AESGP ACTIVITY REPORT 2024

Celebrating 60 years of self-care

1964
2024

Contents

Foreword

by Jonathan Workman, AESGP President

In 2024, we proudly celebrated 60 years of AESGP. Over the past six decades, the evolution of our industry has significantly improved the everyday lives of European citizens, enabling them to self-manage a wide variety of ailments and everyday health issues with safe, effective, and sustainable self-care products.

AESGP was founded in Paris on 3 February 1964 by three companies: Miles, Nicholas, and Vick. They aimed to address the threats and opportunities facing the proprietary medicines industry at the time. The industry was dealing with a challenging political environment, including tighter marketing authorisation procedures, stricter manufacturing controls, and stringent distribution rules. Additionally, there were threats to its ability to advertise and individual rights to self-medicate.

By 1967, our association had grown to include nine national groups, representing over 300 companies. We quickly became the key link between our industry and the European Community institutions. Thanks to our efforts, by the late 1970s and early 1980s, European institutions and international bodies like the WHO began to recognise the critical role individuals could play in maintaining their own health.

AESGP's recognition as a key player continued to grow. In 1981, we were granted non-governmental organisation status within the Council of Europe, and in 1986 we participated in the WHO's annual meeting in Copenhagen. This led to new European legislation in 1992 that recognised the role of non-prescription medicines and allowed them to be advertised to the public.

In 2020, AESGP played a crucial role in supporting both the industry and society during the pandemic, making sure that self-care products remained available in community pharmacies, and helping to relieve the burden on healthcare systems, ensuring that care was reserved for critically ill patients.

In 2024, we saw the adoption of the Urban Waste Water Treatment Directive (UWWTD), which places a significant burden on our industry. A key provision of the Directive introduces a new Extended Producer Responsibility (EPR) system. While AESGP supports the principle of EPR, its selective application – targeting only human medicines and cosmetic products in urban wastewater – is deeply concerning and discriminatory. The Directive's provisions may arguably breach general principles

> *"Our industry has significantly improved the everyday lives of European citizens, enabling them to self-manage a wide variety of ailments and everyday health issues with safe, effective, and sustainable self-care products."*

of EU law, such as the principles of proportionality, legal certainty, and the "polluter-pays" principle. Moreover, Member States now assess the financial implications, and they are finding that actual costs of implementing quaternary treatment are three to eight times higher than originally projected. Therefore, we will continue to engage with partners throughout 2025 and beyond to seek clarity and fairness, using all available avenues to ensure that the UWWTD doesn't undermine our ability to provide affordable self-care solutions for EU citizens and the competitiveness of EU industries.

Our success is the result of the enormous help and collaboration we share with EU authorities, national regulators, policymakers, healthcare professionals, professional bodies, patient and consumer groups, fellow industry associations, and many others.

I would like to extend a huge thank-you to all our members, past and present; board members, past and present; and all AESGP staff, past and present.

You all – we – have achieved this. Let's continue celebrating self-care every day.

"Our success is the result of the enormous help and collaboration we share with EU authorities, national regulators, policymakers, healthcare professionals, professional bodies, patient and consumer groups, fellow industry associations, and many others."

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.

KEY FACTS ABOUT THE SELF-CARE INDUSTRY

Self-care products

Self-care products include three categories of products available without a prescription

Medicines

(e.g., painkillers, antihistamines)

Food supplements

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

Medical devices

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

MEDICINES

4,000+

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

That's over **200 different pharmaceutical ingredients (INN) and their combinations**. At least 13 switches took place in 10 European countries in 2024.[2]

4.7 billion

packs of non-prescription medicines[3]

were sold in Europe in 2024.

1.2 billion

minor health issues per year are self-managed with the aid of non-prescription medicines

Ailments that are typically self-managed with self-care products include allergies, gastrointestinal disorders, cuts, bites and rashes, cough and cold, and pain.

€34 billion

saved for national health systems and economies

Non-prescription medicines save money that would otherwise be spent on unnecessary doctor's appointments, on prescribed medication, and on missed work.

FOOD SUPPLEMENTS

1.3 billion

packs of minerals and vitamins[4]

were bought by Europeans in 2024.

MEDICAL DEVICES

2.2 billion

packs of medical devices[5]

are purchased in Europe every year.

2,000+

companies

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

1, 5 IQVIA Consumer Health Data 2022
2 AESGP Ingredient Database 2025
3, 4 IQVIA Consumer Health Data 2024

Highlights 2024

REPRESENTING MEMBERS

80+
meetings with EU institutions and agencies

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

30+
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.

116+
inter-association meetings

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

110+
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 assist the technical committees on specific matters such as supply chain, switch, etc.

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.

AESGP DIGITAL PRESENCE

Website engagement

- **59,000** website visits 📈

Social media growth

- **1,170** new followers 🌟
- **200+** posts published 📢
- Over **107,000** impressions 👀

Follow us on LinkedIn, X, and Bluesky

FLAGSHIP EVENTS & INITIATIVES

60th AESGP Annual Meeting

AESGP's annual meetings explore key issues and trends impacting the European consumer health industry. The 60th AESGP Annual Meeting was no exception, bringing together more than 300 participants from around the world, including experts, policymakers, stakeholders and members, to reflect on the organisation's achievements and chart the way forward for the future of self-care.

Dedicated to 'Celebrating 60 years of self-care', the 60th AESGP Annual Meeting kicked off on the evening of 4 June with a Self-Care Gala at the recently restored historical stock market in the centre of Brussels. The iconic Bourse – Beurs set the stage for celebrating the milestones of AESGP and the contribution of its members and stakeholders in ensuring access to safe, effective, and sustainable self-care in Europe.

