AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

For a Pharmaceutical Strategy that protects the planet, patients, healthcare systems and EU competitiveness

AESGP Reply to European Commission's Roadmap for the Pharmaceutical Strategy

July 2020

Executive summary

AESGP welcomes the European Commission Roadmap for the Pharmaceutical Strategy, ensuring sustainable innovation and the availability and affordability of medicines and medical technologies for citizens. Working towards patient-centred healthcare systems will require to develop further solutions that are tailored to patients' needs, having in mind the EU member states healthcare systems' sustainability.

In line with this 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.

1. **There is an important role for Self-Care pharmaceuticals and health literacy in the overarching aim for healthcare system sustainability**
   - Self-care aims at promoting and maintaining a healthy status, by preventing disease, and addressing temporary or recurrent symptoms, illness or disability, without requiring supervision of a medical practitioner, saving unnecessary visits to overburdened healthcare systems and strengthening citizens' autonomy
   - Health literacy is key to help EU citizens navigate in these challenging times
   - Prevention can lead to better health outcomes
   - Change of legal status from prescription to non-prescription, particularly for innovations or substances not yet available in the self-care area, could increase opportunities for better healthcare management
   - Real world evidence can strengthen benefits and safety of non-prescription medicines

2. **A healthy competitive market and a resilient supply chain helps to ensure worldwide success of the European Pharmaceutical sector for non-prescription medicines**
   - Pharmaceutical sector in Europe is vital for the European growth and prosperity
   - Keep competitive level playing field and proportional legislation, crucial for business certainty and to attract investment
   - Self-care market is characterised by healthy competition due to the high number of options

3. **European production and procurement need to rely on global supply chain sustainability to reduce effects of eventual medicines' shortages**
   - Europeans benefit from access to large span of affordable self-care products, including non-prescription pharmaceuticals
   - Globalisation of the supply chain is a success and ensures exports
   - There is no evidence that onshoring manufacturing will resolve shortage problems as it's also a protectionist measure
   - Europe needs to address root causes of shortages while balancing it with its reliance on affordable products from third countries
   - establishment of medicines reserves as structural stockpile should be commensurate to the level of risk of the product
   - Regulatory flexibility proved useful during the COVID19 crisis and could also be applied in other cases or be maintained in a post-pandemic scenario.

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4. **Environmental concerns need to be paired with accessibility and affordability of medicines**
   - Symptomatic relief with self-care products in viral infections helps reduce AMR
   - Pharmaceutical Industry has leading examples in greener practices for manufacturing operations
   - Industry is addressing the data gaps for the potential impact of Pharmaceuticals in the Environment to pave the way for effective mitigation measures
   - Unused and expired medicines are target for collection schemes supported by industry under Producer Responsibility organizations and the European level #MEDSdisposal project.
   - Measures aimed at reducing pharmaceutical residues in the environment must not jeopardize patients' rights to access to the appropriate treatments

5. **Smart regulation can be a way forward to increase accessibility and availability of pharmaceuticals to patient**
   - 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,
   - Flexibility and risk-based decisions, adjusting some established regulatory practices and reducing unnecessary regulatory burden, can help ensure continuity of product availability
   - The pharmaceutical industry calls for modernisation of the current variations system (1) to reflect the evolution in technology and regulatory needs and changes in patient behaviours, both on and offline

6. **Protecting Pharmaceutical SMEs and allowing for special regulatory provisions is to safeguard important sources of innovation**
   - Improved framework for carrying out entrepreneurial activities in the EU
   - Incentives should be tailored to SMEs so as to improve innovation, including better regulation and removal of administrative burden
   - Harmonised, risk-based and pragmatic implementation of the legislation

(1) EC variation regulation 1234/2008 and variations classification guideline

About

The **Association of the European Self-Care Industry (AESGP)** is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, an area also referred to as consumer healthcare products.

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There is an important role for Self-Care pharmaceuticals and health literacy in the overarching aim for healthcare system sustainability

AESGP believes that the next European Pharmaceutical Strategy needs to acknowledge the specificities of different pharmaceutical products and their different regulatory pathways. The Self-care industry, namely non-prescription medicines, have been helping to address the challenges of healthcare systems and tried to respond to them by providing solutions that bring rationality and optimal use of resources. Particularities in the regulation of non-prescription medicines have helped to increase their availability and accessibility, having established a competitive market where manufacturers are incentivised to innovate and offer best value at an affordable price.

