Activity report 2018

AESGP

Self-care for better health and well-being

Contents

Foreword

Embracing Change to Move the Self-Care Industry Forward

By **Birgit Schuhbauer**,
AESGP President

2018 was a year of change at AESGP! Dr Hubertus Cranz, AESGP Director General, who started in this position on 1 June 1988 retired in June 2018 after more than 30 years of service. During his tenure, AESGP embodied the voice of the consumer health industry in Europe. His competence, high sense of service and professionalism made him a highly regarded interlocutor with both stakeholders and AESGP members.

The list of AESGP political successes under his leadership is long. It starts with the adoption of the directives on pharmaceutical advertising and classification, and thereby the clear definition and distinction of legal status between medicines subject to prescription and non-prescription medicines in the early 1990s. This laid the groundwork for developing self-care throughout Europe – complemented by further access to all procedures to access the market. Another great development is the enlargement of self-care product categories, namely the addition of food supplements and, more recently, self-care medical devices which has been reflected in the growing scope of the association.

While I pay tribute to the achievements of Dr Cranz, I am equally excited to welcome the new leadership team: Jurate Svarcaite as Director General and Maud Perrudin as Deputy Director. I believe that Jurate and Maud, with their very different yet complementary backgrounds, will form a competent duo at the helm of the association; under their leadership AESGP is best positioned to continue embodying the voice of the self-care industry in Europe and embrace the future of the self-care sector. Bringing Jurate and Maud on board was an important milestone for me and the entire AESGP Board in ensuring a smooth transition of leadership within the association.

This transition comes at a time when significant changes are happening in the self-care environment: individual-centricity, empowerment and moving from product to services, high connectivity and access to mobile technologies, demand for sustainable products, just to name a few drivers for change. Those of particular importance are the developments in the digital space and rise of a new communication channel of social media; the impact of big data and artificial intelligence in health care delivery and regulatory science is indisputable. These could be new roads for opportunity and disruption; the biggest change being that the roads are no longer one way.

The second half of 2018 was therefore logically dedicated to the AESGP strategy 2019-2022. It was an exciting journey for many of us involved at AESGP, which resulted in a roadmap that will guide its next 4 years to embrace changes and move self-care forward. Self-care offers untapped potential for governments and international institutions to free public health resources. In these challenging times with the rising burden of chronic diseases, an aging population, and scarce public resources, we must act and position self-care as the true first step in healthcare. Because it is in our DNA, AESGP will continue to proactively shape the regulatory, legislative, political and economic framework where the consumer healthcare industry operates. We will focus on non-prescription medicines, self-care medical devices and food supplements and will build on cross-category expertise that is our added value/at the heart of our mission. We shall continue to build trust in self-care and in our industry, and remain accountable to our stakeholders. Finally, we will seize the opportunity to focus intently on strengthening and developing a holistic network encompassing all relevant stakeholders and serve as a platform to our member associations.

We begin the new year in an environment of change but with a steady focus on our mission to advance responsible self-care, enabling citizens to take better care of their health needs and contribute to the sustainability of European health care systems. Its value is inherent, and its importance undeniable.

Voice of the consumer health industry

AESGP Mission

Advance responsible self-care, enabling citizens to take better care of their health needs and contribute to the sustainability of European health care systems.

The Association of the European Self-Medication Industry (AESGP) is the **voice of the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe**, also referred to as self-care/consumer healthcare products.

There are **more than 2,000 companies operating in the consumer healthcare sector in Europe.** They are affiliated with AESGP directly or indirectly through the 25 national associations. 50% of the companies in the AESGP constituency are **small and medium-sized (SMEs) companies**[1].

8.5 billion packs of non-prescription medicines and 1.2 billion packs of minerals and vitamins[2] were purchased by Europeans in 2018 with an aim to improve their health and contribute to their wellbeing. Almost **every second pack of medicines dispensed in European community pharmacies has a non-prescription status.** Ailments that can be managed with self-care products typically include allergies, gastrointestinal disorders, cuts, bites & rashes, cough & cold, pain. Collectively, **there are more than 200 active pharmaceutical ingredients (INN) available without prescription in Europe**[3].