AESGP President, Jonathan Workman, opened the meeting with a powerful call to action: to seize the opportunities rooted in the economic and social value of non-prescription medicines, medical devices and food supplements, and build a healthier Europe by enhancing healthcare systems, integrating personalised self-care, and empowering individuals to effectively manage their well-being.

Over the following days, the meeting offered thought-leadership sessions and technical workshops covering critical topics for the sector, such as the role of self-care in transforming health and social care, regulatory systems, sustainable packaging, and many more. Sustainability, digitalisation, and artificial intelligence emerged as key themes, reflecting the industry's commitment to innovation and environmental stewardship.

With its wide-ranging footprint across OTC medicines, food supplements and self-care medical devices, the consumer health industry faces an avalanche of regulations, and AESGP continues to be an effective advocate for its stakeholders, alongside complementary industry partners.

Welcome MEP class of 2024: AESGP Reception with newly elected MEPs

Highlighting the economic and social value of non-prescription medicines, medical devices, and food supplements, AESGP presented its *Vision for a Sustainable Europe* to over 200 representatives from the incoming cohort of Members of the European Parliament (MEPs) and Accredited Parliamentary Assistants (APAs) at a networking reception organised in partnership with The Parliament magazine.

As the European Parliament and Commission prepared for their next leadership cycle, AESGP called for a commitment to a healthier Europe through self-care. By enhancing healthcare infrastructure, promoting personalised self-care, and empowering individuals, we can create a Europe that prioritises well-being and stands as a beacon of health and prosperity.

60th AESGP Annual Meeting

More than **300** participants

5 plenary sessions

6 parallel workshops

60 speakers

#AESGP60AM

FLAGSHIP EVENTS & INITIATIVES

AESGP/TOPRA launch CRED online course on switch in the EU

AESGP, in partnership with TOPRA, organised a CRED course on 'Prescription to non-prescription medicines switch in EU'. The course provided a comprehensive overview of the regulatory framework underpinning the Rx to OTC switch in Europe and the specificities of non-prescription medicines. It also provided several examples to help understand how to turn theory into practice.

Topics covered by the session included:

- What is a switch? Why is it important from an individual, societal and economic point of view?
- What is the regulatory framework around switch in Europe?
- How to switch – the strategy and data package required.
- Case studies to help understand switch in practice.

Presenters included representatives from AESGP, national associations and consumer health companies.

12 webinars organised for AESGP members

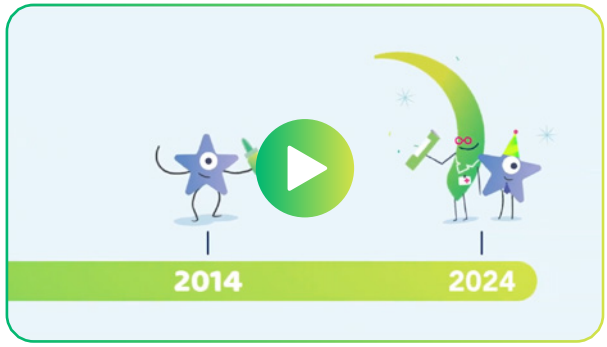
As part of our capacity building and commitment to keeping our members informed of the latest developments, AESGP organised several webinars covering topics including:

- One Substance, One Assessment (OSOA) legislative proposal;
- ESG in communications;
- Packaging and Packaging Waste Regulation (PPWR);
- Pharma Law revision;
- Best practices in extended producer responsibility;
- Transition to electronic product information;
- Introduction to the enhanced AESGP OTC ingredients directory;
- Implementation of the Urban Waste Water Treatment Directive (UWWTD);
- Key trends in self-care;
- The impact of the General Product Safety Regulation and New Product Liability Directive on the medical devices sector;
- The impact of the revised CLP regulation on the self-care sector;
- The responsible use of non-prescription antimicrobials in Europe.

FLAGSHIP EVENTS & INITIATIVES

Celebrating 60 years of AESGP and self-care

During 2024, AESGP proudly marked its **60th anniversary**! Founded in Paris in 1964 – when 'self-care' was often associated with simple home remedies – AESGP has since evolved to become the voice of over 2,000 companies in the consumer healthcare sector in Europe, affiliated directly or indirectly through national associations. Today, self-care is a well-defined concept, recognised by the WHO and international institutions, and has become an integral part of health policy in Europe.



Watch a recap of the last 60 years in self-care here.

Our 60th anniversary celebrations took centre stage at the **60th AESGP Annual Meeting** (June 4–6, Brussels), bringing together 300+ professionals from the self-care sector. From European institutions and pharmaceutical companies to healthcare professionals, regulators, and national authorities, the event was a testament to the strength and reach of our community.

To honour this milestone, we also launched a **special testimonial campaign**, 'Celebrating 60 Years of AESGP and Self-Care', on International Self-Care Day (24 July 2024) across our social media channels. Over the course of seven months, the campaign featured 50 powerful testimonials from AESGP, industry leaders, and key EU stakeholders. These voices – from policymakers to healthcare professionals and consumer health advocates – shared their perspectives on AESGP's impact and the evolution of self-care in Europe.

Testimonials were grouped into four key themes:

- Empowering self-care in Europe and beyond since 1964
- Building new connections to strengthen the voice of self-care
- Working with an ever-expanding network to meet our growing responsibilities
- Advocating self-care as a key to well-being, innovation, and sustainability

With high engagement rates and strong support from our community, the campaign successfully wrapped up in early February 2025, reinforcing the vital role AESGP plays in shaping the future of self-care.

We want to extend a heartfelt thank you to all our members, partners, and supporters who have been part of this journey over the last 60 years. Your dedication and collaboration have been instrumental in advancing self-care and strengthening sustainable healthcare across Europe. As we look ahead, we are excited to continue working together to shape the future of self-care for generations to come!

Read and watch the testimonials!

