	
Regulation on medical devices	
Regulation (EU) 2017/745	Article 86 (1)

Original Text	Proposed Change
1. [...] Manufacturers of class IIb and class III devices shall update the PSUR at least ~~annually~~. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. Manufacturers of class IIa devices shall update the PSUR when necessary and at least every ~~two~~ years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.	1. [...] Manufacturers of class IIb and class III devices shall update the PSUR **in case of significant changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update**, at least **every two years**. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. Manufacturers of class IIa devices shall update the PSUR when necessary and at least every **four** years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. **Manufacturers of devices that have had no serious incident in the last year shall update the PSUR when necessary and at least every five years.** For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

Justification:

Updating PSURs without an apparent need, such as significant changes or serious incidents or a significant increase in known adverse reactions, does not increase the safety of the products. On the contrary, too many resources are tied up and these are then lacking in key areas.

These changes would lead to considerable time and unnecessary costs savings for both manufacturers and Notified Bodies. These costs ultimately have to be covered by the healthcare system without adding to patient safety.

The proposed paragraph would address long established existing products.

MEDICAL DEVICES	
Regulation on medical devices	
Regulation (EU) 2017/745	Article 61 (11)

Original Text	Proposed Change
11 The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84. For class III devices and implantable devices, the PMCF evaluation report and~~, if indicated, the summary of safety and clinical performance referred to in Article 32~~ shall be updated at least annually with such data.	11 The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84. For class III devices and implantable devices, the PMCF evaluation report and shall be updated at least annually with such data. **The summary of safety and clinical performance referred to in Article 32 shall be updated with data if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete**.

Justification

For class III devices, the SSCP must be updated at least annually, even for long established existing products or when no substantial changes have occurred. This leads to considerable time and unnecessary costs incurred for both manufacturers and Notified Bodies. These costs ultimately have to be covered by the healthcare system without adding to patient safety.

In addition, the scope of devices for which an SSCP is considered relevant by the MDCG in MDCG 2019-9 is overly broad as there is no evidence that an SSCP actually benefits or even reaches patients. If there are issues with the devices concerned that patients must know about this can be better achieved through other channels than Eudamed.

The notified body is needed for any interaction with Eudamed for SSCPs but this creates administrative costs and delays – the manufacturer should be able to upload documents himself that are validated in Eudamed by the notified body if needed.

MEDICAL DEVICES	
Regulation on medical devices	
Regulation (EU) 2017/745	Annex VIII – 7.6. Rule 19

Original Text	Proposed Change
All devices incorporating or consisting of nanomaterial are classified as: — class ~~III~~ if they present a high or medium potential for internal exposure; — class ~~IIb~~ if they present a low potential for internal exposure; and — class ~~IIa~~ if they present a negligible potential for internal exposure.”	All devices incorporating or consisting of nanomaterial are classified as: — class **IIb** if they present a high or medium potential for internal exposure; — class **IIa** if they present a low potential for internal exposure; and — class **I** if they present a negligible potential for internal exposure.”

Justification

The European Parliament had already reduced the up-classification to Class III only when the use of nanomaterials is intentional and part of the intended use of the product (amendments 2 and 304).

In its justification, the Parliament stated that “many medical devices contain nanomaterials, but do not pose any danger to the patient.” The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Some of these products have been distributed without incidents for years.

MEDICAL DEVICES	
Rules for electronic instructions for use of medical devices	
Regulation (EU) 2021/2226	**Recital (4) and Article 3 (2)**

Original Text	Proposed Change
[Recital] **(4)** In order to reduce potential risks as far as ~~**possible**~~, the appropriateness of the provision of instructions for use in electronic form instead of in paper form should be subject to a specific risk assessment by the manufacturer.	**[Recital]** **(4)** In order to reduce potential risks as far as **reasonably practicable**, the appropriateness of the provision of instructions for use in electronic form instead of in paper form should be subject to a specific risk assessment by the manufacturer.
[Article] (2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions: (a) they are intended for exclusive use by professional users,	**[Article]** (2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions: (a) they are intended for exclusive use by professional users, **patients or other appropriate user groups**. [...] **(c) eIFUs shall be designed to match the skills and needs of the intended user group, including patients and lay users.** **(d) A printed version shall be made available upon request, free of charge and without delay.**

Justification

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 regulation and align it with the EU's Digital Health Strategy and Green Deal objectives.