1. AESGP Data
2. Source: IQVIA Global OTC Insights
3. AESGP Ingredient database
4. AESGP Data
5. Source: IQVIA Global OTC Insights

Key Facts

AESGP is the voice of the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe

2,000 + companies operate in the consumer healthcare sector in Europe, 1,000 of which are SMEs[4]

8.5 billion packs of non-prescription medicines and 1.2 billion packs of minerals and vitamins[5] were purchased by Europeans in 2018

Ailments that can be managed with self-care products typically include **allergies, gastrointestinal disorders, cuts, bites & rashes, cough & cold, pain**

More than 200 active pharmaceutical ingredients are available as OTC in Europe

1 out of 2 packs of medicines dispensed in a pharmacy is OTC

AESGP strategy 2019 – 2022

Throughout 2018, AESGP has worked on the sector strategy for 2019-2022. The strategy was finalised and approved by the AESGP Board in October 2018 with an objective to:

1/

Promote the individual, societal and economic value and benefits of self-care.

At AESGP, we think 'individual first' in our every action. Individuals can expect that self-care products manufactured by our member companies are safe and effective in addressing their health needs as well as bringing value to European health systems. Self-care enables individuals to continue with normal life (go to work/school, play sports, care for children, travel, etc.) and contributes to their wellbeing. With responsible self-care, unnecessary visits to the doctor or hospital emergency departments can be avoided, thus helping busy doctors surgeries to cope with complex cases and reduce waiting times. It also contributes to workplace productivity because non-prescription medicines make individuals feel better.

2/

Proactively shape the regulatory, legislative, political and economic framework where the self-care industry operates, with a focus on non-prescription medicines, substance-based medical devices and food supplements.

We promote evidence-based regulation and legislation that constantly evolves with the advancement of scientific evidence and recognises patient/individual empowerment. We use the best scientific evidence available supported by sound data to guide our daily work.

3/

Build greater trust in self-care and be recognised as a responsible industry.

We work in an open manner towards our members and stakeholders. It supports our accountability to our members and stakeholders, notably policy makers, regulators and consumers, and builds trust in consumer healthcare products and the consumer healthcare industry.

4/

Strengthen and develop a holistic network encompassing all relevant stakeholders and serve as a platform for member associations.

We are a recognised voice for the European consumer healthcare industry. As a network of national associations and consumer healthcare companies, we are greater than the sum of individuals. Our members share common values and goals and actively participate in setting our policies and making decisions.

AESGP aspires to lead and champion the self-care agenda with a mission to 'advance responsible self-care, enabling citizens to take better care of their health needs and contribute to the sustainability of European health care systems'. The primary way in which our mission is accomplished is through the synergy that occurs by bringing together our members and through meaningful engagement with policy makers, regulators and other stakeholders.

Year at a glance

2018

01

January

- The AESGP Board appointed Jurate Svarcaite as next Director General of AESGP and Maud Perrudin as Deputy Director, taking over from Hubertus Cranz after 30 years' service by the end of May 2018.

02

February

- Improving the availability of self-care products by reviewing the progress against the AESGP Self-Care Agenda 2020 and proportionate implementation of medical devices regulation were key topics of the 9th conference AESGP organized together with the Heads of EU Medicines Agencies (HMA) and the medical devices authorities.

07-08

July - August

- AESGP brainstormed on its future strategy so as to actively and appropriately engage in pursuing AESGP's objectives in the next 3-5 years and shape the future of self-care regulation and policy in Europe.

09

September

- AESGP presented the experience of the industry with the new Risk Minimisation Plans (RMP) guidance and template at the EMA's 12th Stakeholder Forum on Pharmacovigilance in September 2018.
- AESGP participated in the annual hearing of The Working Party on European Union Monographs and European Union List (MLWP) of the Committee on Herbal Medicinal Products (HMPC) in EMA in London.
- AESGP participated in the EFSA Scientific Conference taking place in Parma, Italy, which focused on the future of risk assessment and involved a wide variety of stakeholders discussing the interplay between science, food and society.