Key priorities

REGULATORY FRAMEWORK OF NON-PRESCRIPTION MEDICINES

Revision of general pharmaceutical legislation

AESGP continued its advocacy work on the revision of the general pharmaceutical legislation. Following on from the publication of new European Commission proposals in 2023, our work focused on raising awareness of the position of the self-care industry to both co-legislators, the European Parliament and Council of EU. As well as publishing an overarching position paper on the revision, AESGP developed a number of specific position papers, featuring accompanying evidence, with the crucial support of members and their experience on the ground.

AESGP appreciates that the revision of pharmaceutical legislation addresses affordability, promotes innovation, enhances supply security, and increases regulatory flexibility. Nevertheless, we remain concerned about unintended consequences affecting non-prescription medicines, which may impair the availability of safe and effective self-care options for patients and threaten the sustainability of healthcare systems.

Areas of concern for the self-care industry remain:

- **Prescription status:** AESGP is concerned about the broad definition of antimicrobials in the proposal. Restricting their availability as a self-care intervention without scientific justification could lead to delayed treatment and increased spread of diseases, negatively impacting public health and healthcare systems. Additionally, applying blanket prescription criteria for any medicines classified as hazardous to environment is disproportionate and unjustified. Other risk mitigation measures should be explored first.

We recommend limiting prescription criteria to antibiotics with confirmed antimicrobial resistance risks. Other risk mitigation measures than prescription should be applied for medicines classified as hazardous to environment.

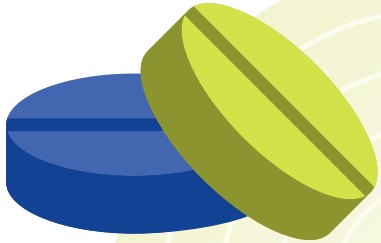
- While AESGP acknowledges the importance of **environmental risk assessments** (ERAs) for human medicines, the legislative proposal has a number of shortcomings, including repetitive studies, inconsistent conclusions, and an unequal testing burden.

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.

- The pharmaceutical industry, including the non-prescription medicines (NPMs) 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.

We propose a risk-based approach, with shortage prevention plans and notification requirements limited to critical non-prescription medicines, and notifications for all medicines submitted at least two months in advance.

- Regarding **product information**, we advocate for a smooth and harmonised EU transition to digital product information, given its numerous benefits.
- **Scope:** advertising and regulatory requirements for traditional herbal and homeopathic medicines should remain unchanged, as they have not been subject to an impact assessment.



Revision of the variation system

AESGP welcomed the revision of the variation system with the aim of modernising it. We provided feedback on the draft delegated Act and the draft variation classification guideline, emphasising the need to leverage digital technology in order to enable direct upload of simple administrative changes into the OMPS/PMS database. We also called for a more risk-based approach and the possibility to downgrade variation classification; a level playing field between chemical and herbal APIs; and the extension of grouping and work-sharing. Throughout the year, AESGP promoted its key proposals in relevant regulatory fora with the European Commission, EMA, CMDh, and National Competent Authorities.

Switch

Switch from prescription to non-prescription status is a key source of innovation for the self-care industry and remains a key focus for AESGP.

In the first half of 2024, with the support of global switch expert Dr Natalie Gauld, we explored a potential revision of the AESGP Self-Care Indication chart from 2002. Key opinion leaders in the area of healthcare and self-care were interviewed and asked to look 20 years into the future to explore how self-care would look like in 2045. They concluded that most indications from the 2002 chart remained relevant and continued to provide a solid basis for identifying unmet self-care needs and future switch opportunities. Throughout the exercise, key elements were identified that would influence self-care in the future, with further reflection on how these could further enable Rx-to-OTC switches.

In parallel, AESGP revised and relaunched its OTC ingredient database with new functionalities and data, in order to make the database more user-friendly and ensure that it is up to date and relevant.

Non-prescription medicines containing antimicrobials

In its efforts to curb antimicrobial resistance (AMR), the European Commission's proposal for revision of general pharmaceutical legislation includes a new prescription criterion (Article 51) that would classify all antimicrobial products (antibiotics, antifungals and antivirals) as prescription-only medicines.

Currently, a number of antifungal and antiviral medicinal products are available as non-prescription medicines and can be sold without the need for a medical prescription. They cover conditions that can be self-managed effectively, such as athlete's foot, cold sores (labial herpes), vaginal thrush, dandruff, warts, etc.

AESGP commissioned a study to understand the impact of this proposal on both individuals and health systems. The study, which was conducted by IQVIA, evaluated the potential health outcomes, socioeconomic consequences, and the impact on the volume of antifungals and antivirals used.

The impact assessment revealed that the proposed reclassification of non-prescription antimicrobials to prescription-only status would have negative socio-economic and healthcare implications:

1. **Delays in seeking care** due to reduced accessibility of treatment could lead to the exacerbation of conditions, resulting in an estimated 19.2 million unresolved cases, plus increased severity of illnesses over time.
2. **Additional burden and costs to the healthcare system.** The shift of patients to the healthcare system would create substantial additional burdens and costs. It is anticipated that there would be an increase of 59 million additional visits to doctors, including 11 million emergency care visits.
3. The **economic impact** on individuals would include productivity losses equivalent to €1.8 billion, resulting from time spent seeking outpatient care and dealing with the consequences of worsening conditions. These productivity losses highlight the broader socio-economic implications of reverse-switching beyond costs related to the healthcare system.
4. Contrary to the intended outcome, reverse-switching may not have the desired impact in reducing the volume of antiviral and antifungal medicines used. Paradoxically, there would be a **potential increase in use** of 58% and 32% respectively.

Therefore, the proposal to restrict access to antimicrobials may not only fall short of its aim to reduce consumption of those products but could also introduce new complexities in managing public health.

