AESGP

AESGP ACTIVITY REPORT 2025

Prevention through Self-Care

Contents

Foreword

*by **Jonathan Workman**, AESGP President*

It is a great honour to reflect on the work of AESGP during 2025, a year that once again demonstrated the essential role of self-care in supporting healthier citizens and more resilient healthcare systems across Europe.

Throughout the year, AESGP strengthened its role as a trusted leader and expert voice across an increasingly complex and fast-moving policy landscape. We actively supported the implementation of the Medical Devices Regulation, closely monitored ongoing efforts to further harmonise maximum levels of vitamins and minerals across the EU, and contributed meaningfully to the revision of the General Pharmaceutical Legislation, politically agreed at the end of 2025. With this milestone reached, we stand ready to support its effective and pragmatic implementation. Together, these legislative frameworks are fundamental to ensuring patient safety, regulatory clarity, and a well-functioning internal market for self-care products.

At the same time, 2025 brought significant challenges. The adoption of the revised Urban Waste Water Treatment Directive marked a critical moment for our industry. While AESGP supports extended producer responsibility and the broader objectives of environmental protection, we remain deeply concerned by the selective and disproportionate application of these obligations to the self-care sector. Targeting medicinal and cosmetic products alone – while excluding other contributors to micropollutant residues – raises serious concerns regarding proportionality, fairness, and legal certainty. Moreover, Member States have since reported that the actual costs of implementing quaternary wastewater treatment are three to eight times higher than initially projected. This risks placing an unsustainable burden on our industry and, ultimately, undermining access to affordable self-care options for European citizens.

Against this backdrop, the guiding theme of AESGP's work in 2025 and our flagship event – Annual meeting – Prevention through Self-Care – could not be more timely. Empowering individuals to take charge of their health is not only beneficial for personal wellbeing; it is a societal imperative. Well-designed self-care policies help prevent disease, reduce unnecessary healthcare consumption, and strengthen the sustainability of European health systems.

Throughout the year, AESGP focused its efforts on four strategic priorities: strengthening the competitiveness of the European self-care industry; supporting health literacy and digital empowerment so that citizens can make informed and responsible decisions; fostering innovation and investment through a simplified, coherent, and future-ready regulatory framework; and advancing sustainability and environmental responsibility without compromising access, affordability, or patient choice.

These objectives are not abstract ambitions. They are practical and achievable – provided that regulators, policymakers, industry, and stakeholders work together in a spirit of partnership and trust. A key message from 2025 is clear: if Europe is to continue delivering accessible, innovative, and affordable self-care solutions, the regulatory environment must support innovation rather than hinder it. Simplification, proportionality, and coherence are not luxuries; they are prerequisites for public health progress and industrial competitiveness.

In an increasingly complex geopolitical and economic context, AESGP remains firmly committed to constructive engagement with European institutions, including the leadership of the European Commission as well as the broader ecosystem of stakeholders. We stand ready to be a forward-looking partner. Building on the discussions and insights of this year, AESGP will continue to put forward concrete, solution-oriented proposals to simplify regulation, stimulate innovation, and safeguard the long-term contribution of self-care to Europe's health and resilience.

As this Annual Report demonstrates, 2025 was a year of significant advocacy, collaboration, and strategic positioning for AESGP. I would like to thank our members, partners, and stakeholders for their continued trust, expertise, and commitment. Together, we will continue to work towards a future in which self-care is fully recognised, supported, and celebrated as a cornerstone of sustainable healthcare in Europe.

About AESGP

AESGP, the Association of the European Self-Care Industry, is the voice of manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe.

Our mission

Staying healthy as a society starts with each of us. Our mission at AESGP is to support access to safe, effective, and sustainable self-care in Europe, empowering everyone to take better care of their own and their families' health.

Self-care products include 3 categories of products available without a prescription:

Medicines
(e.g., painkillers, allergy, cough and cold symptom relief)

Medical devices
(e.g., nasal wash, wart removal gels, lubricant eye drops)

Food supplements
(e.g., vitamins, minerals, probiotics)

Key facts about the self-care industry

Self-care products

The European self-care market continued to expand in 2025, reaching

€250 billion

in value, including a 2% increase in product volumes.

MEDICINES

(e.g., painkillers, allergy, cough and cold symptom relief)

4,000+

non-prescription medicines[1] are available without prescription in Europe.

That's over 250 different pharmaceutical ingredients (INN) and their combinations.

4.5 billion

packs of non-prescription products[1]

were sold in Europe in 2025.

FOOD SUPPLEMENTS

(e.g., vitamins, minerals, probiotics)

1.2 billion

packs of minerals and vitamins[1]

were bought by Europeans in 2025.

MEDICAL DEVICES

(e.g., nasal wash, wart removal gels, lubricant eye drops)

2.1 billion

packs of medical devices[1]

were purchased in Europe in 2025.

2000+ companies

Are active in the self-care/consumer healthcare sector in Europe, half of which are small and medium-sized enterprises (SMEs).

1 IQVIA Consumer Health Data 2025

Highlights 2025

Representing members

107+
meetings with EU institutions

These included meetings with the European Commission, the European Medicines Agency, and the European Food Safety Authority, among others.

73+
external engagements

On behalf of the self-care industry, AESGP participated in events organised by the European Parliament, national member associations, partners, healthcare professional associations, and other expert groups.

Global leadership

AESGP represents its members at the Global Self-Care Federation (GSCF), an organisation that connects associations and manufacturers of self-care products across more than 30 countries globally.

120+
inter-associations meetings

As part of inter-associations initiatives, AESGP meets with other industry trade associations to work on and discuss sector-specific topics, such as: pharmaceuticals in environment, broader environmental sustainability topics, electronic product information, ingredients, implementation of medical devices, and food regulations.

110+
committees AESGP committees and expert group meetings

AESGP primarily operates via nine technical committees. These are made up of AESGP member representatives and meet regularly to develop positions in key areas. Alongside these committees, a number of expert working groups and taskforces assist the technical committees on specific matters such as supply chain, switch, public affairs etc.

AESGP digital presence

Website engagement

25,000
website visits

Follow us

Social media growth

1,477
new followers

160+
posts published

Over
86,000
impressions

Flagship events & initiatives

61st AESGP Annual Meeting

The 61st AESGP Annual Meeting took place in Warsaw from 2 to 4 June, bringing together over 200 delegates to explore the evolving role of self-care in a rapidly changing world. The overarching theme was resilience, relevance, and responsibility, with a particular focus on prevention. Among the delegates were high-level representatives from European institutions and national medicines agencies, along with healthcare professionals, patient organisations, and the self-care industry. Participants discussed topics including the future of self-care product regulation, innovation, and the sector's competitiveness.