Self-care is a part of European citizens everyday lives, which aims at promoting and maintaining a healthy status, by preventing disease, and addressing mild, temporary or recurrent symptoms, illness or conditions, without requiring supervision of a medical practitioner. Self-care entails a responsible self-assessment, self-treatment and self-monitoring, only possible by consumer and patient empowerment, increasing health literacy and professional guidance on healthy lifestyle choices. **Self-care has the potential for citizens to take better care of their health needs and also to contribute to the sustainability of European health care systems, mostly by relieving pressure on primary healthcare and hospital visits.**

During the pandemic, there was a significant increase in the use of online health information. At the same time, we have seen an increase in fake news, mainly fake news related to treatment advice and information about particular drugs. AESGP believes that health literacy is key to help EU citizens navigate in these challenging times and we encourage dialogue on how health literacy and the understanding of self-care can become part of adult education and school curriculums.

Prevention can lead to better health outcomes and prevent or reduce the severity of a disease. Looking into the future of healthcare services and some of the challenges facing Europe with ageing populations and increase in obesity, AESGP would encourage that prevention becomes a more central part of the pharmaceutical strategy.

As part of the lifecycle of pharmaceutical products, many of these become available as non-prescription medicines, after being available on the market for many years on prescription, due to a well-known safety profile.

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 contribute to empower individuals with user friendly tools, which support adherence and the responsible use of medicines.

AESGP is aware of the high potential for Real World Data for non-prescription medicine, throughout their life cycle, and would appreciate that the reference would not be limited to supporting the development of medicinal products for unmet medical needs. For example, the use and acceptance of RWD-RWE may help strengthen benefits through substantiation of efficacy/efficiency 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.

Self-care has the potential for citizens to take better care of their health needs and also to contribute to the sustainability of European health care systems

A healthy competitive market and a resilient supply chain helps to ensure worldwide success of the European Pharmaceutical sector for non-prescription medicines

The pharmaceutical sector in Europe has been vital for the European growth and prosperity. It has a global reputation for quality and sustainability and is a big employer of skilled workforce. AESGP finds it very positive that the Commission's intention to keep an EU competitive level playing field. **The current legislation is fit for purpose however some issues may arise from divergent interpretation, disharmonised application and addition of gold plating or administrative elements.** AESGP would be supportive of non-legislative initiatives fostering a stable, integrated, predictable, coherent and proportional regulatory and administrative framework, which is crucial for business certainty and to attract EU and foreign investment.

There are more than over 4.000 different products available without prescription in Europe, made of around 200 active pharmaceutical ingredients. The market for self-care products is characterised by healthy competition due to the high number of alternative products containing same active principles and/or therapeutic alternatives that people and healthcare professionals can choose from. This is the reason why shortages of one product will hardly impact a patient or his ability to self-care.

European production and procurement need to rely on global supply chain sustainability to reduce effects of eventual medicines' shortages

Europeans benefit from access to affordable non-prescription medicines to manage increasing number of ailments. More than 9,5 billion packs of non-prescription medicines were purchased in 2019 alone. Globalisation of the supply chain – a market reality for the entire pharmaceutical sector – is a success story. **Thanks to the strong regulatory framework, Europe has one of the most reliable supply chains in the world.** It is home for a number of key global manufacturing sites of non-prescription medicines that are manufactured in Europe and then supplied to countries around the world.

Shifting more manufacturing and production of non-prescription medicines and API to Europe as part of the diversification of the supply chain might be considered as a long-term strategic option, but it is simply not feasible or desirable in the short-term. The impact of such option is not documented and should be weighed against the risk of other parts of the world following the same strategy. The onshoring of entire production lines and manufacturing sites is a lengthy and costly process that, if done in an uncoordinated and precipitated manner could be detrimental to people's access to the medicinal products they need, including non-prescription medicines, due to manufacturing and supply delays. It could, therefore, have a further negative impact on accessibility and affordability of non-prescription medicines. In addition, a component of manufacturing would always remain global, as excipients, solvents, and raw materials would still be sourced from third countries.