AESGP also issued two evidence papers on antivirals and antifungals, illustrating that the risk of resistance to antimicrobials available in non-prescription form was linked to underlying conditions (e.g. immunocompromised patients), for which antifungals and antivirals are already prescribed at high doses and via systemic routes.

Shortages and critical medicines

Due to low shortage prevalences and the wide range of alternative non-prescription medicines available, **AESGP supports submission of shortage notifications two months in advance, with shortage prevention plans only implemented for critical non-prescription medicines in the ongoing revision of general pharmaceutical legislation.**

The second Union list of critical medicines, published in late 2024, supports the industry's call for proportional measures to address shortage risks. It includes only three non-prescription ingredients: hydroxocobalamin, medicinal charcoal, and caffeine.

In February 2024, AESGP became a member of the Critical Medicines Alliance (CMA). The aim of the Alliance is to strengthen cooperation between the Commission, national governments, industry, and civil society. It has a five-year mandate and aims to identify the challenges, priorities for action, and possible policy solutions to the issue of shortages of critical medicines in the EU. The Alliance is a consultative mechanism that will also act as a network to accelerate the delivery of EU action in this field. AESGP was invited to join the CMA's Steering Board.

The work of the Alliance is primarily carried out via two working groups:

- **Working Group 1** 'Strengthening manufacturing capacities in the EU for critical medicines to better prevent and fight their shortages'
- **Working Group 2** 'Diversification of supply chains, international partnerships and cooperation'

AESGP has nominated three experts to the working groups. The Alliance's first deliverables include a report on medicines supply chain vulnerabilities and remedies – concerns which formed the basis for the Critical Medicines Act. This report, which was finalised in 2025, proposes a number of industrial policy actions to strengthen the supply chains of critical medicines and medical devices.

Herbal medicines

AESGP organised a joint meeting of its Herbal Medicinal Products Committee (HMPC) and the EMA Committee on Herbal Medicinal Products (HMPC). Discussions centred around Real-World Data (RWD) and Real-World Evidence (RWE) and the revision of the variation's framework. AESGP presented its paper published in Planta Medica calling for better descriptions of herbal medicines in registries, databases and publications to unleash the potential of RWD-RWE for herbal products, as well as the outcome of its work in a dedicated group on RWD-RWE for herbals. On variations, it emphasised the need for a level playing field between chemically defined products and herbal ones.

AESGP continues to provide a platform of exchange for both member organisations and other trade associations that are active in the field of homeopathic medicines. These exchanges include advocacy activities that are linked to the targeted review of general pharmaceutical legislation, as well as ensuring that homeopathy – which is out of scope and has not been impact assessed – remains so.

Pharmacovigilance

At the request of the French Medicines Agency (ANSM), the EMA Pharmacovigilance Risk Assessment Committee (PRAC) conducted a review of medicines containing pseudoephedrine (PSE) under Article 31. This was in response to concerns about the risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), which are conditions that affect blood vessels in the brain. They are extremely rare, and are reversible, but can have very serious consequences if not treated rapidly.

In response to a call for data for the referral procedure, AESGP coordinated the group of affected companies and engaged Professor Ronald Eccles, a key opinion leader in upper respiratory tract infections, to gather new evidence. The learnings of the PSE referral procedure were presented to the EMA. The experience in coordinating the Direct Healthcare Professional Communication (DHPC) was presented to the CMDh.

To address data gaps and misunderstandings concerning the mode of action and safety of pseudoephedrine, AESGP supported the publication of an article by Professor Eccles. Entitled 'A review and benefit-risk assessment with reference to the risk of Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS)', the article was published in the *Open Journal of Respiratory Diseases*.

During the EMA pharmacovigilance platform meeting on 15 November 2024, AESGP highlighted the impact of the modified Periodic Safety Update Report (PSUR) on its members, with reference to the frequencies of the European Union References Dates (EURD) list entries. As a result of a new methodology being used by the EMA, which is based on a statistical tool, a significant number of these frequencies have been modified. These changes have had a negative impact on resources, workload and planning.

During 2024, AESGP contributed to a number of meetings hosted by regulators on the topic of pharmacovigilance, including participating in the Pharmacovigilance Inspectors Working Group.

MEDICAL DEVICES REGULATION IMPLEMENTATION AND REFORM PROCESS

On 9 July 2024, Regulation (EU) 2024/1860 amending both the In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) and the Medical Devices Regulation (EU) 2017/745 (MDR) was published in the Official Journal of the European Union. It extends the transitional period for certain IVDs, enables a gradual roll-out of the European database on medical devices (EUDAMED), and introduces a requirement for manufacturers to notify interruption or discontinuation of supply of certain medical devices and IVDs.

The Regulation came into force on the day it was published in the Official Journal, with a six-month transition period for notification obligations for manufacturers relating to the interruption or discontinuation of supply of devices (applicable from 10 January 2025).

Following publication of the Regulation, the European Commission developed question and answer documents addressing the three areas of amendments introduced by Regulation 2024/1860. They organised a number of workshops to draw up the Q&As, which AESGP participated in and contributed to.

Implementation of the MDR has presented ongoing challenges relating to predictability, opacity, and resource-intensive processes. These pose significant challenges for businesses, particularly SMEs, and in April AESGP published its White Paper on lessons learnt with MDR implementation. This highlighted the difficulties resulting from the implementation of the MDR and proposed targeted reforms to enhance the regulatory framework. By building on existing provisions, the White Paper aims to foster a regulatory framework that guarantees transparency, predictability, efficiency and legal certainty, while maintaining a high level of health and safety for people who rely on self-care medical devices.

