AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

A fit Pharmaceutical Legislation to benefit EU citizens and health systems

AESGP Reply to European Commission's Combined Evaluation Roadmap / Inception Impact Assessment on the *Evaluation and revision of the general pharmaceutical legislation*

AESGP welcomes the European Commission's combined Evaluation Roadmap and Inception Impact Assessment to provide sound information that can support the establishment of a Pharmaceutical Strategy for Europe, that follows plans set on the Industrial Strategy, and under the continued efforts to build a stronger European Health Union.

AESGP supports a pragmatic and risk-based regulatory framework that fosters a stronger role for self-care and prevention. The current structure is overall fit for purpose although some issues may arise from divergent interpretation, disharmonised application and addition of gold plating or administrative elements. These can be tackled through non-legislative initiatives.
AESGP fully supports the 'targeted approach' pursued by the Commission for this exercise based on the recognition of the well-established dual marketing authorisation system in the EU. For the sake of legal certainty and regulatory efficiency, keeping the existing legal instruments fits best the objective of this targeted approach. Updates to existing policy and guidance documents must be considered as valid instruments to deliver on the objectives.

We believe that a solid analysis of the existing regulatory framework and impacts of the proposed measures under each of the considered policy options is critical to achieve a proportional legal proposal. AESGP is committed to engage in an open dialogue with all the involved stakeholder groups to achieve the common objectives of this initiative. In carrying out this analysis, the interconnection of the pharmaceutical legislation with the ongoing proposals for the reinforced role of EMA, the creation of HERA, the ongoing implementation of the Medical Devices Regulation must be taken into account so as to avoid unnecessary duplication of initiatives.

AESGP would also like to highlight some of the policy areas identified by the European Commission and some important considerations:

Legislative instruments are fit for a stable, integrated, predictable, coherent and proportional regulatory and administrative framework

Following the revision process, AESGP suggests keeping the current duality in the legal instruments with the Directive 2001/83/EC and Regulation (EC) No 726/2004 as these are well-established, adopted and working well. **A change of the existing system could prove to be disproportionate, time-intensive and burdenso**me as it would require the increased allocation of human resources from the legislation and administration bodies, both at EU and national levels. The **current structure is fit for purpose** considering the targeted approach of the revision of the pharmaceutical legislation and ensures the affordability, accessibility and availability of medicinal products in the Member States.
AESGP observed that most issues may arise from **divergent interpretation**, **disharmonised application** and addition of **gold plating** or administrative elements. AESGP is of the opinion that much

can be achieved without legislative changes. Even so, if change in the legislative instrument is considered, it should aim at fostering a pragmatic implementation and a stable, integrated, predictable, coherent and proportional regulatory and administrative framework, encouraging and appropriately rewarding innovation.

Opportunities to improve health outcomes and sustainability of health systems

The Commission's Roadmap proposes a number of areas to strengthen access to affordable medicines as well as other measures with possible use to control health expenditure across the EU. AESGP highlights the **opportunity for self-care and prevention to play a larger role** in the healthcare continuum. Enabling wider access across the EU with more options for self-care has the downstream potential for positive economic impact on EU member states, lessening the burden on healthcare systems and empowered citizens.

Incentives for safe switches of medicines from prescription to non-prescription

Consideration should be given to **facilitating and encouraging the change of legal status of medicines**, to ensure greater access and availability of pharmaceuticals to patients, recognising the wider benefits of non-prescription medicines for individuals, national systems and public health in general by, e.g., granting a minimum data protection period of 3 years as implemented in the USA and Japan. Furthermore, data exclusivity should apply to all relevant types of studies required for switches. Easing regulatory procedures for trusted molecules that have been available for many years and where large amounts of safety data is already available, would help increment switch processes and make them more transparent and streamlined across the EU.

Access to non-prescription medicines is an important **enabler for self-care**, however National healthcare systems, regulatory practices and medical history differ within Europe, resulting in **unequal access to non-prescription medicines**. An EU agenda promoting self-care as a first step in health and encouraging health literacy is needed.

Modernisation of the mutual recognition and decentralised procedures should take place notably increasing the transparency and enforcing respect of timelines to better predict product launch.

An agile variations system allows for quicker adaption to health needs

AESGP, together with other pharmaceutical industry stakeholders, calls for the **modernisation of the current variations system** to capitalise on the evolution of technology and telematics system and regulatory needs.

AESGP would like to see the risk-based approaches extended to variation categorisation for, e.g., **herbal medicines**.

The regulatory dossier should remain lean and the quality part focused on elements needed by the evaluators for their review and kept to a **reasonable level of detail**.

Learnings of COVID-19 have shown the way to ease regulatory burden

Regulatory flexibility proved useful during the COVID19 crisis and could also be applied in other cases or be maintained in a post-pandemic scenario: specific measures which have been introduced with regards to, for instance, QP discretion, acceptance of digital versions of documents, remote inspections and variations could be considered for permanent establishment.

