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AESGP Welcomes EU Pharma Revision But Warns Of 'Unintended Negative Consequences'

by David Ridley

European self-care industry association AESGP says it supports the revision of the EU pharmaceutical legislation "in principle," but has concerns that some of the proposals "may have unintended negative consequences."

European self-care industry association, AESGP, sees positives and negatives in the European Commission's long-awaited proposals for revising the European Union's legislative framework for pharmaceuticals.

AESGP has welcomed that there are no substantial changes to marketing authorization procedures, as well as proposed changes aiming to reduce regulatory burden, such as unlimited authorization periods and the removal of the "sunset clause" for medicines not placed on the market within three years.

However, more could be made of the self-care industry's contribution to the EU's wider objective of ensuring the "continued and equitable supply of safe, quality and affordable medicines and medical devices to citizens," the association argues. For example, self-care innovation and access to medicines could be furthered by extending data exclusivity periods for Rx-to-OTC switches from one to three years, AESGP suggests.

The Commission's proposed definitions of real-world data and evidence (RWD, RWE) could also be expanded to take into account the life-cycle of non-prescription medicines, it continues, which have no routinely collected data outside of pharmacovigilance data.

The AESGP is also "very concerned" about certain proposals, such as the inclusion of two new prescription criteria for antimicrobial products and medicines containing persistent,

bioaccumulative and toxic active substances.

Proposals addressing the environmental impact of medicines, the introduction of electronic product information and aimed at avoiding future medicines shortages all need to be more carefully considered, AESGP says, to avoid market disruption and increasing the administrative burden on self-care companies.

"AESGP supports the revision of the EU pharmaceutical legislation in principle," commented the association's director general Jurate Švarcaite. "While we welcome the regulatory simplifications introduced by the revision, we are voicing some concerns on behalf of non-prescription medicines manufacturers that may have unintended negative consequences."

"We are committed to actively contributing to the dialogue with co-legislators and stakeholders so that the final text is fit for the rapidly changing world we live in, embraces the evolution of science and, ultimately, responds to the needs of people while ensuring the highest level of public health protection," Švarcaite added.

Negative Impacts

AESGP has identified two proposals it thinks will have a "negative impact" on the self-care sector, and therefore impact public health.

First is the proposed change to include two new prescription criteria: antimicrobial products (in particular, antifungals and antivirals) and medicines containing active substances that are persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; persistent, mobile and toxic; or very persistent and very mobile.

"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."

Secondly, 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 points out.

AESGP says this extended definition could "threaten the core benefit-risk approach of the medicinal product authorization system for human use," and result in OTC medicines being refused solely because of environmental concerns, "especially if no chances are given for mitigating potential risks."

“Decisions to minimize 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,” the association argues.

Room For Improvement

AESGP also marked several proposals as “requiring improvement,” beginning with the omission of extended data protection for Rx-to-OTC switch.

Longer data exclusivity periods should be considered in cases where new, pivotal evidence is generated, the association suggests, for example from one to three years in line with other markets such as the US and Japan.

The proposal to introduce electronic patient information leaflets (ePILs) – a long time coming – are also potentially problematic, AESGP notes, because the revised legislation would leave it up to individual member states to decide whether medicinal products would need to include a paper or an electronic leaflet, or both. (Also see "*Electronic Patient Information Leaflets Are The Future, But Paper Not Going Away Any Time Soon*" - HBW Insight, 15 Apr, 2019.)

There are many benefits of ePILs, AESGP insists. For example, they facilitate quick updates, widen access to information by allowing multiple languages and modes of presentation, and also enable the use of multimedia and other digital tools such as QR codes, also increasing accessibility.

However, AESGP wants a “phased and harmonized approach” to digitalization, and for the physical availability of information to be maintained with regards to 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.”

The Commission has also missed an important opportunity to leverage the power of real-world data and evidence for the regulation of OTC medicines, AESGP argues. Because most non-prescription medicines are not prescribed or reimbursed, there is no routinely collected data outside of pharmacovigilance data. (Also see "*Real-World Evidence Can Play Important Role In OTC Regulation – AESGP Study*" - HBW Insight, 13 Oct, 2021.)

To enable RWD and RWE to be used for OTCs, the former should be defined as “data used for decision making that are not collected in conventional randomized controlled trials” and the latter as “evidence regarding the usage and potential benefits or risk of a medical product derived from analysis of RWD.”

No Shortages For OTCs?

The final point of contention for AESGP is the Commission's proposal to prevent future

medicines shortages, including a notice period for critical medicinal products of up to six months and a requirement for marketing authorization holders "to have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market."

AESGP argues that non-prescription medicines, "due to a highly competitive market and to regulatory and supply chain particularities, are rarely in short supply." Shortages, when they do occur, happen only in "exceptional and then time-wise very limited situations" and result in a "lack of self-care options."

Pharmacists and parents in Germany, for example, may not agree, given the severe and long-term shortages of pediatric fever products that beset the country for most of last year – an issue that other countries such as the US, France and the UK also saw. (Also see "*Blame The 'Hamsters': Germany's Paediatric Fever Medicine Shortage Worsens*" - HBW Insight, 23 Dec, 2022.) (Also see "*OTC Shortages Top Of Mind For North American, European and Asia Pacific Consumers*" - HBW Insight, 26 Jan, 2023.)

Contrasting the UK and German pediatric OTC markets, however, perhaps proves the AESGP's point. In the UK, there are several OTC children's analgesic brands, with a large proportion of these sold through the grocery channel – a point made forcefully by the country's consumer healthcare industry association, PAGB, in response to "partial and incomplete reporting" by mainstream media outlets. (Also see "*PAGB Calls Out 'Partial And Incomplete' Reports Of UK OTC Cough & Cold Shortages*" - HBW Insight, 19 Jan, 2023.)

In other countries that have also experienced strong demand for these products, supply and pricing restrictions have made it more difficult for manufacturers to meet the increased demand driven by new and unpredictable waves and strains of flu and COVID-19. In Germany, the AMPreisV system for reimbursable medicines, which are designed to keep prices low, have made supply uneconomical for many manufacturers, especially those of widely used generics like paracetamol and ibuprofen. (Also see "*Why Did Novartis/1A Pharma Withdraw Its Paracetamol Liquid From The German Market?*" - HBW Insight, 25 Aug, 2022.)

"Any measures to mitigate shortages should be proportionate and aimed at the critical medicines that do not have alternatives and have concentrated supply chains," AESGP concludes.