Furthermore, the phrase "as far as possible" in Recital (3) enforces an unrealistic zero-risk philosophy. Replacing it with "as far as reasonably practicable" (ALARP) introduces proportionality, reflects ISO 14971, and ensures that risk reduction remains balanced with usability and innovation.

Opening the eIFU framework to patients improves accessibility, reduces packaging waste, supports multilingual information management, and lowers production costs—without compromising safety, provided user-appropriate design is ensured.

MEDICAL DEVICES	
Guidance on borderline between medical devices and medicinal products	
MDCG 2022 – 5 Rev. 1	Point 1.2.2.

Original Text	Proposed Change
"Pharmacological means" is understood as an interaction ~~typically at a molecular level between a substance or its metabolites and a constituent of the human body which results in initiation, enhancement, reduction or blockade of physiological functions or pathological processes. Examples of constituents of the human body may include, among others: cells and their constituents (cell membranes, intracellular structures, RNA, DNA, proteins, e.g. membrane proteins, enzymes), components of extracellular matrix, components of blood and components of body fluids. Examples of action via pharmacological means: • interaction between a ligand (e.g. agonist, antagonist) and a receptor; • interaction between a substance and membrane lipids; • interaction between a substance and components of the cytoskeleton.~~	"Pharmacological means" is understood as an interaction **between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.** **[Restoring previous definition under MEDDEV 2.1/3-Rev.3]**

Justification

The revision introduced in MDCG 2022-5 should be seen as an opportunity for simplification. By reverting to a clearer, narrower definition of "pharmacological means"—as previously outlined in MEDDEV 2.1/3 Rev.3—the EU can reduce legal uncertainty, avoid overlapping interpretations, and support a more innovation-friendly internal market. Simplification in this context means ensuring that legal definitions are precise, consistently interpreted across Member States, and do not inadvertently broaden regulatory scope.

The amendment to the definition from MEDDEV 2.1/3 Rev.3 to MDCG 2022-5 of "pharmacological means" has replaced "direct response" with "change in physiological or pathological characteristics," which could lead to the classification of nearly any substance as a medicinal product.

This change is problematic, especially for natural substances, which interact with the body through a combined action of all their constituents rather than a direct interaction with a specific biological target.

The definition in MDCG 2022-5 could create uncertainty for companies regarding whether their products should be classified as medicinal products or medical devices, increasing the number of products regulated as medicinal. This approach conflicts with several EU legal principles.

While not legally binding, the MDCG guidelines are commonly used by regulators and national courts as a reference for implementation. This practice can create uncertainty and potential obstacles in the post-market phase. Divergent interpretations by national authorities may result in regulatory fragmentation and undermine the free movement of goods within the EU. Therefore, adopting our proposed change would enhance harmonisation within the EU internal market, providing greater clarity and certainty for both producers and competent authorities.

MEDICAL DEVICES	
Guidance on borderline between medical devices and medicinal products	
MDCG 2022 – 5 Rev. 1	**Point 2.**

Original Text	Proposed Change
[Chapter 2. Herbal Products]	**[DELETE]**

Justification:

A simplified and legally sound approach to product classification must rely on clear, case-by-case scientific assessments, rather than on generalised presumptions.

The regulatory classification of a product should be based on its primary intended action and principal mode of action, evaluated on a case-by-case basis using up-to-date scientific evidence. EU case law consistently supports this individualized assessment approach for borderline products, considering all relevant characteristics such as composition, intended use, and dosage.

However, MDCG 2022-5 appears to disregard these principles. The guideline lists numerous products as medicinal without providing clear justification—often omitting critical details like composition, dosage, and mechanism of action, and instead relying on traditional associations with certain substances.

This issue is particularly problematic for products containing herbal substances. Chapter 2 of the guideline lists plants presumed to be medicinal by function, regardless of dosage, usage, or mechanism of action, and based solely on their traditional medicinal use in some Member States. This contradicts the key regulatory distinction between medical devices and medicinal products, which is based on the demonstrated mechanism of action.

This creates a conceptual inconsistency: while regulatory classification should depend on a product's mechanism of action, the guidance assumes medicinal status without requiring its demonstration. The guidance risks introducing a presumption system that undermines the legal obligation for case-by-case assessment. Instead, any examples provided should include a sound scientific and regulatory rationale aligned with current standards.

A simplification exercise would involve removing such blanket assumptions and returning to a system based on individual evaluation supported by scientific evidence. This would streamline regulatory decision-making, reinforce consistency with EU case law, and make the framework more predictable and transparent for both regulators and businesses.