Proposed reforms include:

- Unlimited validity of certificates;
- Defined timelines in relation to conformity assessment procedures set out in Annex VII of the MDR;
- Provision for predictability of costs associated with product or QMS certification and other procedures;
- Establishment of structured dialogues between manufacturers and notified bodies, notably before conformity assessments;
- Reform of the Helsinki procedure;
- Establishment of a publicly accessible registry as an exchange system for decisions reached by competent authorities on classification disputes;
- Reduced administrative burden for notified bodies and greater focus on safety and performance aspects during conformity assessments.

AESGP echoed the need for reforms along with the specific proposals outlined above during regulatory discussions within the Medical Devices Coordination Group (MDCG), as well as in other discussion fora and conferences. As such, AESGP was highly engaged in the exchange with regulators, notified bodies and other stakeholders concerning structural issues in the MDR implementation process relating to regulatory structure and governance. Consequently, AESGP supported the European Parliament's resolution calling for the Commission to make full use of legislative and non-legislative tools to resolve issues of divergent interpretation and practical application to streamline the regulatory process, improve transparency, and eliminate unnecessary administrative work for notified bodies and manufacturers, particularly SMEs.

In the same context and throughout 2024, AESGP and its members actively contributed to the European Commission's study on regulatory governance and innovation in the field of medical devices through various activities, notably by participating in stakeholder interviews and workshops. The study, which was concluded by the end of 2024, aimed to identify key benefits and challenges of the governance structure of the MDR/IVDR, and make proposals for optimising it.

Data on the self-care medical devices market in Europe

In February 2024, AESGP published a white paper in collaboration with IQVIA on the dynamics of the self-care medical devices market in Europe. The white paper analyses the market size and trends for self-care medical devices against the background of the regulatory challenges faced by the implementation of the MDR. In particular, the paper looked at the market size, key categories and dominant product areas across 19 European countries, while also addressing the opportunities and challenges that this innovative and growing sector presents. This is the first comprehensive review of the self-care medical devices market.

FOOD SUPPLEMENTS

AESGP closely followed scientific and political developments regarding the European Commission's initiative for setting maximum levels for vitamins or minerals in food supplements, on the basis of Article 5 of the Food Supplements Directive. Anticipating a public consultation on this topic from the European Commission, AESGP commissioned an independent study to assess the impact of harmonised maximum levels for vitamins and minerals on consumer behaviour and public health. The study will also gather data to reinforce awareness of the value of food supplements for public health. It is expected to conclude in Q2 2025.

In addition, AESGP focused its activities on the use of food additives and novel foods, as well as on the safety of substances other than vitamins or minerals covered by Article 8 of Regulation 1925/2006, with the overarching aim of ensuring a balanced and pragmatic approach concerning the implementation of the legal and regulatory framework applicable to food supplements.

One specific focus of AESGP's activities related to food supplements containing herbal ingredients was the initiative by EDQM on the safe and correct use of herbal products. AESGP responded to the public consultation on the draft guidance for healthcare professionals and draft information for patients and consumers, pointing out apparent misconceptions about regulatory framework covering food supplements.

SUSTAINABLE SELF-CARE

In 2024, AESGP continued to build on its strong commitment to environmental sustainability and the regulation of chemicals impacting self-care products. With sustainability at the core of its strategic priorities, AESGP worked to support its 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, AESGP enabled its members to exchange knowledge, share best practices, and work together to improve sustainability across the self-care sector.

Revision of the Urban Waste Water Treatment Directive (UWWTD)

AESGP has actively engaged in the ongoing legislative process relating to the revision of the Urban Waste Water Treatment Directive (UWWTD), and in particular has highlighted its potential negative impact on the availability of medicines. The revised UWWTD was published in the Official Journal in December 2024. The directive introduces Extended Producer Responsibility (EPR) for pharmaceuticals and cosmetics, requiring contributions from both industries to fund wastewater treatment upgrades. The directive mandates a gradual implementation starting in 2027, with full compliance expected by 2045. While AESGP supports the overall goals of the directive, the association expressed concerns about its disproportionate financial impact on the pharmaceutical sector, and in particular the affordability of non-prescription medicines.

In November 2024, AESGP and EFPIA issued a joint statement highlighting that the UWWTD, while aimed at reducing water pollution, risks undermining the availability and affordability of medicines if its application is not carefully managed. AESGP emphasised the need for the polluter-pays principle to apply fairly across all sectors, advocating for a more balanced approach to funding wastewater treatment infrastructure. The associations also stressed the importance of ensuring that accessibility of medicines is not compromised in the process. AESGP has been in ongoing discussions with EU policymakers and national authorities to ensure that the EPR framework is workable, proportionate, and does not unduly burden the pharmaceutical sector.

AESGP calls on the EU and national authorities to ensure that all substances contributing to pollution by micropollutants are included when the directive is transposed into national law, so that all individual contributors to these substances start contributing at the same time as the pharmaceutical and cosmetics industries.

In addition, AESGP calls on Member States to co-contribute with 20% to the establishment of quaternary water treatment to cover the costs of non-traceable micropollutants, as foreseen in the Directive. A proportionate and fair approach is essential to effectively address water pollution, while maintaining the competitiveness of the pharmaceutical industry and its ability to supply affordable medicines.

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

AESGP continued to monitor the revision of the Water Framework, Groundwater, and Environmental Quality Standards Directives in 2024. In collaboration with industry partners, including EFPIA, Medicines for Europe, and AnimalhealthEurope, AESGP has continued to call for the revised directives to take into account the impact on the availability and accessibility of medicines for patients and animals.

In April 2024, the European Parliament adopted its position on the directives, with the Council following suit in June. AESGP, together with the associations listed above, shared a joint paper with the European Commission and the 27 Permanent Representations ahead of trilogue negotiations, ensuring the positions of industry partners are carried through the trilogue process.

AESGP continues to be actively involved in the European Commission's Chemicals Working Group, which plays a central role in the implementation of the Water Framework, Groundwater, and Environmental Quality Standards Directives.