Securing a well-functioning global supply chain of pharmaceuticals should be the primary objective of the European response to address the issue of medicine shortages. The possibility of importing increases the potential number of suppliers and possibly the access to surplus stocks. Protectionism, however, concentrates risk domestically, reduces the diversity of potential suppliers and diminishes the pressure of competition and economies of scale. **Trade agreements or preferential treatment from supplying countries, ring fencing material goods for Europe, will go a long way in avoiding any future disruptions.**

AESGP considers it important for the European Commission to address shortages of medicines taking into account a diverse internal market and protectionist measures taken by third countries as part of their national business agendas and even by some EU member states in times of crises (such as was the case with Covid-19 pandemic). **Europe needs to address root causes of shortages while balancing it with its reliance on affordable products from third countries, which help reduce healthcare budgets.** For this purpose, the EU needs to ask for the international respect of trade rules, prices, tariffs and duties and establish partnerships for market access and business opportunities.

In this respect, AESGP would also recommend caution on the establishment of medicines reserves as structural stockpile. **Any 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. For as much as it is known, the main problem of medicines availability during the pandemic was an unnecessary rush to stocks (panic buying), national protectionism and border controls, both in Europe and with trade partners from third countries. These problems, during the COVID-19 pandemic, were addressed pre-emptively, in due time, through pragmatic solutions to ensure the proper functioning of the internal market, regulatory flexibility for market access and diplomatic channels with third countries' partners, in a joint effort of pharmaceutical industry, wholesalers, the Commission, EMA and its agencies, as well as the network of Member States.

In more concrete terms, AESGP would like to draw from the learnings of the COVID-19 pandemic, that specific measures around regulatory flexibility which have been introduced with regards to, for instance, QP discretion, variations, and GMP topics could be considered for permanent establishment. This would mean that supply shortages could be handled irrespective of the crisis while ensuring the quality, efficacy and safety of pharmaceuticals in the EU.

Environmental concerns need to be paired with accessibility and affordability of medicines

Self-care products are used for symptomatic relief of self-limited viral infections (e.g. seasonal colds or flu, gastrointestinal flux), where antibiotics would not be effective, thus avoiding antibiotics misuse and overuse. **This an important contribute to address antimicrobial resistance, one of the main environmental concerns of pharmaceuticals.**

AESGP members have been concerned with the climate urgency and has worked in leading examples of manufacturing adaptation to encompass **greener practices and more sustainable performances (2)**.

Also, along with other pharmaceutical industry partner associations, AESGP has been working, for the past decades, in addressing the many knowledge gaps that still exist on the potential impacts of pharmaceuticals in the environment. AESGP members have supported research programs, including IMI, that have been shedding light on these issues (3). There are currently still many knowledge gaps, which the pharmaceutical industry is addressing via research programs including IMI. However, in a worst-case scenario estimation, **only about 10% of pharmaceuticals are considered to pose a potential risk for the environment (4).** Also on a very conservative approach, **it is esteemed that only 2% of pharmaceuticals in the environment are attributed to waste from production.** Work is still ongoing but already research outcomes in this field are paving the way for further effluents management and control beyond regulatory standards.

Regarding disposal of medicines, several take-back schemes have been put in place in Member States, avoiding littering and household disposal through solid waste (when it is not incinerated) or through water effluents. Some of these take-back schemes were established and financed by the different stakeholders of the medicines value chain – manufacturers, wholesalers and pharmacies – under their social and environmental responsibility, by constituting voluntary Producer Responsibility Organizations (PRO). That is the reason for expired and unused medicines collection schemes to have been established in some countries long before the implementation of Directive 2004/27/EC, which enshrined this obligation. Information on these systems has been assembled in the industry led initiative MEDSdisposal (5), which has also been the title of several awareness campaigns on this topic.

(2) https://www.imi.europa.eu/projects-results/success-stories-projects/chem21-step-towards-greener-and-more-efficient
(3) iPiE and follow-up project PREMIER
(4) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4213597
(5) http://medsdisposal.eu/

Pharmaceuticals should be available and any measures aimed to reduce pharmaceutical residues in the environment must not jeopardize patients' access to the appropriate treatments

There is a big degree of shared responsibility among all stakeholders, throughout the decision process that leads to the use of pharmaceuticals and, then, to its residues ending up in the environment. These are factored by clinical necessity and appropriateness of a specific medicine, followed by particularities of human physiological pathways, as well as wastewater network planning and design, and wastewater treatment plants capacity. This is of particular importance as around 88% of pharmaceuticals in the environment come from patient use and excretion.