10

October

- The AESGP Board revised AESGP mission and adopted its Strategy 2019-2022.
- AESGP participated in the EMA multi-stakeholder Regulatory Science to 2025 workshop and notably emphasised the need to address the unmet self-care needs of citizens, made proposals to enable more 'switches by design' and requested clarification of the respective and collaborative role between notified bodies and medicines regulators to avoid disproportionate regulatory burden in device assessment.
- During the Austrian Presidency of the Council of the European Union, AESGP, for the first time together with the Austrian Medicines and Medical Devices Agency (AGES), organised a joint EMA-AESGP Herbal Medicinal Products Committee meeting.
- AESGP adopted its position paper on Rule 21 together with a product examples table on classification rules outlining concrete examples and its position paper on Rule 14 to the regulatory authorities.

03 March

- AESGP participated in the first Medical Device Coordination Group (MDCG) stakeholder meeting where representatives of the competent authorities provided an update on the ongoing implementation work with regard to Regulation (EU) 2017/745 (Medical Devices Regulation) and Regulation (EU) 2017/746 (In Vitro Diagnostic Regulation).

04 April

- AESGP participated in the plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health where the Commission presented its proposal for a revision of Regulation (EC) No 178/2002 on the General Food Law (GFL) tackling transparency of risk analysis, risk communication, the quality and reliability of scientific studies as well as the European Food Safety Authority's need to maintain a high level of scientific expertise and to engage with stakeholders and member states.

05 May

- AESGP attended a workshop organised by the EMA-HMA Task Force on Big Data, the purpose of which was to inform thinking on big data and the recommendations the taskforce was planning to make.
- AESGP addressed the Annual Meeting of the European Association of Faculties of Pharmacy that took place in Parma, Italy.

06 June

- The 54th AESGP Annual Meeting entitled "Connecting the smart consumer" looked at the evolving self-care market place, addressing challenges related to digital space and e-commerce, and how to best serve the expectations of the newly informed consumer.
- Dr Hubertus Cranz retired from his role as AESGP Director General after 30 years of service.
- AESGP participated in the European Food Safety Authority 5th Roundtable with industry associations.

11 November

- AESGP actively contributed to the European Antibiotic Awareness Day.
- AESGP participated in the EFSA Stakeholder Forum.

12 December

- AESGP had its annual bilateral meeting with the EDQM on the quality of medicinal products.

2019

2018 in detail

AESGP primarily operates via its 6 technical committees, namely the Regulatory Affairs Committee, Herbal Medicinal Products Committee, Medical Devices Committee, Food Supplements Committee, Pharmacovigilance Committee and the Economic/Public Relations Committee. The Committees are composed of AESGP members' representatives; they meet regularly and develop AESGP positions in key areas.

AESGP is a stakeholder recognised by the EU legislative and regulatory bodies, including the European Commission, the European Medicines Agency and the European Food Safety Authority.

A summary of the topics AESGP was actively involved in (mainly through its technical committees) and key achievements in 2018 is presented hereinafter.

Regulatory Affairs Committee

Food Supplements Committee

Herbal Medicinal Products Committee

Pharmacovigilance Committee

Medical Devices Committee

Economic / Public Relations Committee

Non-prescription medicines and switching

Improving the availability of self-care products by reviewing the progress against the AESGP Self-Care Agenda 2020 was a **key topic of the 9th Conference AESGP organised together with the Heads of EU Medicines Agencies (HMA).** The meeting took place in Lisbon on 26-27 February 2018 and discussed the impact of the EU Medicines Agencies Network Strategy to 2020 and the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) strategy having a common objective to increase access to non-prescription medicines.

The AESGP key objective remains to promote switches as well as their timely access to the market independent of the procedure chosen and an essential part of this is engaging with authorities across the entire European regulatory network for medicines. In October 2018, **AESGP participated in the EMA multi-stakeholder Regulatory Science to 2025 workshop and notably emphasised the need to address the unmet self-care needs of citizens and made proposals to enable more 'switches by design'.**

AESGP took part in the HMA-EMA joint workshop on the availability of authorised medicines held in November 2018. In the panel discussion, **AESGP** called for early dialogue and consultation in developing guidance on reporting supply disruption and **warned that the immediate notification of any shortages of medicinal products may present a disproportionate burden to regulators as well as the industry. A risk-based approach was called for instead.**

AESGP actively follows developments on big data and real-world evidence and participates in relevant EMA and HMA events. In May 2018, AESGP attended a workshop organised by the EMA-HMA Task Force on Big Data, the purpose of which was to inform thinking on big data and the recommendations the taskforce was planning to make. Prior to this, Thomas Senderovitz, Director General, Danish Medicines Agency and Chair of this task force created in March 2017, shared his reflections at the AESGP Conference with the Heads of EU Medicines Agencies during the Bulgarian EU Council Presidency held in February 2018 in Lisbon.