ECHA stakeholder accreditation

In April 2024, AESGP was successfully accredited as a stakeholder by the European Chemicals Agency (ECHA). This accreditation enables AESGP to actively participate in discussions within the Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC), enhancing the association's role in regulatory discussions concerning chemicals legislation.

One Substance, One Assessment (OSOA) package

During 2024, AESGP continued to monitor the One Substance, One Assessment (OSOA) reform package, particularly the proposal to establish a Common Data Platform (CDP) for chemicals. In April, AESGP responded to the European Commission's public consultation on the OSOA package, with a focus on the CDP proposal. AESGP's priorities include ensuring that the EMA leads benefit/risk evaluations and manages medicinal product data within the CDP, while safeguarding confidential business data and providing clear guidelines for data migration. Additionally, AESGP emphasised the need for ECHA to be adequately resourced to manage its increased responsibilities under the new system.

Following the publication of the legislative proposal in December 2023, the Council adopted its position on the CDP-related regulation in June 2024. AESGP continued to engage with the European Parliament in parallel.

Microplastics Regulation

In 2024, AESGP continued to support members with the implementation of Commission Regulation (EU) 2023/2055, which restricts the use of synthetic polymer microparticles (SPMs) in various product categories. In addition, AESGP actively engaged in the European Chemicals Agency (ECHA) consultation on the reporting requirements for estimated emissions of SPMs to the environment for derogated uses. The consultation, which opened in 2024, seeks feedback on various aspects of the reporting system, including the feasibility of using a unique identification number, assigned by the Chemical Abstracts Service (CAS) and considerations around confidentiality.

Classification, Labelling, and Packaging (CLP) Regulation

AESGP has closely monitored the revised CLP Regulation, which entered into force on 10 December 2024. The regulation strengthens health and environmental protections, introduces clearer online sales labelling, and promotes sustainable practices.

AESGP hosted a webinar on 12 November 2024 on the impact of the revised CLP regulation on the self-care sector. The session covered CLP compliance requirements, updates on hazard classes, and practical guidance on label formatting. Key changes include simplified labelling, more transparent hazard information, and provisions for substances already in the market to remain in supply chains until mid-2028.

Packaging and Packaging Waste Regulation (PPWR)

In 2024, AESGP continued to closely follow the developments of the Packaging and Packaging Waste Regulation (PPWR) and its potential impact on the self-care industry. The regulation, which entered into force on 11 February 2025, aims to reduce environmental impact and improve recyclability across the EU. AESGP supports the sustainability goals of the PPWR but emphasises the need to maintain the functionality and safety of self-care products, ensuring that new standards do not compromise product integrity.

In April 2024, AESGP hosted an exclusive, member-only webinar titled 'Unveiling the Packaging and Packaging Waste Regulation (PPWR): navigating implications for the self-care industry'. The session provided comprehensive insights into the final text of the PPWR.

In September, AESGP engaged with the European Commission's Joint Research Centre (JRC) on a targeted stakeholder consultation regarding the EU harmonised label for packaging waste sorting instructions. This consultation sought feedback on the design and implementation of standardised labels for packaging and waste receptacles across the EU. AESGP's input focused on ensuring that the design of these labels would be compatible with the specific characteristics of medicinal product packaging.

Green Claims Directive

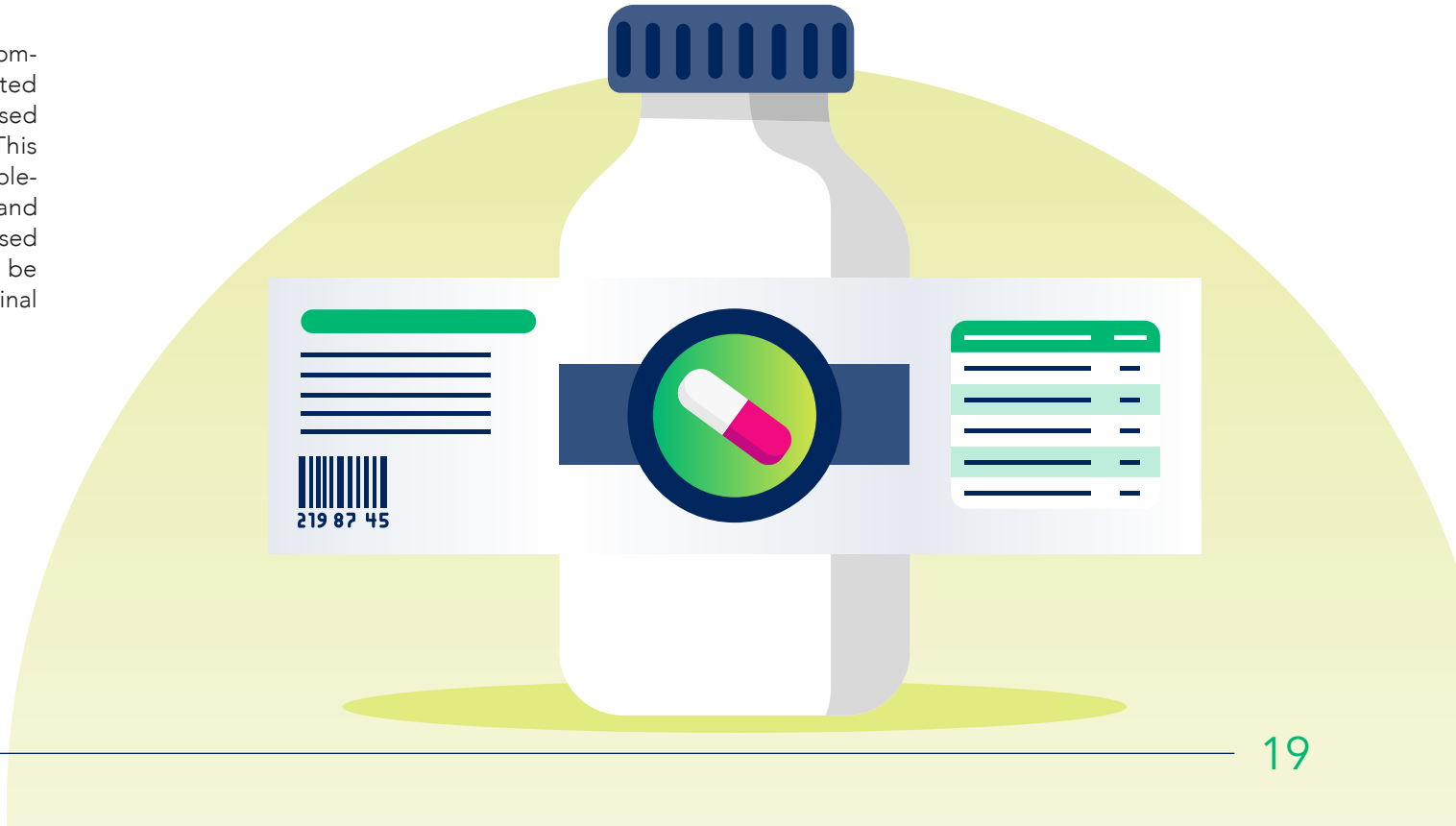
In 2024, AESGP continued to monitor the progress of the Green Claims Directive, which aims to ensure reliable, comparable, and verifiable environmental claims. The European Parliament adopted its position in March 2024, followed by the Council in June 2024.

