AESGP Statement on The Revision of EU Pharmaceutical Legislation

Self-care industry asks for a revised pharma legislation that benefits EU citizens and health systems

AESGP, the Association of the European Self-Care Industry, welcomes the European Commission's proposal for a revision of the EU pharmaceutical legislation. This legislation review has been long awaited by AESGP members who are particularly implicated in this regulatory framework, as operators in the sector of self-care pharmaceutical products (non-prescription medicines). Non-prescription medicines are equally impacted by the revision of the EU pharmaceutical legislation as prescription medicines.

We believe the new legislative package will be key in addressing current challenges and will enable the EU to meet its overall objectives of ensuring the **continued and equitable supply** of **safe, quality and affordable medicines and medical devices to citizens**, and of **supporting the European pharmaceutical industry's competitiveness and innovation efforts**.

This holistic approach is much appreciated at a time where the global public health and economic situations have highlighted the need for greater resilience of supply chains and health systems, and for global crises preparedness.

In line with the European Commission's commitment for regulatory and administrative simplification, AESGP agrees that it is crucial to pursue a **better regulation agenda** for the pharmaceutical sector, to **reduce red tape** and **improve effectiveness**.

AESGP is committed to actively contributing to the development and implementation of an EU pharmaceutical strategy that:

1. considers the importance and value of non-prescription medicines when practicing self-care
2. promotes and rewards innovation, and fosters EU competitiveness and attracts investment
3. enables digital transformation
4. balances environment, sustainability, and healthcare needs
5. enhances smart regulation and regulatory efficiency to benefit the European population by increasing access to medicines
6. addresses prevention and mitigation of shortages with risk-balanced and proportional measures

AESGP
7 avenue de Tervuren
1040 Brussels, Belgium
Tel : + 32 2 735 51 30
Fax : + 32 2 735 52 22
info@aesgp.eu
www.aesgp.eu

Key Asks from The Self-Care Industry

AESGP supports a pragmatic and risk-based regulatory framework that fosters a stronger role for self-care and prevention. Against this background, based on its initial assessment of the published text, AESGP would like to highlight some of the regulatory provisions introduced by the European Commission and some important considerations with relevance for the self-care (non-prescription) sector:

● **AESGP expresses its concerns about the following proposals, as they have a negative impact on the sector, therefore impacting public health:**

1. **Prescription status criteria**

   AESGP is very concerned by the proposed changes to include two new prescription criteria. While supporting the European Action Plan against Antimicrobial Resistance and the objectives of the Chemical Strategy for Sustainability, the prescription status of antimicrobial products (in particular, antifungals and antivirals) or of medicines containing an active substance which is persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile is not an appropriate risk mitigation measure. It will have a negative impact on the accessibility of self-care products and add an additional burden on national health funds.

   The risk of antimicrobial resistance was already part of the prescription criteria and AESGP believes that a case-by-case decision on each medicinal product, considering the specific properties of the active substance and the ability for applicants to propose environmental risk mitigation measures, is a more appropriate and proportionate approach to ensure the objective of safeguarding public health while reducing the environmental impact of medicines.

2. **Incentives for switching from prescription to non-prescription status**

   The current proposals do not foresee a change regarding data protection related to switching from prescription to non-prescription status, but AESGP believes that **a longer data exclusivity period should be considered in cases where new, pivotal evidence is generated. This period should be extended from +1 year to +3 years, to ensure continued stimulation and attractiveness of EU innovation in line with other global markets such as USA and Japan, while recouping the investment**.

3. **Environment:** Proposed changes include tougher environmental provisions for medicines:

   The definition of 'risks related to the use of the medicinal product' has been extended to include 'undesirable effects on public health due to the release of the medicinal product in the environment, including antimicrobial resistance'. AESGP believes **this extended definition could threaten the core benefit-risk approach of the medicinal product authorisation system for human use, which goes against the objective expressed by the legislator with the new legislative package**. This is a move that, we believe, could potentially indirectly negatively impact citizens, if medicines are refused solely because of environmental concerns and if no chances are given for mitigating potential risks. **Decisions to minimise the environmental impact should always lead to proportional risk mitigation measures and never interfere with clinical priorities and benefit/risk assessments that ensure EU citizens get access to the healthcare products they need.**

AESGP believes that a different approach should be taken: an Extended Environmental Risk Assessment (eERA)[1] should be the main regulatory tool for assessing environmental risks of APIs, as it is crucial to not only consider environmental risks at the point of a market application but also post-authorisation and across products containing the same active pharmaceutical ingredient (API). **The proposed changes to ERA will not address repetition of studies, inconsistent and conflicting ERA conclusions and non-equitable testing burdens on individual companies which are unforeseen at the point of application** unlike the eERA approach.