The meeting opened with remarks from AESGP President Jonathan Workman, PASMI President Ewa Jankowska, and MEPs Adam Jarubas and Borys Budka. They emphasised that Europe is at a pivotal moment, with an ageing population and growing pressure on healthcare systems. Faced with these challenges, empowering individuals through self-care and prevention is increasingly important. Speakers stressed the need for self-care to become a central pillar of the political agenda, supported by a regulatory environment that ensures access, drives innovation, and maintains stability for economic operators. They also highlighted ongoing work on an ambitious European life sciences strategy.

Regulatory cooperation and future preparedness were also central themes. Contributors included senior representatives from the European Medicines Agency, the Polish Medicines Agency, the Greek Medicines Agency, and the Medicines Evaluation Board of the Netherlands. Collectively, they exchanged views on the strategic direction of the European Medicines Regulators Network. This included sharing perspectives on the importance of stronger regulatory collaboration and enhanced engagement with the self-care sector. They also discussed collective action to address public distrust in science and regulators, counter misinformation, and ensure that Europe's regulatory system is resilient and fit for the future.

As well as regulatory and policy discussions, the meeting had a strong focus on market dynamics, innovation, and consumer behaviour. Experts from IQVIA, Simon-Kucher, and the financial sector presented data-driven insights into emerging trends and new business models in the self-care market.

Parallel sessions and roundtables saw over 40 speakers explore topics including longevity, health literacy and the value of vitamin and mineral supplements. Other discussions centred on drug-device combinations, sustainability, electronic product information, branding, and the growing use of artificial intelligence. They provided valuable perspectives that will shape AESGP's policy and advocacy priorities in the year ahead.

AESGP/TOPRA CRED course on switch

Building on a very positive first edition, AESGP and TOPRA organised a second CRED course on "Prescription to non-prescription medicines switch in EU". This provided a comprehensive overview of the regulatory framework on the Rx to OTC switch in Europe, along with the specificities of non-prescription medicines. It included examples and case studies to help turn theory into practice.

Topics covered included:

- What a switch is, and why it's important from an individual, societal and economic point of view
- The regulatory framework around switch in Europe
- How to switch – the strategy and data package that's required
- Case studies to help visualise and understand switch in practice

The course was delivered by representatives from AESGP, national associations, and self-care companies.

13 webinars organised for AESGP members

As part of our capacity-building work and commitment to keeping our members informed of the latest developments, we organised webinars covering topics including:

- Pharma law revision
- Applicability of AI Act for non-prescription medicines and self-care medical device manufacturers
- Interruption or discontinuation of supply under Article 10a of the Medical Devices Regulation
- Environmental risk assessment
- EU Sustainability Omnibus
- Ethanol – the impact of BPR and CLP procedures on self-care products
- Introduction to REACH and CLP
- Better Health Report 2025 by Simon-Kucher
- The EU Deforestation Regulation
- Evaluating credibility in digital campaigns: a practical guide and example with Influencer Monitor
- Evolution of Medical Devices in the European Self-Care Market

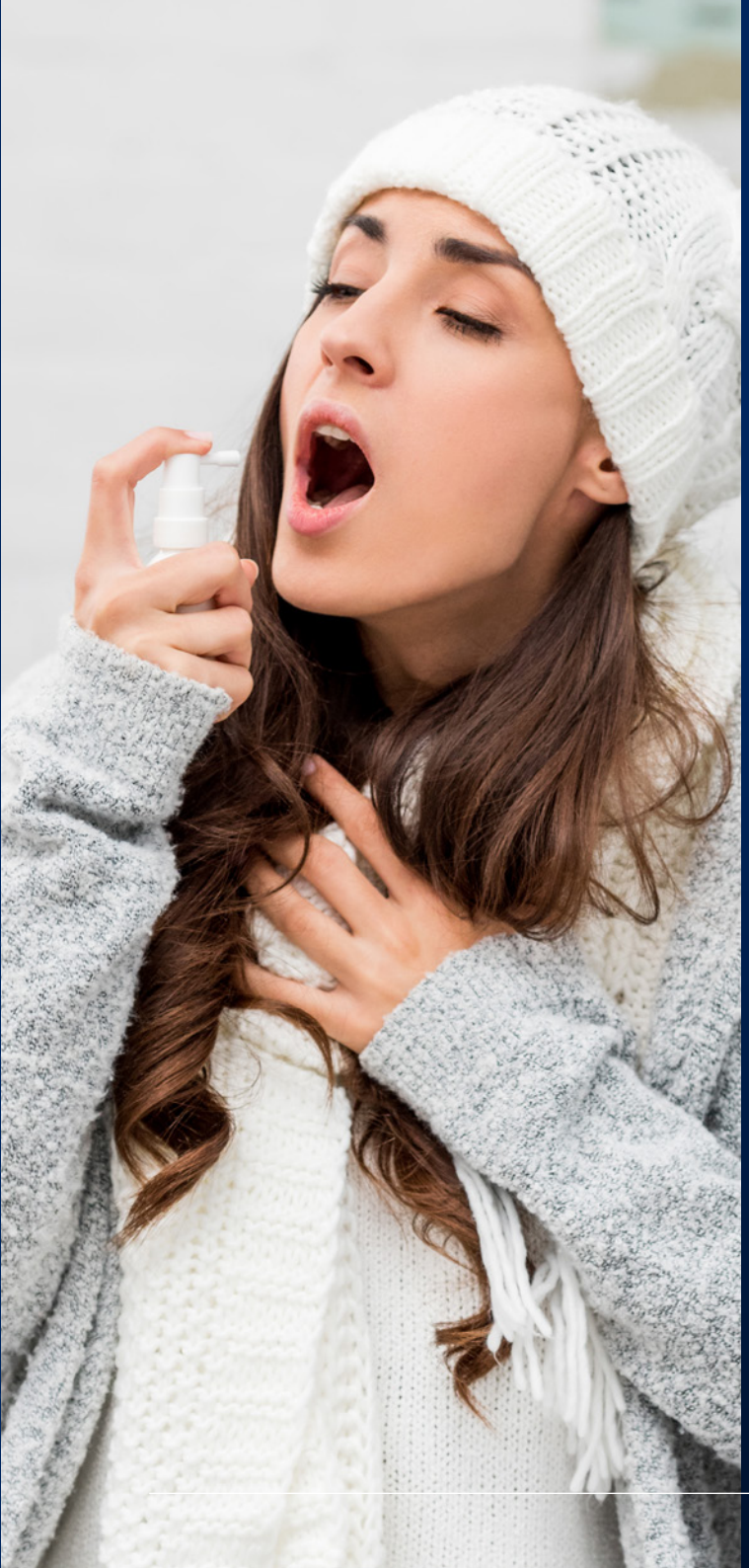
Self-Care Insight & Inspire

AESGP marked International Self-Care Day with the launch of "*Self-Care Insight & Inspire*", a new digital platform highlighting inspiring self-care initiatives from across Europe. This includes examples of awareness campaigns, health literacy programmes, and sustainability actions. The platform serves as a central hub for initiatives led or supported by the consumer healthcare industry in partnership with healthcare professionals, sectoral associations, and public authorities.