However, as a principle, pharmaceuticals should be available and any measures aimed to reduce pharmaceutical residues in the environment must not jeopardize patients' access to the appropriate treatments. This is the main reason for AESGP to support a balanced approach to extend and improve the current Environmental Risk Assessment (6), in scientific coordination with the European Medicines Agency level.

Furthermore, AESGP considers the Pharmaceutical Strategy to be an opportunity for Europe to align sustainable action with a competitive industry. This should be enabled through a level playing field across global economies, in view of higher costs incurred for those companies with environmentally sustainable sourcing and manufacturing.

Smart regulation can be a way forward to increase accessibility and availability of pharmaceuticals to patients

AESGP believes that to ensure greater access and availability of pharmaceuticals to patients that consideration should be given to facilitating and encouraging the reclassification of medicines, which in turn eases the burden on hospitals and GPs and drive patients to manage their own health care more effectively.

Consideration should be given to facilitating and encouraging the change of legal status of medicines, particularly the first switch in line (new substances, new APIs), in the frame of the collaborative care concept (7), to ensure greater access and availability of pharmaceuticals to patients. AESGP supports greater self-care incentives for reclassification applications as well as reducing administrative burden with initiatives such as use of electronic patient information and multilingual packs.

Ensuring on-going access to medicines is critical during COVID-19 pandemic. In this emergency, Regulators displayed flexibility, openness for dialogue and search of beneficial solutions and made risk-based decisions, adjusting some established regulatory practices to help ensure continuity of product availability. This approach to the granting of licenses and maintaining access to quality, safe and effective medicinal products should be encouraged outside of a pandemic situation to prevent supply chain tensions or disruptions. 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.

(6) https://www.efpia.eu/media/25278/pillar-3-extended-environmental-risk-assessment-eera.pdf
(7) https://aesgp.eu/content/uploads/2019/10/THE-ECONOMIC-AND-PUBLIC-HEALTH-VALUE-OF-SELF-MEDICATION.pdf

Protecting Pharmaceutical SMEs and allowing for special regulatory provisions is to safe-guard important sources of innovation

More than 2.000 companies operate in the consumer healthcare sector in Europe, half of which are small and medium-sized enterprises. Therefore, AESGP would suggest that the Roadmap also addresses healthcare manufacturer and MAHs SMEs and start-ups concerns in the design of EU policies, as these are a valuable pool of research and innovation. Amongst others, the regulatory framework should be optimised and any administrative hurdles not serving science should be removed. This would be in line with the EU Industrial Strategy to unleash the full potential of European SMEs through the SME strategy for a sustainable and digital Europe.

AESGP believes that it is important and necessary that the framework for carrying out entrepreneurial activities in the EU needs to be further improved, in particular for the manufacturers of medicinal products and medical devices. This would include infrastructure, such as broadband expansion, as well as the overall social and legal requirements that need to be further developed to encourage and facilitate company activities.

AESGP would support a proposal which reduces the cost of placing medicines on the market and consequently lowering the cost of goods. For example, application of a more risk-based licensing approach to those products where the safety and efficacy are well characterised could allow resources to be focused on innovation.

Greater harmonisation of the way requirements are applied through international collaboration could not only avoid duplication but provide earlier guidance for innovators. AESGP believes that to support EU influence and competitiveness registration and life cycle management of alternative sources should be risk-proportionate and applied in a harmonised way across the EU.

Conclusion

It is paramount that the EU Pharmaceutical Strategy takes into account the work being developed at industry level and national best practices so as to avoid unnecessary duplication of initiatives, to guarantee a proportional and adequate effort allocation, and to create the necessary synergies with other policies and stakeholders.

An economic crisis is looming, and it is thus important to conduct innovation-driven policies to speed up recovery, as foreseen by the EU industrial strategy and by the policy orientations of the incoming Council Presidency Trio of Germany, Portugal and Slovenia.

AESGP is determined to keep the dialogue with the European Commission, to contribute to the outcomes of a Pharmaceutical Strategy that responds to the needs of European citizens and to collaborate with proportional policies that ensure the sustainability of the planet, of healthcare systems and of a successful industrial sector in Europe.