AESGP supports the directive's objective of promoting transparency in environmental claims and recommends including avoidance-based offsets alongside reductions and removals in the regulation. The association also emphasises the need for clear, harmonised, and time-bound verification procedures to prevent delays and disruptions in the market. AESGP has collaborated with partner associations to shape a regulatory framework that fosters credibility and prevents misleading claims.

Other activities

AESGP reinforced its commitment to sustainability through the update of AESGP Pledge to the Charter for Environmentally Sustainable Self-Care, focusing on **Pharmaceuticals in the Environment (PiE)**.

AESGP remains an active participant in the Inter-Association Initiative (IAI) on PiE, collaborating with both the innovative and generic pharmaceutical sectors to tackle the environmental impact of pharmaceuticals. The initiative focuses on reducing the release of active pharmaceutical ingredients (APIs) into the environment, a key priority for the association. Furthermore, AESGP continues to promote MedsDisposal awareness programmes at the European level, emphasising the safe disposal of unused medicines to minimise environmental impact.



DIGITAL TRANSITION

AESGP pursued its advocacy efforts in key strategic areas in line with its digital strategy published in 2021. These strategic areas include: real-world data and evidence, artificial intelligence, product and disease information, the building of digital workforce capacity, and eCommerce.

European Health Data Space

On 26 February, AESGP, as part of a coalition of 35 large health stakeholder organisations representing patients, health professionals, researchers and industrial actors in the healthcare ecosystem at both the European Union (EU) and Member State level, expressed its shared concerns about the latest negotiations on the proposed Regulation on the European Health Data Space (EHDS).

These concerns were subsequently addressed, and on 22 April, AESGP, together with other health stakeholder organisations, welcomed the agreement on the European Health Data Space (EHDS) proposal and provided key recommendations to ensure this will be implemented in a way that provides the most added value for patients and European health systems.

e-Commerce

In June 2024, AESGP released a position paper on how to harness online advertising for better healthcare. In the paper, AESGP took stock of the evolving landscape of self-care product advertising, emphasising the shift from traditional to digital platforms. Having analysed the challenges and opportunities presented by both media, AESGP proposed a set of recommendations to ensure responsible and trustworthy online advertising for self-care products. In addition, AESGP organised a roundtable on online advertising during its 60th Annual Meeting.

Digital product information

Electronic product information for medicines

The AESGP Position Paper on the transition of patient information was published on 20 March 2024. This built on the previous consumer study commissioned from IPSOS to better understand EU consumers' perceptions and expectations with regard to product information for non-prescription medicines and their readiness to use digital formats.

To mark the launch of the position paper and the publication of the consumer survey, a webinar titled 'From paper to digital leaflets: making patient information more inclusive' was organised on 14 May. This featured a presentation of the study results, followed by a panel discussion with representatives of patients, pharmacists, the EMA and the European Commission. Panellists discussed optimal ways to transition from paper to digital leaflets.

In addition to the work carried out by its dedicated WG on ePI, AESGP also pursued its engagement through the Inter-Association Task Force for ePI.[1] AESGP co-leads the two existing working groups and is a member of the steering group.

At steering group level, AESGP continued to work on the assessment of proposed changes to the general pharmaceutical legislation with regard to implementing ePI, and developed a set of position papers for desired changes. Throughout 2024, the steering group engaged on a number of topics with different stakeholders, such as the European Medicines Agency (EMA), and the European Association of Hospital Pharmacists (EAHP).

Under the leadership of AESGP, the Content WG developed a set of recommendations informed by input from patients, carers and user-testing companies to improve patient leaflet content. Those recommendations were crystallised into a position paper entitled 'Patient information on medicinal products – how to make it patient-centric?' with the aim of making leaflets shorter and more patient-centric. Those recommendations were presented to the EMA Quality Review of Documents (QRD) group and informed the revision of the QRD template.

Under the leadership of AESGP, the Inter-Association Task Force WG also advocated against the Key Information Section (KIS) which would make leaflets longer without addressing any of the shortcomings of the current format. KIS was supported by patients, healthcare professionals and EMA's QRD group. Industry recommended instead to first implement the proposed changes.