Self-Care Insight & Inspire reflects the industry's contribution to promoting public health. It goes beyond showcasing innovation to document the sector's investment in education, engagement, and empowerment. The projects featured reinforce self-care as a core element of prevention and a tool for keeping health systems sustainable. As it continues to evolve, the platform will serve as a reference point to discover, connect with, and amplify best practices in self-care.

The initiatives share a common ambition: supporting wellbeing and improving access to safe, sustainable, and responsible self-care. They cover topics including health literacy, the proper use and disposal of medicines, and managing minor ailments more effectively. Together they reflect a growing movement across Europe to strengthen preventive care and enhance individual empowerment.

Following its launch on 24 July 2025, we promoted the platform through our social media channels. Stakeholders were encouraged to share content and contribute new campaigns. Through this shared resource, we are enhancing the visibility and impact of health literacy and self-care initiatives across Europe.



Key priorities

White Paper on simplification

In 2025, we contributed to the European policy debate on regulatory simplification, building on our constructive dialogue with EU institutions and policymakers. The engagement reflected a growing recognition at EU level that the increasing complexity of Europe's healthcare regulatory framework can create unnecessary administrative burdens and slow down innovation and patient access, particularly in the self-care sector.

Our White Paper on Simplifying EU Healthcare Legislation to enhance Self-Care benefits, developed in partnership with our members, highlighted opportunities to streamline regulatory requirements for non-prescription medicines, medical devices and food supplements. The paper also addressed areas such as digitalisation, the use of real-world evidence, and environmental legislation, where overlapping or inconsistent rules risk undermining efficiency and legal certainty.

The paper focused on targeted and proportionate measures that preserve high standards of safety and consumer protection, while improving coherence and regulatory agility. By combining concrete examples with the experience of our members, we set out the case for a more future-proof regulatory environment that strengthens Europe's competitiveness, promotes innovation, and empowers citizens to take a more active role in managing their health.

Regulatory framework of non-prescription medicines

Revision of general pharmaceutical legislation

AESGP continued its advocacy work on the revision of the general pharmaceutical legislation, with a primary focus on shaping the **Council position.** We also influenced the discussion among the co-legislators in the **trilogue negotiations:** the European Parliament, Council of the EU, and European Commission.

Alongside our main position paper on the revision, we prepared several more specific position papers, trilogue briefings and evidence papers in 2025. These were developed with strong input from our members, and reflected developments in the legislative discussions on issues of particular relevance to non-prescription medicines.

We recognise that the revision aims to improve affordability, support innovation, strengthen supply security, and introduce more flexibility in the regulatory system. At the same time, we remain concerned about unintended effects on non-prescription medicines. These could affect the availability of safe and effective self-care options and, in turn, have an impact on the resilience of healthcare systems.

Several areas of concern for the self-care industry remain:

- **Prescription status.** AESGP continues to oppose a blanket prescription requirement for all antimicrobials, as this is not supported by scientific evidence and would restrict access to well-established self-care treatments. Non-prescription antifungals and antivirals used for self-limiting conditions do not contribute to antimicrobial resistance and should remain accessible without medical consultation. A study commissioned by AESGP and undertaken by IQVIA shows that delayed treatment of these conditions will likely lead to a higher dose of a product and longer treatment duration, which will increase antimicrobial use and undermine the intended purpose of this proposal.

We recommend limiting prescription criteria to antibiotics with confirmed antimicrobial resistance risks and removing their classification as hazardous to the environment.

- While AESGP acknowledges the importance of **environmental risk assessments** (ERAs) for human medicines, concerns remain about overlapping requirements, lack of proportionality and the risk of unnecessary delays in market access. ERA should not lead to automatic restrictions or refusals of non-prescription status where appropriate mitigation measures can be applied.

We recommend extending ERA (eERA) across the entire life cycle of a medicinal product as a primary regulatory tool, and emphasise the need for high-quality scientific data and alignment across agencies and legislative frameworks.

Risk mitigation measures should be used before considering the status of the product.

- The pharmaceutical industry, including the non-prescription medicines (NPM) sector, is committed to **preventing and mitigating shortages**. Thanks to a competitive marketplace and resilient supply chains, non-prescription medicines are rarely in short supply and should not be included in overly burdensome requirements.

We recommend a risk-based system, with proportionate notification timelines and standardised reporting tools that ensure the protection of commercially sensitive information.

- Regarding **product information**, AESGP supports a step-by-step approach to the implementation of electronic product information, with both paper and electronic formats available to begin with. A second stage should ideally involve the harmonised adoption of a digital-only format at EU level, with paper formats available on request. It is also crucial that unnecessary changes that could reduce usability for patients are avoided.
- AESGP has consistently called for **elements that function well** within the current framework to remain unchanged. These include rules on traditional herbal medicinal products, homeopathic medicines and advertising, which are outside the scope of the revision and have not been subject to impact assessment.

Revision of the variation system

The revision of the variation system continued with the introduction of the new **Variation Regulation** from 1 January 2025. AESGP's Variations Task Force monitored how the new provisions were implemented. We also made successful suggestions for the pragmatic application of some of the new provisions, notably with regards to the annual update exception for third countries relying on an EU licence. Separately, we analysed the variation classification guideline in advance of its implementation on 15 January 2026.

Switch

Switch from prescription to non-prescription status remains a key driver of innovation for the self-care industry, supporting competitiveness and broader access to self-care solutions. As such it continues to be a priority for AESGP.

To support alignment and knowledge exchange among our members, we organised a meeting with national associations in March that focused on switch. This gave members a platform to present their switch initiatives and share progress made at national level, fostering collaboration and mutual learning.

We initiated work on a potential revision of the EU guideline on changing the classification for the supply of a medicinal product for human use (Switch Guideline). The first phase examined what has worked well under the current framework, as well as identifying existing opportunities and determining areas for improvement. In parallel, we continued our reflection on how data exclusivity can be addressed within the guideline, including the evidence needed to support this approach in light of its role in innovation and competitiveness. This preparatory work will serve as the foundation for the development of a concrete proposal.