AESGP also held a teleconference meeting with the European Directorate for the Quality of Medicines and Healthcare (EDQM) in December 2018 regarding the classification of medicines with reference to their supply. The meeting provided a good opportunity to exchange general updates, remarks and observations on the EDQM Medclass Database, as well as proposals to further develop the collaboration between AESGP and EDQM.

Brexit has been a major challenge for the industry in the past year and AESGP has actively monitored the developments as well as participated in numerous meetings and webinars in order to support the industry in its preparations and mitigate the impact.

> *"The AESGP key objective remains to promote switches as well as their timely access to the market independent of the procedure chosen and an essential part of this is engaging with authorities across the entire European regulatory network for medicines.*

Pharmacovigilance

Non-prescription medicines have a well-known safety profile documented by their long use and presence on the market and AESGP continuously makes the case for a proportionate risk-based approach for non-prescription medicines. AESGP is actively contributing to the Coordination Group for Mutual Recognition and Decentralised Procedures CMDh-led HaRP (Harmonisation of Risk Management Plans) project and has participated in the survey on the uptake of the revised RMP guidance and template. **AESGP presented the industry experience with the new RMP guidance and template at the EMA 12th Stakeholder Forum on Pharmacovigilance in September 2018.** Results from the survey were positive and showed a faithful and reassuring application of the new guidance document in practice.

Herbal and homeopathic medicinal products

During the Austrian Presidency of the Council of the European Union, AESGP, for the first time together with the Austrian Medicines and Medical Devices Agency (AGES), organised a dialogue between members of the HMPC and the industry on 15 October 2018 in Vienna. The dialogue was seen, on both sides, as an excellent platform for the exchange of ideas and proposals in a cordial and open atmosphere, which should be repeated in the future. In Vienna, AESGP also participated in the workshop with the Homeopathic Medicinal Products Working Group (HMPWG).

Pyrrolizidine alkaloids (PA) contamination of herbal medicinal products were a focus of a number of AESGP meetings with authorities, notably the AESGP hearing with the EMA HMPC Working Party on European Union Monographs and European Union List (MLWP) in September 2018 and the annual AESGP-EDQM bilateral meeting in December 2018.

Electronic product information

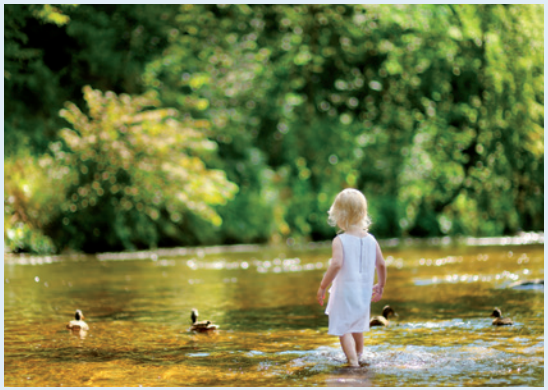
Following the successful dialogue that took place in July 2018 between the industry, stakeholders and the HMA e-product information task force, a workshop on electronic product information for medicines (ePI) took place at the EMA with representatives of the industry, stakeholders, NCAs, EMA and European Commission. The objective of the meeting, to which AESGP took part, was to further facilitate its development to improve its access to patients and healthcare professionals. **As member of the industry's Inter-Association Task Force on e-product information, AESGP supported the potential of an e-leaflet as complementary to the paper version. It is critical for the self-care sector that a paper leaflet continues to be provided in the pack but could be complemented by an e-leaflet, as the patient may have no or little interaction with a healthcare professional.**

Environment

AESGP is a member of the IAI Pharmaceuticals in the Environment (PiE) Task Force, which also includes EFPIA and Medicines for Europe. The Task Force supports the holistic lifecycle approach to minimising the impact of pharmaceuticals on the environment. The IAI PiE Task Force has developed an Eco-Pharmaco-Stewardship (EPS) initiative and a number of projects, such as the #Medsdisposal campaign raising awareness of the safe disposal of medicines and the Innovative Medicines Initiative project **"iPiE". As part of IAI Task Force, AESGP contributed to both the respective expert and the public *EC consultations on pharmaceuticals in the environment***. AESGP also actively participated in the Commission Working Group on Chemicals.