MEDICAL DEVICES	
Guidance on standard fees	
MDCG 2023-2	**List of Standard Fees**

Original Text	Proposed Change
List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body XXXX (NB No) […] Administrative charges […] • ~~**Annual certificate maintenance fee (provide details which activities covered)**~~	List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body XXXX (NB No) […] Administrative charges […] **[DELETE ROW]**

Justification

MDCG 2023-2 includes a list of standard fees for "conformity assessment activities".

It is not justifiable why notified bodies are able to charge an (internal) annual "maintenance fee" that is not part of conformity assessment activities rendered to a manufacturer. It is completely unclear and not explained (contrary to what it says in the guidance) what particular "activity" would justify another annual fee for "maintenance".

As part of the surveillance obligations, notified bodies conduct audits on at least an annual basis. These activities are already subject to fees charged, as well as any other service in relation to the conformity assessment activities (e.g. changes, issuance of certificate etc.)

It is not plausible at all that a company should pay continuously for the use of a certificate when the one-off service– i.e. the issuing of the certificate – has long since taken place and has already been paid for.

MDCG 2023-2 in regard an annual maintenance fee goes beyond MDR and needs to be eliminated.

MEDICAL DEVICES	
Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices	
EMA/37991/2019 Rev.5	**Point 3.2.1.**

Original Text	Proposed Change
3.2.1 If co-packaged medical devices class I and class IIa, are supplied without an individual packaging and it is not technically feasible to implement the labelling requirements on the device itself, what alternative solutions could be considered to display the labelling requirements? […] **[NEW]**	3.2.1 If co-packaged medical devices class I and class IIa, are supplied without an individual packaging and it is not technically feasible to implement the labelling requirements on the device itself, what alternative solutions could be considered to display the labelling requirements? […] **D. The co-packed medical device's information may be provided within the section 6 of the Product Information Leaflet of the given medicinal product.**

Justification

The current solutions are not sufficient and technically complex when it comes to adding an extra label. To approach the inclusion of the co-packed medical device's information particulars in an environmentally sustainable, practical, and pragmatic way, it should be made possible to include the information within the relevant section of the PIL.

FOOD SUPPLEMENTS	
Guidance on nutrition and health claims made on foods **Conclusions of the standing committee on the food chain and animal health**	
14 December 2007	**Point III.1.**

Original Text	Proposed Change
III.1. Nutrition claims / health claims [...] The following examples aim at better explaining the difference between the two categories of claims using the term "contains": • A claim is a nutrition claim if in the naming of the substance or category of substances, there is only factual information; Examples: “contains lycopene” ; “contains lutein” • A claim is a health claim if in the naming of the substance or category of substances, there is a description or indication of a functionality or an implied effect on health, Examples: “contains antioxidants” (the function is an antioxidant effect); “contains probiotics/prebiotics” (the reference to probiotic/prebiotic implies a health benefit); • Equally, claims which refer to an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a health claim. ~~**Examples: “with prebiotic fibres” or “contains prebiotic fibres”;**~~ [...]	III.1. Nutrition claims / health claims [...] The following examples aim at better explaining the difference between the two categories of claims using the term "contains": • A claim is a nutrition claim if in the naming of the substance or category of substances, there is only factual information; Examples: “contains lycopene” ; “contains lutein” • A claim is a health claim if in the naming of the substance or category of substances, there is a description or indication of a functionality or an implied effect on health, Examples: “contains antioxidants” (the function is an antioxidant effect); “contains probiotics/prebiotics” (the reference to probiotic/prebiotic implies a health benefit); • Equally, claims which refer to an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a health claim. [...]

Justification

Lack of Specificity: The terms "probiotic" and "prebiotics" encompass a broad category of microorganisms, each with different effects.

In particular, the term probiotics does not imply a specific health claim. the definition from FAO/WHO define Probiotic as "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.", in the same understanding a Vitamin or a Mineral confers multiple benefits to the consumer, moreover those definitions are not considered a group of substance that imply a specific functional effect. Per the Regulation, it is possible to claim that a given product contains a nutrient, like a vitamin or mineral, without being considered a health claim. Overall, the current position of the Commission has led to fragmentation between Members States taking into account that several Member States disagree that probiotics or prebiotics claims should be viewed as health claims.