In November, we presented to the European Directorate for the Quality of Medicines and Health Care (EDQM) Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO). This provided an opportunity to share recent initiatives on switch, along with ongoing work at European level focusing on the value of non-prescription medicines and self-care. We emphasised the importance of continued dialogue, along with our commitment to further strengthening collaboration with the Committee to support an enabling environment for the Rx-to-OTC switch in Europe.

AESGP guidance on umbrella branding for nonprescription medicines

In 2025 AESGP published a guidance document on umbrella names for non-prescription medicinal products, prepared by a dedicated taskforce on behalf of the Regulatory Affairs Committee. This set out best practices to support and guide companies entering the self-care space. The guidance is founded on existing practices, and includes a comprehensive framework enabling companies to create and oversee umbrella names for non-prescription medicinal products. Using the guidance will ensure the umbrella name delivers on its expected benefits in a safe and controlled environment.

The guidance is based around a decision tree that explores various scenarios under which a company might choose an umbrella name. It includes advice on key factors to consider in order to ensure accurate identification of the medicinal product. Elements covered include:

- General safety considerations for umbrella names and how they support responsible self-care choices
- A decision tree and accompanying explanations to ensure the proper selection and recognition of the product
- Risk assessment and mitigation steps relating to the selection of an umbrella name
- A reminder of the pharmacovigilance measures and post-marketing monitoring measures required to track real-world data and act on signals
- A toolkit including naming essentials, a risk assessment table, and factors influencing user behaviour towards umbrella branding in the post-marketing setting

Herbal medicines

AESGP met the EMA's Herbal Medicinal Products Committee (HMPC) for a bilateral meeting in November to discuss Real-World Data and Real-World Evidence (RWD-RWE) in the context of the new pharmaceutical legislation. We argued in favour of a clear exemption for herbal medicines from Article 13 on a legal basis, reflecting the existing legal framework that refers to bibliographic applications for HMPs. On RWD-RWE, we presented the findings of two study reports documenting the use of HMPs in children.

Pharmacovigilance

During 2025, the Pharmacovigilance Committee focused on three action areas. The first of these explored the role of social media in pharmacovigilance, and involved surveying our members and collecting detailed insights on their use of social media.

The second action area was an impact assessment of modified Periodic Safety Update Report (PSUR) frequencies on European Union References Dates (EURD) list entries. The committee concluded that these lacked transparency and that implementing PRAC recommendations has led to additional challenges. The findings were communicated to the EMA.

Finally, the committee was involved in the revision of the switch guideline and in collaboration with the Regulatory Affairs Committee considered what changes would be desirable if it was reopened.

Throughout 2025 AESGP contributed to several meetings on pharmacovigilance hosted by regulators, including participating in the Pharmacovigilance Inspectors Working Group.

Medical Devices Regulation evaluation and revision

At the start of 2025, AESGP and its members contributed to the European Commission's consultation on the Medical Devices Regulation (MDR), evaluating the regulatory framework to assess its effectiveness, efficiency, and coherence. AESGP submitted its contribution in March, highlighting that the regulatory framework as currently implemented is characterised by several problematic elements. These include unpredictability and opacity, as well as cumbersome and resource-intensive processes that do not add benefits to patients and adversely affects business operators, and in particular small- and medium-sized enterprises. AESGP emphasised that the regulatory framework as currently set out undermines the competitiveness of the medical device industry and its ability to innovate, as well as hindering rapid and cost-effective market access for medical devices.

Furthermore, multi-layered governance system affects the efficiency of the CE marking process. This leads to delays in the availability of devices, while undermining the competitiveness of Europe's medical technology sector. In collaboration with other European trade associations, we prepared a joint discussion paper focusing on the centralisation of key tasks. This described specific roles and responsibilities for a future centralised governance structure for medical devices, aimed at improving efficiency and effectiveness. The Joint discussion paper on Future governance of medical technologies in Europe was published in March.

In August, the Commission announced that a legal proposal for revising the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) under the ordinary legislative procedure was planned for the end of 2025. It subsequently launched a call for evidence relating to the simplify EU rules for medical devices and in vitro diagnostics. The goal of this revision was to streamline the regulatory framework and make it more cost-efficient and proportionate while continuing to ensure high level of patient safety.

Specific objectives of the proposal included:

- Reducing the administrative burden (including reporting obligations)
- Enhancing the predictability and cost-efficiency of certification processes
- Making conformity assessment requirements more proportionate, especially for low- and medium-risk devices and those that cater to special patient needs
- Enabling further digitalisation
- Streamlining procedures, including those on governance

In our response to that call for evidence, we expressed strong support for reforming and simplifying the existing medical device regulatory regime and put forward specific reform measures that aligned with the objectives of the revision. We stressed that the primary goals of the revision must be linked to simplifying and streamlining the regulatory framework, enhancing cost-effectiveness, and ensuring a more proportionate system.

Specific reform measures proposed included:

- Reducing the frequency of certain reporting obligations, such as those relating to PSUR
- Removing the requirement for re-certification, and instead granting certificates indefinite validity
- Enabling further digitalisation by permitting electronic use instructions for self-care medical devices, underpinned by clear usability and accessibility safeguards
- Providing clarification on certain classification rules and their interpretation to make conformity assessment requirements more proportionate, especially for low- and medium risk devices

To reinforce the rationale behind these proposed reforms, we also launched an economic impact assessment of current regulatory requirements under the MDR to better understand the associated costs. Using data gathered from our members, we compiled aggregated and anonymous cost data, which was included in our response to the consultation.

In other work, we actively engaged with partner industry associations to publish two joint papers. These related to the need to remove the re-certification requirement, and the importance of further meaningful integration of digitalisation within the regulatory framework.