Specific ERA provisions for medicinal products authorized before 30 October 2005 have been included. 30 months after the date of entry into force of the Directive, the EMA shall set a programme for the ERA of those medicinal products that have not been subject to an ERA and that are identified as potentially harmful to the environment. AESGP believes that the **IMI PREMIER project, scheduled to end in 2026, would be instrumental to help prioritize legacy compounds presenting a risk and should be taken on board**.

- **AESGP identifies the following proposals as requiring improvements in the final version of the legislation:**

1. **<u>Product information</u>**

The new legislative package provides for Member States to decide whether medicinal products should include a paper or an electronic leaflet, or both. AESGP agrees with the benefits of the electronic leaflet, (e.g., facilitating quick updates, multiple language availability and readability, accessibility to information, addition of multimedia and other tools to help increase medication and health literacy). However, **AESGP advises that a phased and harmonized approach to digitalisation should be taken, and that the physical availability of information should be maintained with non-prescription medicines, as long as we cannot ensure a viable means of access to information for all in the absence of advice from a healthcare professional. Having a common EU harmonised introduction of the digital leaflet across all Member States will reduce access asymmetries for the users of medicines and avoid overburdening regulators and companies.**

Proposed changes now also include specific information requirements for antimicrobials, with the inclusion in the packaging of awareness cards containing information on antimicrobial resistance and appropriate use and disposal of the product. AESGP believes **this new risk mitigation measure should be limited to antibiotics and other antimicrobials where the risk of resistance has been evidenced.**

2. **<u>Real-World Data / Real-World Evidence (RWD/RWE)</u>**

AESGP believes that the new legislative package lacks definitions of RWD and RWE. Most non-prescription medicines are indeed not prescribed nor reimbursed and therefore have no routinely collected data (outside of pharmacovigilance data). RWD should therefore be defined as "*data used for decision making that are not collected in conventional randomized controlled trials*".

RWE should therefore be defined as *"evidence regarding the usage and potential benefits or risk of a medical product derived from analysis of RWD*". RWE has the potential to inform authorities decision on medicinal products, notably on the change of legal status, safety, and effectiveness

[1] Extended Environmental Risk Assessment (eERA) proposal "Proactively managing the environmental risks associated with the patient use of human medicinal products": https://aesgp.eu/content/uploads/2023/04/EFPIA-eERA_BROCH_V08.pdf

3. **Shortages**

Non-prescription medicines, due to a highly competitive market and to regulatory and supply chain particularities, are rarely in short supply. Eventual shortages only in exceptional and then timewise very limited situations translate to a lack of self-care options to the citizens in the EU given the availability of alternatives available on the market either with the same active pharmaceutical ingredients (APIs) – but different brand – or with different APIs in the same therapeutic category.

Therefore, AESGP believes that **any measures to mitigate shortages should be proportionate and aimed at the critical medicines that do not have alternatives and have concentrated supply chains**. The proposed six-month notice would generate a huge amount of information traffic to authorities considering that supply chain issues for non-prescription medicines are usually quickly resolved and do not lead to market disruption. Similarly, the new requirement for Shortages Prevention Plans (SPP) should be restricted to critical products.

4. **Pharmacovigilance**

AESGP welcomes the proposal to no longer request Risk Management Plans for generics and biosimilars. AESGP believes that such an exemption can be extended to medicinal products of well-established use. For other product categories **a risk-based approach should be applied to the Risk Management Plan (RMP) based on existing API safety information and indication**. Requirement for a Risk Management Plan should for these categories be **delinked from the legal basis to minimise unnecessary work for both authorities and industry** (i.e., a full marketing authorisation application based on an old API should benefit from the same waiver as a generic application no longer required to provide an RMP).

● **AESGP welcomes the following proposals and supports their retention in the final version of the legislation:**

1. **Regulatory agility**

We welcome **that there are no substantial changes to marketing authorisation procedures access and related requirements**. In addition, AESGP welcomes the proposed changes aiming to reduce regulatory burden, with marketing authorisations now granted for an unlimited period and the sunset clause removed. AESGP also welcomes the proposed modernization and digitalisation of the Variations system.

AESGP is committed to actively contributing to the dialogue with the EU institutions and all involved stakeholders on the proposed revision of the EU pharmaceutical legislation, with the objective that the final text responds to the needs of European citizens while addressing current challenges with science-based, risk-balanced and proportional measures.

Brussels, 26 April 2023

Related documents

- AESGP Reply to European Commission's Roadmap for the Pharmaceutical Strategy (July 2020)
- AESGP reaction to European Commission's Communication on the EU Pharmaceutical Strategy (November 2020)
- AESGP Reply on the Evaluation and Revision of Pharma Law (April 2021)

AESGP
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