Innovative changes to established regulatory management could help reduce some unnecessary regulatory burden, allowing agencies to focus on essential regulatory activities to protect medicines users.

The pandemic has highlighted our dependencies in the European Union of having **strong supply chains** and we understand the political drive to broaden out sources of supply, and the political ambition as expressed in the Pharmaceutical Strategy for Europe. For the large majority of OTC products, we have not been faced with supply issues during the pandemic and for some of the products, such as paracetamol, we have even been able to increase our manufacturing to meet the growth in demand across the EU.

Global supply chain robustness gives more options to availability and affordability

Any legislative measures aiming to prevent shortages should be commensurate to the level of risk of the product to be in short supply and not having any therapeutic alternatives. Smart regulation can be a way forward to increase accessibility and availability of pharmaceuticals to patients. Pharmaceutical supply chains are global in nature and countries should not restrict the flow of goods jeopardizing manufacturing or supply of medicines. AESGP would encourage **greater diplomatic action** ensuring that worldwide pharmaceutical supply chain mitigates export constraints to reduce the risk of shortages.

To maintain affordability of non-prescription medicines in the EU, any changes to supply chains and manufacturing of API's must ensure that **cost of goods is competitive** with existing **sourcing options**, as it is critical to maintain these products affordable.

Digital tools allow supple procedures, better medicine use and more patient safety

The potential for digitalization needs to be considered in the whole pharmaceutical ecosystem. AESGP supports the **increasing acceptance of digital documents and physical processes using digital technologies** and telematics to ensure safety, quality and efficacy of medicines, particularly in the interactions between MAH and regulatory authorities. In that, AESGP calls for **stronger commitments on telematics** projects and deliverables, based on a proportionate and realistic approach (included regulators' resources).

AESGP supports the development of initiatives such as the **electronic patient information** for human medicines, as it can be a helpful addition to the paper leaflet, and increase patient safety and foster availability of medicines. The Commission recommendations based on the NIVEL reports should pave the way to improved leaflets.

AESGP is aware of the high potential for **Real-World Data and Real-World Evidence**, also applicable to non-prescription medicines, throughout their life cycle. For example, the use and acceptance of real-world effectiveness may help complement efficacy data of medicinal products challenged by new safety findings. RWD-RWE can also support request to change legal status of a medicinal product from prescription to non-prescription. As a consequence, AESGP would appreciate that the Roadmap reference to RWD/RWE would not be limited to supporting the development of medicinal products for unmet medical needs.

AESGP has released a particular position paper on ***Paving the way for the digitalisation of the selfcare sector***[1].

Scientific-based environmental concerns help to drive risk-pondered solutions that ensure medicines accessibility

AESGP supports the further implementation of the existing framework developments addressing environmental concerns from the manufacture, use and disposal of medicines, while safeguarding the access to effective medicines. Any approach should be based on research and sound scientific principles and data, with a risk-based prioritisation for any relevant actions. AESGP strongly supports that the outcomes of existing joint **partnership research initiatives** in environment (under IMI) are used to build science-based and risk-based requirements.

AESGP advises that perspectives on '**greener' pharmaceuticals**, although desirable are not always possible, given technical constraints that make medicines useful in the first place. Therefore, proportionate approaches based on evidence-based concepts should be envisaged as potential solutions to the problem.

AESGP also believes that there is room to extend and improve the current **Environmental Risk Assessment**, and adapt it to reflect the life-cycle of medicines. Caution should be taken, however, to ensure that overall human benefit-risk decisions on medicines approval is privileged, and does not negatively impact citizens access to effective medicines.

[1] https://aesgp.eu/content/uploads/2021/03/AESGP_PP_Digital_Strategy_2021-1.pdf

The Roadmap should also consider to promote the development of non-legislative initiatives fostering responsible use of pharmaceuticals, proper collection (where necessary) and **disposal of medicines**. AESGP further supports the management of environmental risks from medicines through the **education of patients and consumers and healthcare professionals** on correct use and disposal of medicines.

Health literacy helps taking health decisions and the responsible use of medicines

European countries currently spend approximately 80% of their total healthcare budget on chronic diseases that can be considered to be largely preventable. These diseases share the same behavioural risk factors, including smoking, alcohol consumption, unhealthy diets and physical inactivity. Despite these risk factors being largely preventable if citizens followed a healthier lifestyle, only 3% of the total healthcare budget of European countries is spent on prevention.

Prevention goes hand-in-hand with health education, to ensure citizens understand how to stay healthy and treat minor ailments and understand which medicines are appropriate in different situations. Healthcare professionals can play a key role in self-care, being well-placed to provide proper advice on the use of medicines and to refer onto medical care when necessary. Educating citizens on the expertise and skills of **pharmacists** could result in a closer connection between the two in terms of **self-care management and monitoring**.

AESGP is looking forward to the dialogue with the Commission, European Parliament, Member States and European Medicines Regulators on the proposed actions.

Brussels, 27 April 2021