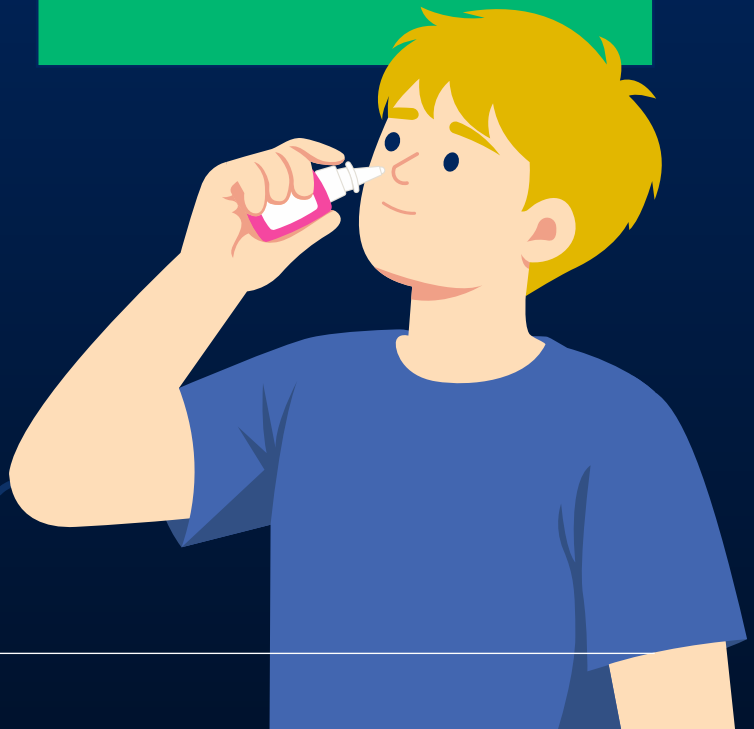
- On 4 November, we co-signed a paper calling on the European Commission and co-legislators to permit the use of a Digital label for authorised representatives and importers via the upcoming MDR/IVDR legislative revision
- On November 5, we co-signed 'Re-certification under the MDR and IVDR – Frequently Asked Questions'. This examines the challenges posed by the five-year re-certification requirement under the MDR and IVDR. It explains how continuous monitoring, audits, and post-market activities already achieve the intended safety objectives, making fixed-period re-certification largely redundant, while adding significant administrative burden and cost

On 16 December, the Commission published its legislative proposal for amending the MDR and IVDR with the aim of simplifying applicable rules, reducing the administrative burden on manufacturers, and enhancing the predictability and cost-efficiency of the certification procedure by notified bodies. The changes were also intended to safeguard existing high levels of public health protection and patient safety. In our press release on the legislative proposal, we strongly welcomed the draft reforms and their goal of simplifying the medical device regulatory regime.

In parallel with the MDR revision, the Commission started work on an implementing act to set out rules for uniform application of the requirements to be met by notified bodies listed in Annex VII of the MDR and IVDR. This work was geared towards achieving greater predictability and efficiency of conformity assessment procedures. We actively participated in associated Commission workshops and provided input and proposals on how to structure defined timelines and processes relating to conformity assessment procedures.

Data on the self-care medical devices market in Europe

In December, we presented an update on the size of the self-care medical devices market in Europe, along with accompanying trends, in collaboration with IQVIA. This was based on market data from September 2022 to June 2025 and covered 26 European countries, with a section on overall European market dynamics. The scope of the report was expanded, with seven additional countries included, compared with our first market report published in 2022. The updated report includes market size and evolution for self-care medical devices in terms of value and volume.



Food supplements

We continued to closely monitor scientific and political developments impacting the Commission's initiative to set maximum levels for vitamins or minerals in food supplements on the basis of Article 5 of the Food Supplements Directive. As part of a coalition of European trade associations representing the food supplements and fortified food sector, we engaged with relevant stakeholders to express concerns over the proposed model for calculating maximum levels.

Over the summer, we finalised an independent study to assess the impact of harmonised maximum levels for vitamins and minerals on consumer behaviour and public health. The study looked at socio-economic considerations of setting up maximum levels and produced new data reinforcing perceived value of food supplements by consumers. Study findings were circulated to members and relevant stakeholders, including the European Commission.

We produced a summary brochure entitled 'The value of Food supplements containing minerals and vitamins' aiming to simplify and streamline study results. This provides a comprehensive overview of the sector, with information on regulatory context, market size, consumer behaviour, and key trends, as well as recommendations for sustainable growth.

Our work in 2025 also focused on the use of food additives and novel foods, as well as the safety of substances other than vitamins or minerals covered by Article 8 of Regulation 1925/2006. Our work aims to ensure that the legal and regulatory framework applicable to food supplements takes a balanced and pragmatic approach.

Sustainable self-care

During 2025 we continued to build on our strong commitment to environmental sustainability and the regulation of chemicals impacting self-care products. With sustainability at the core of our strategic priorities, we worked to support our members in navigating evolving environmental and chemical policies, while ensuring the safety and accessibility of self-care products. Through active participation in key legislative discussions and industry collaborations, we enabled our members to exchange knowledge, share best practices, and work together to improve sustainability of self-care products.

Revision of Urban Waste Water Treatment Directive (UWWTD)

Throughout 2025, the Urban Waste Water Treatment Directive (UWWTD) emerged as a major crosscutting file for AESGP, combining legal and financial uncertainty, reputational sensitivity and longterm policy implications – notably through the introduction of Extended Producer Responsibility (EPR) obligations for pharmaceutical and cosmetic products.

Our work focused on four interlinked pillars:

- Monitoring legal actions and litigation
- Strategic communications
- Technical and economic substantiation (costs, scope, boundaries)
- Engagement with EU institutions and Member States

In spring 2025, Poland formally lodged a direct action for annulment against the UWWTD, targeting Article 9(1) and Annex III concerning EPR obligations. This action was registered as Case C193/25 and published in the Official Journal in April 2025. We closely monitored this development due to its potential systemic implications for the EPR framework

Legal challenges were also pursued directly by EFPIA, Cosmetics Europe and individual companies manufacturing generic medicinal products.

In light of our members' significant concerns about the UWWTD's disproportionate financial burden on the pharmaceutical sector and its flawed application of the polluter-pays principle, we submitted a request to the General Court of the European Union to intervene in EFPIA's legal action (Case T-158/25) against the Urban Wastewater Treatment Directive (UWWTD) in July.

We actively participated as an observer in the European Commission's UWWTD Expert Group, including Subgroups II and III (Monitoring Methodologies). This engagement focused on the preparation of implementing acts under Articles 8, 17 and 21. Together with other sectoral trade associations that are subject to extended producer responsibility, we presented the 10 Key Principles for the implementation or EPR, focusing on fair and balanced implementation. We ensured continuity of representation and systematic feedback to members and back to the EC.

Along with EFPIA and Cosmetics Europe, we have engaged PwC to support EPR implementation and transposition of the Directive. Deliverables of this collaboration include setting cost boundaries for EPR, with the aim of defining the scope of the costs of EPR that are not clearly defined in the legislation.

Throughout 2025, we focused on supporting national associations with the implementation of UWWTD, offering support and guidance. We circulated several implementation notes and advocacy arguments to underpin consistent national implementation. Several Member States questioned the EC's cost assumptions, and expressed a desire to carry out national data-gathering exercises on toxic loads, with a view to reassessment or a phased implementation. This reinforced our argument that implementation should not run ahead of evidence.

Revision of the Water Framework, Groundwater, and Environmental Quality Standards Directives

In 2025, we engaged intensively with the revision of the Water Framework, Groundwater, and Environmental Quality Standards Directives.