HORIZONTAL	
Urban Wastewater Treatment Directive	
Directive (EU) 2024/3019	**Articles 9 and 10**

Recommendations
• Pause application of Article 9 and 10 until a new impact assessment is conducted to address the shortcomings and the science gaps • Run a new impact assessment by the EU Commission based on transparent and realistic data that takes into account all sources of micro-pollutants and trace substances. Evaluate the actual costs of upgrading and operating treatment plants with quaternary treatment as well as the bureaucratic burden of setting up PROs and management systems. • Re-equate the political options of applying EPR and consider legislative measures already successfully implemented and less bureaucratic such as the Swiss model (financing through consumer wastewater temporary supplementary charges)

Justification

The EPR requirements of the UWWTD lead to massive bureaucratic burdens for authorities, governments, and industry. For several thousand substances, individual and legally compliant contributions must be determined based on the annual sales volume and the substance-specific ecotoxicity. The whole system is impractical and jeopardizes security of supply.

The EPR system should not be implemented and should be replaced by the efficient, cost-effective, and successfully implemented model used in Switzerland.

HORIZONTAL	
Urban Wastewater Treatment Directive	
Directive (EU) 2024/3019	Article 33

Original Text	Proposed Change
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2 to 11 and 14 to 26 and Annexes I, III, V and VI by ~~**31 July 2027.**~~ They shall immediately communicate the text of those measures to the Commission.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2 to 11 and 14 to 26 and Annexes I, III, V and VI by **[OP please insert = 2 years after the publication of new Impact Assessment]** . They shall immediately communicate the text of those measures to the Commission.

Justification

Based on the current uncertainty concerning the actual financial impact on the industries in scope (pharmaceuticals and cosmetics) and the significant bureaucratic burden for affected enterprises, the transposition period in the Member States should be prolonged until the EC has published a comprehensive impact assessment of the Extended Producer Responsibility.

An appropriate time span would be 2 years, moving the transposition deadline to 31 July 2029. This would provide sufficient time to conduct an evidence-based impact analysis, and generate insights about the toxic load, the distribution among relevant micro-pollutants and a verifiable cost calculations for the affected industries.

Additionally, prolonged timelines would remove the legal uncertainty involved in the UWWTD due to multiple legal challenges before the European Court of Justice.

HORIZONTAL	
Packaging and Packaging Waste Regulation	
Regulation (EU) 2025/40	Article 6 (11)

Original Text	Proposed Change
11. This Article shall not apply to the following:	11. This Article shall not apply to the following:
(a) immediate packaging as defined in Article 1, point (23), of Directive 2001/83/EC and in Article 4, point (25), of Regulation (EU) 2019/6;	(a) immediate packaging as defined in Article 1, point (23), of Directive 2001/83/EC and in Article 4, point (25), of Regulation (EU) 2019/6;
(b) contact-sensitive packaging of medical devices covered by Regulation (EU) 2017/745;	(b) contact-sensitive packaging of medical devices covered by Regulation (EU) 2017/745;
(c) contact-sensitive packaging of in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;	(c) contact-sensitive packaging of in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;
(d) outer packaging as defined in Article 1, point (24), of Directive 2001/83/EC and in Article 4, point (26), of Regulation (EU) 2019/6 in cases where such packaging is necessary to comply with specific requirements to preserve the quality of the medicinal product;	(d) outer packaging as defined in Article 1, point (24), of Directive 2001/83/EC and in Article 4, point (26), of Regulation (EU) 2019/6 in cases where such packaging is necessary to comply with specific requirements to preserve the quality of the medicinal product;
(e) contact-sensitive packaging for infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes as defined in Article 1, points (a), (b) and (c), of Regulation (EU) No 609/2013;	(e) contact-sensitive packaging for **food supplements as defined in EU Directive 2002/46 as well as for** infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes as defined in Article 1, points (a), (b) and (c), of Regulation (EU) No 609/2013;

Justification

Include under these exemptions food supplements as defined in EU Directive 2002/46 (amended).

FS are supplied in small packaging and will face the same challenges as other products in small packaging that will benefit from this exemption.

As an illustrated example:

- liquid food supplements can be filled into glass bottle with child resistant closure (plastic).
- due to the bottle cap featuring a child resistant closure, it is relatively high in weight compared to total weight of the packaging unit.
- this means that the “less than 5%” threshold for the foreseen derogation will not be met.

Considering the same bottle model may be used for food supplements as for medicinal products and medical devices that benefit from a general exemption, this will have impact on material purchase and operations and lead to duplication of purchase and sourcing.