In their response to the EC consultation on the Water Framework Directive fitness check roadmap, the industry reiterated its support for the objective of the WFD but underlined its concerns relating to the implementation of the Directive with regards to pharmaceuticals and the fact that the use of robust science was paramount.

AESGP also participated in the IMI iPiE (Intelligence-led Assessment of Pharmaceuticals in the Environment) **Scientific Advisory Board meeting in November 2018**. This IMI initiative aims to develop a predictive model to provide early information on the environmental risk of new chemical entities but also information on substances not having environmental data. One of the outputs of the initiative will be a public database showing substances and whether environmental data is available.



"Minimizing the impact of medicines on the environment while safeguarding access to effective treatments for patients is a critical issue across all sectors of the pharmaceutical industry.

Food supplements

A key part of AESGP's activities is the representation of its members in all regulatory, legislative and political debates in relation to food supplements. **AESGP fosters fruitful collaboration with EU authorities active in this area and is therefore actively involved in the work of the European Food Safety Authority (EFSA) and the European Commission (DG Sante) by participating in relevant meetings and consultations.**

In September 2018, AESGP participated in the EFSA Scientific Conference taking place in Parma, Italy, which focused on the future of risk assessment and involved a wide variety of stakeholders discussing the interplay between science, food and society. AESGP also took part in the 2nd EFSA Stakeholder Forum on 20 November 2018. As a member of the Advisory Group on the Food Chain and Animal and Plant Health, AESGP participated in the plenary as well as in relevant ad hoc meetings with the European Commission.

AESGP has actively monitored and engaged together with other stakeholders in the follow up to the Fitness Check process of the General Food Law and the subsequent targeted

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Food supplements (continued)

revision, which introduces new rules around governance, transparency and financing of EFSA. Following the publication of the legislative proposal on the transparency and sustainability of the EU risk assessment in the food chain, **AESGP expressed support for improving citizens' trust in the EU risk assessment by enhancing its transparency and sustainability while providing the effective protection of confidential business information.**

AESGP is committed to evidence-based policy making and therefore actively supports the ongoing work of EFSA in the safety assessment of certain other substances added to foods and other relevant calls for data. Furthermore, **AESGP continues to coordinate various submissions of food supplements industry data to support the Commission and EFSA work on the re-evaluation of the safety of food additives**. All food additives permitted for use in food in the EU must undergo a safety re-evaluation by EFSA. This scientific assessment (exposure) needs to be supported by data submitted by the industry that adequately reflect the current use levels of food additives in food.

In 2018, AESGP actively engaged in a close dialogue with the European Commission and other stakeholders on the next steps in ensuring that the necessary data regarding key additives for the food supplements sector, in which EFSA has identified issues that require a follow-up, are collected and submitted in an appropriate manner. **In order to ensure sustainable conditions for the use of food additives in food supplements, AESGP is engaging with the Commission on the reorganisation of the food supplement categories in which food additives are allowed as well as the introduction of a separate category for infants and young children**. In its activities, AESGP has been committed to providing timely and necessary support to its member associations and companies in gathering and reporting requested data.

Medical devices

2018 was a busy year in the medical devices sector. AESGP – representing manufacturers of self-care medical devices on a European level – participated and actively contributed to the work in all of the relevant European Commission working groups and task forces that have been set up to steer the implementation of the new rules under the Medical Devices Regulation (MDR). In these fora, **AESGP consistently advocated a proportionate and risk-based implementation of the MDR requirements for self-care medical devices with a special focus on substance-based medical devices – namely the classification of Rule 21 based on the assessment of each individual device, taking into account all of the characteristics of such devices.** In doing so, AESGP has been engaging with all of those operating in the sector to raise awareness on the challenges of the sector and increase knowledge of the substance-based medical devices.