Our work focused on science based advocacy, coalition building, and timely outreach to EU institutions and Member States during the trilogue process.

We worked in a formal coalition with EFPIA, Medicines for Europe, and AnimalHealthEurope to coordinate positions, outreach and messaging towards the EU institutions, ensuring consistency across the life sciences sector.

During the year several joint position papers were developed, finalised and circulated, particularly ahead of trilogue negotiations. We consistently advanced several core recommendations

- Removal of EQS for "total pharmaceuticals"
- Not lowering Commission-proposed EQS for individual substances without scientific justification
- Rejection of EPR mechanisms under the Water Framework Directive (WFD) for monitoring costs
- Reservation of the ordinary legislative procedure for pollutant list updates
- Exclusion of TFA from PFAS group limits
- Clear cooperation between ECHA and EMA with feasible timelines for compliance (up to 2039)

The revised Directives introduced expanded watch lists (microplastics, antimicrobial resistance indicators), mandatory effect-based monitoring and enhanced reporting obligations. We followed these developments closely and provided expert input on them.

In late 2025 it was confirmed that the European Chemicals Agency (ECHA) would progressively take over scientific responsibilities from the Commission, with the Joint Research Centre (JRC) focused on pollutant prioritisation, EQS derivation, and watchlist management. We flagged shorter consultation timelines and the need for early industry preparedness.

By the end of 2025, a provisional political agreement had been reached on WFD, the Groundwater Directive (GWD), and the Environmental Quality Standards Directive (EQSD). The key industry red lines (total pharmaceuticals EQS, EPR) were largely reflected and AESGP was recognised as a credible, science-driven interlocutor. The file transitioned from negotiation to implementation and monitoring preparedness. The WFD/GWD/EQSD process also directly informed our positioning on UWWTD, EPR, and broader environmental pharmaceutical legislation.

'One Substance, One Assessment' (OSOA) package

During 2025, we continued to monitor the One Substance, One Assessment (OSOA) reform package, particularly the proposal to establish a Common Data Platform (CDP) for chemicals. The OSOA package was published on 12 December 2025 and came into force on 1 January 2026. Our priorities were to ensure that the EMA led on benefit-risk evaluations for medicinal products and retained responsibility for the management of medicinal product-related data within CDP. This is necessary to secure confidential business information while promoting proportionate, well-defined rules for data migration to the new platform. We also highlighted the importance of adequate resourcing for ECHA to reflect its expanded mandate under the OSOA framework.

Packaging and Packaging Waste Regulation (PPWR)

We continued to monitor developments of the Packaging and Packaging Waste Regulation (PPWR) and evaluate its impact on the self-care industry. The regulation, which came into force on 11 February 2025, aims to reduce environmental impact and improve recyclability across the EU. We supported the overall goals of the PPWR but emphasised the need to maintain the functionality and safety of self-care products, which is often inseparable from product packaging, in order to ensure that new standards do not compromise product integrity.

Other activities

Pharmaceuticals in the Environment (PiE) continued to be a crosscutting policy theme in 2025, intersecting environmental protection, public health, antimicrobial resistance (AMR), water legislation and industrial sustainability.

Our engagement in this area focused on:

- Scientific evidence and risk contextualisation
- Participation within the Inter-Associations Initiative (IAI) PiE Task Force
- Targeted responses to high-profile publications and policy debates
- Avoiding disproportionate or misdirected regulatory responses that could affect access to medicines and self-care products

We continued to be an active participant in the IAI PiE Task Force, working alongside EFPIA and Medicines for Europe. The task force serves as the main platform for information exchange, scientific discussion, and alignment of advocacy messages. In 2025, discussions increasingly linked PiE with Water legislation (WFD, UWWTD), drinking water, the impact of azole fungicides (outside of human use), manufacturing emissions, and climate-related impacts on river dilution capacity.

We formally engaged with the European Commission by submitting detailed written comments to the Pharmaceutical Committee AdHoc Working Group on +Pharmaceuticals in the Environment, contributing to the follow-up of the EU Strategic Approach on PiE. We welcomed the report's holistic, lifecycle-based approach and used the consultation to highlight the substantial progress already achieved by industry and other stakeholders in areas such as safe manufacturing practices, environmental risk assessments (ERA), mitigation measures and research initiatives. The submission aimed to ensure that these contributions are duly recognised alongside those of public authorities, academia and civil society, and to support a balanced and evidence-based understanding of the current state of play.

Through our comments, we also provided targeted recommendations to strengthen the report's conclusions and implementation perspectives. These included stressing the importance of prudent and responsible use of medicines without undermining clinical decision-making; supporting the integration of environmental considerations into medical education and professional training; and endorsing harmonised guidance on environmental aspects in advertising and prescription practices. We raised specific concerns regarding the inappropriate, and sometimes equivocal, use of the term "over-the-counter (OTC)" in EU regulatory and scientific contexts; advocated for proportionate and science-driven waste management approaches; and supported improved environmental expertise within EU committees and networks. Overall, we reaffirmed our commitment to continued collaboration with the European Commission and stakeholders, offering our expertise and data to support pragmatic, effective and patient-centred environmental policies.

Digital transition

We pursued our advocacy efforts in key strategic areas in line with our digital strategy, published in 2021. These strategic areas include: real-world data and evidence, artificial intelligence, product and disease information, building the capacity of the digital workforce, and eCommerce. We also initiated a review of our digital strategy to ensure it remains aligned with evolving regulatory requirements and recent digital developments. This review will focus on identifying opportunities to further support members in leveraging digitalisation within the EU regulatory framework.

European Health Data Space

On 5 March, AESGP, as part of a coalition of 39 health stakeholder organisations representing patients, health professionals, researchers and industrial actors in the healthcare ecosystem at both EU and Member State level, published a joint statement welcoming the publication of the European Health Data Space (EHDS) regulation and sharing some key recommendations for its implementation. Of these, the establishment of a well-resourced stakeholder forum was seen as critical.

We also provided comments on the implementing act on EHDS board operations. In our response, we highlighted that while the draft implementing act clarifies certain operational elements, we believe that additional formalisation of specific provisions is necessary to ensure consistency. The nature and frequency of interactions between the Stakeholder Forum and the EHDS Board should be formalised, guaranteeing structured and periodic dialogue. In addition, expertise from a wide range of stakeholders should be further leveraged through consultations and the use of subgroups.

Digital product information

Electronic product information for medicines

In 2025 the AESGP ePI working group for nonprescription medicines (NPM) focused on developing a shared industry understanding and position on how electronic product information should be accessed by individuals. The group coordinated member input to the EMA public consultation on linking ePI to EU medicine packages, ensuring that the specificities of the self-care sector were clearly reflected. It also held dedicated exchanges to explore feasible approaches for non-prescription medicines. This work informed ongoing dialogue with the regulator. Discussions and technical analysis continued into 2026 to further refine our position and support the implementation of ePI.