The Technical WG focused on three main topics during 2024: the best alternatives to the paper package leaflet, the best ePI Identifier (ID), and dissemination of ePI through channels other than the EMA/HMA portal. Draft position papers on the two topics have been developed and shared with AESGP members. In addition, the WG provided support to the nominated ePI SMEs and shared with the EMA what was perceived as being needed before going live with the ePI portal.

Electronic instructions for use (eIFU) for medical devices

According to the Medical Device 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 defined in Regulation (EU) 2021/2226 (eIFU Regulation), these IFUs may be provided in electronic form only. On 2 February 2024, a joint statement co-signed by AESGP was released by medical devices industry associations proposing a targeted update to extend the scope of Regulation (EU) 2021/2226 to encourage a level playing field.

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

Publications

New industry papers

During 2024, AESGP published a series of new positions, articles, responses to major events, and key EU legislative and policy proposals:

Value of self-care

- AESGP Call to Action for the coming mandate of the European Parliament and European Commission
- Health economic study on impact of reverse-switching antifungal and antiviral non-prescription medicines (IQVIA, 2024)
- The economic and social value of non-prescription antimicrobial medicines for the treatment of fungal and viral infections (AESGP, 2024)

Medical Devices

- AESGP Statement on the European Commission's legislative proposal amending the IVDR and MDR
- IQVIA Consumer Health x AESGP White Paper "Dynamics of Self-Care Medical Devices in Europe"
- AESGP White Paper: Lessons learned with the MDR Implementation
- AESGP Statement on Regulation (EU) 2024/1860 amending the IVDR and MDR
- AESGP Statement on the European Parliament's Call to Urgently Revise the Medical Devices Regulation

Digital

- AESGP Position Paper on the transition of patient information
- IPSOS perception study on non-prescription medicines and digital product information
- AESGP Position Paper on Trustworthy and Responsible Online Advertising of Self-Care Products
- Basic Requirements and Framework Conditions of RWD on Herbal Medicinal Products (AESGP, Thieme Planta Medica 2024)

Environment

- AESGP feedback on the "One Substance, One Assessment" legislative package

Joint papers and statements

The following joint papers and statements were released in partnership with other trade associations:

Medical Devices

- Joint statement supporting the expansion of the use of Electronic Instructions For Use (eIFU) in the medical devices sector

Digital

- Multi-stakeholder statement on "Draft text of the European Health Data Space (EHDS) in trilogues sparks deep concerns in the European healthcare ecosystem"
- Joint stakeholder statement on the implementation of the EHDS
- Joint Position Paper on Patient information on medicinal products – how to make it patient-centric?

Environment

- Joint statement from the human pharmaceutical industry on the Urban Wastewater Treatment Directive

Engaging with the media

AESGP communicated with different media outlets on pressing issues for the sector, including:

HBW Insight

- Association Focus In 2024: Self-Care, Sustainability And Prospects For Political 'Reorientation'
- Podcast / Over The Counter 20 Feb 2024: AESGP's 60th Birthday Celebrations In 2024 Including Annual Meeting, With Jurate Švarcaite
- Continued Growth of Self-Care Med Devices Market Rests On Addressing MDR Challenges
- AESGP: Despite MDR Failures, 'Complete Overhaul' Not Needed
- Electronic Or Paper Patient Information Leaflets? EU OTC Users Want Both
- AESGP Meeting: Industry Must Be 'Organized, Bold And Unapologetic' About Value Of Self-Care
- AESGP Meeting: Medicine Packaging Exemption 'Not Helpful' For Circular Economy
- AESGP Meeting: Climate Inaction Could Cost Healthcare Companies 10–20% Operating Profit
- AESGP Annual Meeting: OTC Firms Must 'Innovate Harder' To Realize Growth Opportunity
- AESGP Meeting: Real World Evidence Could Drive Rx-To-OTC Switch, If Regulators Embrace It
- AESGP Publishes Guidance For EU Companies Advertising Self-Care Products Online
- AESGP Finds 'Significant Variation' In OTC Medicines Availability Across Europe
- 'Inside Regulatory Affairs' With AESGP's Christelle Anquez-Traxler and Oliver Hartmann
- Reverse-Switching OTC Antimicrobials Could Cost Europe An Additional €10bn Per Year
- EU Urban Wastewater Directive 'Highly Disproportionate,' Says AESGP

The Parliament Magazine

- Empowering Europe's Health: The Vital Role of Self-Care

Open Access Government

- Self-Care: A Pillar of Modern Public Health

POLITICO Europe

- Partnership with the Politico Healthcare Newsletter, raising awareness of AESGP's vision for a sustainable healthcare

Videos

- AESGP Anniversary: Celebrating 60 years of self-care
- From paper to digital leaflets: making patient information more inclusive

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 2023–2025

Jonathan Workman

General Manager for Northern Europe Business Unit

Haleon

AESGP Vice-President 2023–2025

Traugott Ulrich

Executive Director

Schwabe Pharma

AESGP Vice-President 2023–2025

Bernard Mauritz

Director General

Neprofarm, *the Netherlands*

AESGP Treasurer 2023–2025

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

Barbara Brusca
Environmental Sustainability 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

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
ΕΦΕΧ
IGEPHA The Austrian Consumer Health Care Association
ipha IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION
lif
LMI Legemiddelindustrien
MAGYOSZ
Neprofarm
Nères
PAGB
PASMI
PHARMA DEUTSCHLAND
LääketeollisuusPharma Industry Finland
pharma.be
RASCI
SPMA The Slovenian Pharmaceutica Manufacturers Association
SVOPL

International Companies

BAYER
HALEON
kenvue
Opella. Health. In your hands.
P&G Health
Perrigo
reckitt
SCHWABE
UPSA

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
convert group

AESGP

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