In February 2018, AESGP organised a conference in Lisbon with representatives of the medicines authorities, including the Heads of EU Medicines Agencies (HMA), and the medical devices authorities, including the Chair of the Competent Authorities for Medical Devices (CAMD), to discuss the new legal provisions applicable to self-care medical devices. With regard to substance-based devices, AESGP reminded authorities that the requirement for notified bodies to consult the medicine authorities within the context of the conformity assessment under the MDR only applies to devices falling under the first indent of Rule 21. **It is critical that a common understanding of this rule applies so that notified bodies do not consult medicine authorities in a disproportionate manner.** In addition, key challenges in implementing the MDR affecting the medical devices industry as a whole, including the issues arising from notified body designation timelines

"AESGP consistently advocated a proportionate and risk-based implementation of the MDR requirements for self-care medical devices with a special focus on substance-based medical devices.

Medical devices (continued)

and interpretation of transition periods provided for. These transition periods granted under the MDR are particularly critical for substance-based medical devices currently falling under Class I, for which there are no existing certificates with defined periods, which will be the first required to fully meet the MDR requirements from 26 May 2020 onwards. **In this allotted transition period, the industry is highly concerned that notified bodies may not be available and be able to certify the vast number of products early enough to avoid any disruption in the supply of medical devices to the market, taking into account additional constraints due to Brexit.**

Following this event and throughout the year, AESGP has been fostering intensive collaboration between medical devices and medicines regulators and engaged with EMA on the practical implementation of the MDR.

Following a public presentation of its position in early October, AESGP circulated its **position paper on Rule 21 together with a product examples table on classification rules outlining concrete examples and its position paper on Rule 14 to the regulatory authorities**. The initiative aims to complement AESGP ongoing efforts, calling for the harmonised and consistent implementation of MDR classification rules by regulators as well as notified bodies regarding substance-based medical devices.

In light of the important role currently played by the UK notified bodies in the certification, in the past year Brexit has increasingly put pressure on the soon-to-apply MDR system and AESGP has actively monitored the developments as well as participated in numerous meetings in order to voice the industry challenges in their preparations and mitigate the impact.

AESGP 54th Annual Meeting

The 54th AESGP Annual Meeting – the annual gathering of the self-care sector in Europe – was held in Amsterdam, the Netherlands, from 5 to 7 June 2018. **The conference entitled "Connecting the smart consumer" looked at the evolving self-care market place, addressing challenges concerning digital space and e-commerce, and how to best serve the expectations of the newly informed consumer.**

The two-day discussions on the future challenges for the self-care industry in Europe were marked by various concepts and ideas, and opportunities for the industry to expand its role and promote self-care:

- **The self-care industry is making a significant contribution to healthcare systems** across Europe. Initiatives promoted by national associations are an effective way of creating a positive environment by also improving the public perception of self-care.
- **In order to enable the full potential of self-care, the switching of medicines from prescription to non-prescription status should be encouraged and supported.** Enablers for switching were identified and include the unmet health needs of the population, market readiness and stakeholder engagement.
- **Digitalisation was an overarching topic**, however with specific challenges yet to be addressed on a legal and regulatory level, primarily in relation to big data and access to data, the increasing relevance of e-commerce and the evolving expectations from connected consumers.
- **The industry is pro-actively responding to the changing needs of consumers** by positioning connected consumers as their core focus and offering holistic solutions so that they can become full actors of their own health and engage further in prevention.

Governance

The highest governing body is the AESGP General Assembly, composed of all members of the association.

The strategic leadership and management of the association is in the hands of the AESGP Board, composed of representatives from member associations and companies.

The AESGP Board is led by the Executive team headed by the President. Birgit Schuhbauer, Global Vice President OTC Franchise at Johnson & Johnson is AESGP President 2018-2020.

AESGP is member of the World Self-Medication Industry (WSMI), a federation of over 50 member associations in all continents.

AESGP supports the #Medsdisposal campaign to raise awareness on the safe disposal of medicines and the European Antibiotic Awareness Day campaign to promote appropriate and responsible use of antibiotics.

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

Hubertus Cranz (until 1st June 2018) /**Jūratė Švarcaitė**
Director General

Maud Perrudin
Deputy Director General

Christelle Anquez-Traxler
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Gaëlle Jouvenceau
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Lucy Gits
Events and Finance Administrator

Alix Marchal
Communication and Member Services Manager

Members

There are more than 2,000 companies operating in the consumer healthcare sector in Europe. They are affiliated with AESGP directly or indirectly through the 25 national associations.

National associations

International companies

Associated companies/associations

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