As well as the contribution made by our dedicated working group on ePI, we participate in the Inter-Association Task Force for ePI1. We co-lead the task force's two working groups, and are a member of the steering group.

In January, AESGP, EFPIA and Medicines for Europe jointly released a series of position papers advocating for the speedy implementation of electronic Product Information (ePI) and improvement of the content included in patient leaflets. The pharmaceutical industry urged regulatory bodies across Europe to adopt a harmonised implementation of ePI. This transition is critical both to advance patient care and to enhance regulatory operations and address environmental challenges.

In June, we submitted a response on linking to ePI from the EU medicines packages on behalf of the Inter-Association Task force for ePI. At steering group level, we continued to work on the assessment of proposed changes to the general pharmaceutical legislation with regard to implementing ePI. The steering group engaged with a number of topics with different stakeholders, such as the European Medicines Agency (EMA), throughout 2025.

Under our leadership, the Content Working Group coordinated the Inter-association task force's response to the revised QRD template. It also met

1 The Inter-Association Task force comprises AESGP, EFPIA and Medicines for Europe.

regularly with the EMA's QRD subgroup to discuss labelling and translation quality issues.

With regards to the Key Information Section (KIS) proposal, industry identified risks in extending already long leaflets by duplicating some of the information, potentially creating confusion and making the life cycle more complex. These arguments were supported by concrete user-testing results performed by a volunteer company. Based on the industry data submitted, the proposal was not retained in the final text. We continue to argue in favour of measures promoting short and concise leaflets based on patient needs.

The WG Technics focused on three main topics during 2025: the best alternatives to the paper package leaflet; the most appropriate ePI Identifier (ID); and dissemination of ePI beyond the EMA/HMA portal. The group also provided support to the nominated ePI subject matter experts and shared what was perceived as being needed with the EMA before going live with the ePI portal.

Electronic instructions for use (eIFU) for medical devices

According to the Medical Devices Regulation (MDR), manufacturers must provide detailed instructions for use (IFU) to guide the proper and safe use of medical devices. For specific categories of devices and under certain conditions (such as administration by healthcare professionals, and further defined in Regulation (EU) 2021/2226), these instructions may be provided in electronic form only. We have been advocating for an extension of the use of electronic instructions for medical devices, both to enhance access to information and enable information to be provided in different formats and languages.

Consortia

In 2025, we launched a series of ingredient consortia to facilitate the generation of environmental risk assessments (ERAs) for active pharmaceutical ingredients used in the self-care sector. This initiative was introduced in response to evolving EU regulatory expectations and the growing need for robust, up-to-date environmental data for legacy products, where the concept of originator is no longer applicable.

While the first consortia focus on ERA, the framework is designed with flexibility in mind and can support collaboration on a wider range of ingredient-related regulatory challenges as needs emerge. Against this background, the consortia provide companies with a structured and legally compliant platform to collaborate on shared regulatory priorities – particularly where joint data generation and data sharing are required. They enable participating companies to pool expertise and resources, reducing duplication of effort and animal testing, and ensuring fair cost-sharing.

We act as a neutral coordinator, manager, and facilitator of the consortia, providing the necessary structure and support for their functioning. We also serve as a single interface with external service providers. Together, these elements enable efficient collaboration, while ensuring compliance with competition law and confidentiality requirements.

Stakeholder engagement

Stakeholder engagement with EU institutions and international public authorities

During 2025, we maintained continuous and structured engagement with EU institutions and international public authorities, positioning the self-care sector as a constructive and evidence-based interlocutor. At EU level, we interacted regularly with the European Commission, the European Parliament, the Council and EU agencies including EMA, ECHA and EFSA. These interactions took place through formal consultations, expert group participation and targeted submissions on pharmaceuticals legislation, environmental policy, chemicals regulation and the availability of medicines.

Beyond the EU, we also monitored and engaged with international public health bodies, including the World Health Organization (WHO) and Organisation for Economic Co-operation and Development (OECD), particularly in relation to pharmaceuticals in the environment, antimicrobial resistance policies, and the use of terminology affecting nonprescription medicines. This ensured alignment between EU-level policy discussions and broader global health and regulatory debates, while allowing us to anticipate reputational and policy spillovers from international guidance.

Engagement with Member States, Permanent Representations and national authorities

Our stakeholder engagement during 2025 relied strongly on Member State outreach, both directly and via our network of national associations. We actively encouraged and coordinated contacts with national ministries, regulators and Permanent Representations based in Brussels during critical legislative moments. Interactions included Council-level discussions on environmental files, food supplements, pharmaceuticals in the environment and access to medicines. National associations were mobilised to relay joint industry messages, gather intelligence from capitals, and feed national perspectives back into EU-level advocacy. This engagement reinforced our role as a bridge between EU institutions and the realities of national markets. It ensured that factors such as the feasibility of implementing measures, subsidiarity and national health system considerations were consistently reflected in policy debates.

Cross-industry and inter-association engagement

A significant share of our 2025 stakeholder engagement took place through cross-industry and inter-association coordination. We worked closely with European peers such as EFPIA, Medicines for Europe, MedTech Europe, and Food Supplements Europe. We also engaged with packaging and sustainability platforms and standardisation bodies, aligning positions on a range of shared priorities. These included pharmaceuticals in the environment, PFAS restrictions, the UWWTD, electronic product information, and broader industrial competitiveness. This cooperation extended to joint meetings, as well as joint policy positions and evidence generation, plus coordinated messaging towards policymakers and agencies.

Engagement with consumer organisations, patients and civil society

In 2025, we also engaged with the consumer, patient and civil-society ecosystem to ensure that AESGP remains centred around the needs of individuals and society. In particular, we worked closely with patient organisations, including the European Patients' Forum, as well as broader alliances, such as World Patient Alliance. These interactions enabled us to pursue a dialogue on topics including health literacy, the responsible use of medicines, the impact of environment policies, and sharing of regulatory knowledge. It supported capacity-building within patient and other communities, in turn enabling us to incorporate patient needs and the real-world use of self-care products into our work.

Publications

New industry papers

During 2025 AESGP published a series of new positions, articles, responses to major events, and key EU legislative and policy proposals:

Medicines

- AESGP Evidence Paper: Antivirals used in the self-care sector
- AESGP Evidence Paper: Antifungals used in the self-care sector
- AESGP Position Paper: Industry Guidance on Umbrella Names for Non-Prescription Medicinal Products
- AESGP welcomes political agreement on the EU pharmaceutical package to strengthen access and competitiveness

Medical devices

- AESGP welcomes EU's push for smarter Medical Devices Regulation

Environment

- UWWTD: AESGP expresses concerns over disproportionate and unfair application of Extended Producer Responsibility
- AESGP Submits Request to Intervene in EFPIA Legal Action on UWWTD

Joint papers and statements

Together with other trade associations, the following joint papers and statements were published:

Medical devices

- Joint Paper: Clinical strategy as part of pre-submission dialogue between manufacturer and Notified Body
- Article 10a MDR / IVDR: Notification in Case of Interruption or Discontinuation of Supply – Decision Guide Flowchart
- Joint discussion paper : Future governance of medical technologies in Europe
- Open letter to the European Commission: protecting Europe's medical technology sector from the risks of tariffs
- Re-certification under the MDR and IVDR – Frequently Asked Questions

Digital

- Inter-Association Task Force Position Papers on Electronic Product Information
- Joint Statement: A Call for Effective Stakeholder Engagement and Capacity Building during the Implementation of the European Health Data Space
- Joint Position Paper: Digital label for authorised representative and importer

Environment

- Joint Statement: European Commission risks repeating past mistakes in Urban Wastewater Treatment Directive cost study

Engaging with the media

AESGP's position and activities were reflected in different media outlets, including*:

HBW Insight

- Associations On 2025: Self-Care Adoption, Innovation And Sustainability On Agenda
- EU Industry Calls For Earlier And Harmonized Adoption Of Electronic Product Information
- AESGP Slams 'Deeply Concerning And Discriminatory' EU Wastewater Directive
- Over The Counter: What To Expect From The 61st AESGP Annual Meeting, With Jūratė Švarcaitė
- AESGP: 'No Evidence' Of Antimicrobial Resistance With OTC Antifungals Or Antivirals
- Plenty For Industry To Do As EU Wastewater Directive Faces Legal Challenges
- US Tariffs Pose 'Existential Threat' To EU Medical Devices Industry
- AESGP Annual Meeting: Wastewater Directive Impact Assessment 'Fundamentally Flawed'
- AESGP Annual Meeting: Commission Must 'Think Carefully' Before Reverse-Switching Antimicrobials
- AESGP Annual Meeting: Harmonizing EU VMS Max Levels Could Cost Sector Over €200m
- AESGP Annual Meeting: European OTC Market Outlook 'Very Positive' Thanks To Prevention Trend
- AESGP Annual Meeting: Consumer Health Sector Still Safe Bet For Investors
- International Self-Care Day: 'Cyberchondria' In The UK, Best Practices In The EU
- Urban Wastewater Directive: AESGP Requests Intervention In EFPIA's Legal Action
- eBOOK – New Rules. Market Shifts. What's Next for EU Consumer Health?
- Over The Counter: Celebrating Europe's Consumer Health Best Practice, With AESGP's Luis Rhodes
- 'Lessons Have Not Been Learned' On UWWTD Ahead Of Fresh Study By EU Commission
- Industry Blasts Commission's Urban Wastewater Directive Cost Review

The Parliament Magazine

- Self-care: Europe's most underused health system ally

Open Access Government

- Self-Care: A Pillar of Modern Public Health

Other

- The "Poranek PO" campaign appreciated in Poland and Europe (Termedia, Poland)
- El autocuidado europeo celebra el pacto legislativo como un "paso decisivo hacia la modernización" (Diario Farma, Spain)

* Since AESGP does not rely on a specialised press tracking tool, the above list might not fully represent the number of articles published.

Governance

The highest governing body is the **AESGP General Assembly**, to which all members of the Association belong.

The strategic leadership and management of the Association is in the hands of the **AESGP Board**, made up of representatives from member associations and companies. The AESGP Board is led by the Executive team and chaired by the President:

AESGP President 2025–2027

Jonathan Workman
General Manager for Northern Europe Business Unit
Haleon

AESGP Vice-President 2025–2027

Traugott Ulrich
Executive Director
Schwabe Pharma

AESGP Vice-President 2025–2027

Bernard Mauritz
Director General
Neprofarm, *the Netherlands*

AESGP Treasurer 2025–2027

Jaume Pey
Director General
anefp, *Spain*

AESGP team

The day to day operations of the AESGP are placed under the direction of the Director General and Deputy Director appointed by, and responsible to, the AESGP Board. The Director General and Deputy Director are supported by the AESGP Secretariat, located at the AESGP offices in Brussels.

AESGP Secretariat members are:

Jūratė Švarcaitė
Director General

Maud Perrudin
Deputy Director General

Christelle Anquez-Traxler
Senior Regulatory Science and Strategy Lead

Klavdija Kmetič
Regulatory Affairs and Policy Manager

Oliver Hartmann
Regulatory and Legal Affairs Director

Ville-Waltteri Virtanen
Regulatory Affairs Manager

Viviane Papas
Junior Public Affairs Manager

Paul-Etienne Schaeffer
Life-Sciences Regulatory Affairs Manager

Luis Rhodes Baiao
Governmental and Public Affairs Manager

Laura Pascual
Office and Events Manager

Alix Marchal
Communications and Projects Manager

Mihai Ionita
Regulatory Affairs Manager

Letizia Andres Calvo
Junior Regulatory Affairs Manager

Sonia Terekova
Projects Manager

Members & Partners

More than 2,000 companies operate in the consumer healthcare sector in Europe.

They are affiliated with AESGP either directly or through one of the **21 national associations.**

National Associations

anefp Autocuidado de la Salud
apifarma
ASSGP
FEDERCHIMICA ASSOSALUTE
BACHI
ΕΦΕΞ
iGEPHA The Austrian Consumer Health Care Association
ipha
lif
LMI Legemiddelindustrien
MAGYOSZ
Neprofarm
Nères
PAGB
PASMI
PHARMA DEUTSCHLAND
LääketeIlisuus Pharma Industry Finland
pharma.be
RASCI
SPMA
SVOPL

International Companies

BAYER
HALEON
Kenvue
Opella.
P&G Health
Perrigo
reckitt
SCHWABE
UPSA
Bionorica

Associate Members

Aboca
ALKALOID SKOPJE
ASSOBIOMEDICA
BOIRON
Boots
GALDERMA
indena
MAYOLY SPINDLER
medicalbrands
Pierre Fabre

Partners

Partners support AESGP in its efforts to represent the self-care industry and benefit from opportunities to establish new business relations with actors from the self-care sector.

SIMON KUCHER Unlocking better growth
IQVIA CONSUMER HEALTH
HBW INSIGHT CITELINE COMMERCIAL

AESGP

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