AESGP ACTIVITY REPORT 2019

Evolving the self-care environment

AESGP

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Foreword

By **Birgit Schuhbauer**, AESGP President

2019 has been a special year in many aspects, and not only for AESGP. Significant developments happened in the European Union: a new European Parliament and a renewed Commission took office; Ursula von der Leyen became the first woman to be nominated President of the European Commission…

We are extremely pleased to see health recognized as a prominent issue for the European Union in the mission letter to Stella Kyriakides, Commissioner for Health. During her first months in office, she has proven to be a great health advocate and an inspiring leader. **We very much look forward to working with Ms Kyriakides and her team, as well as with other Commissioners, in advancing responsible self-care, enabling citizens to take better care of their health needs, and contributing to the sustainability of European health care systems.**

Self-care products (namely non-prescription medicines, self-care medical devices and food supplements) represent a significant push towards new and greater self-efficacy, autonomy and engagement in health for individuals. Self-care offers an untapped potential to free public resource for governments. **We must act and position self-care as the true first step in healthcare if we are to address appropriately the rising burden of chronic diseases, aging population and scarce public resources.**

Throughout 2019, AESGP has continued its efforts in implementing its Strategy 2019-2022. The strategy has now been translated into an action plan to guide us in embracing changes and moving self-care forward. The AESGP team, responsible for the day-to-day operations of our association, has expanded, reflecting the increasing importance of AESGP and the self-care sector.

We continued to proactively shape the regulatory, legislative, political and economic framework where the self-care industry operates, with a focus on non-prescription medicines, self-care medical devices and food supplements. Building on a cross-category expertise that is our added value and at the heart of our mission, we continue to build trust in self-care and in our Industry, and remain accountable to our stakeholders. We focus intently on strengthening and developing a holistic network encompassing all relevant stakeholders, and serve as an effective platform to our members.

As part of the implementation of our strategy, we have undergone a significant 'makeover': our website has been redesigned; our visual identity, refreshed. **These changes come along with the aspiration to become a go-to source on self-care in Europe.** Our video "What is self-care", released on International Self-Care Day (24th July), is a reminder that the value of self-care is inherent and its importance undeniable.

We begin 2020 in a very distinct public health situation: the global pandemic of COVID-19. This exceptional plight requires businesses and each and every one of us to embrace new public health measures and change our way of life. At the Self-care Industry, we are all working around the clock to maintain the continuity of our supply chains in order to ensure that European citizens benefit from an uninterrupted access to self-care products through their regular suppliers (e.g. pharmacies).

Optimizing the availability of healthcare professionals, infrastructure, equipment and therapeutics is essential in a time where an unprecedented number of patients require urgent care. At the time of global pandemic, access to self-care products is vital in order to avoid any unnecessary pressure on health systems and allow the rational allocation of scarce resources. As the European Commission is coordinating a common European response to the COVID-19 outbreak, we are taking part in a number of coordinated actions aimed to reinforce public health and health systems.

Because of our joint efforts, there will come a day when the pandemic is over. We will come out of our houses and go to eat out. We will celebrate. I don't know when that day will come, but it will. Until that day though, we are together in this. Stay safe out there and thank you for reading!

Industry Facts and Figures

The Association of the European Self-care Industry (AESGP) represents manufacturers of healthcare products that people can purchase without a doctor's prescription. These are known in the industry as "over the counter" (OTC) or "self-care" products. Self-care products include medicines, e.g. paracetamol, antihistamines etc.; food supplements, e.g. vitamins, probiotics etc.; and medical devices, e.g. nasal wash, wart removal gels, lubricant eye drops etc.

Known commercially as the "consumer healthcare sector", this area of healthcare includes over 2000 companies in Europe. At least half of these are **small and medium-sized companies (SMEs)**[1] and they can join the AESGP either directly or indirectly via their national association, if one exists.

Self-care is booming. Last year, **Europeans bought more than 9.7 billion packets of non-prescription medicines and 1 billion packs of minerals and vitamins**[2] in their attempt to treat minor ailments and/or improve their general wellbeing in 2019.

In total, more than **200 active pharmaceutical ingredients (INN) in more than 4000** different products are available in Europe without prescription. These include medicines for common ailments such as allergies, stomach upsets, cuts, bites & rashes, coughs & cold, pain.

AESGP Mission

To advance responsible self-care so that citizens may take better care of their health needs thereby contributing to the sustainability of European health care systems.

2000 + companies are involved in the self-care/consumer healthcare sector in Europe.

~9.7 billion packs of non-prescription medicines and 1 billion packs of minerals and vitamins were bought by Europeans in 2019.

More than 4000 different healthcare products are available OTC.

[1]AESGP Data
[2]Source: IQVIA CH Global Data
[3]AESGP Ingredient database

2019 at a glance

January

- AESGP is now a stakeholder of the European Antibiotic Awareness Day (EAAD), an initiative to promote the responsible use of antibiotics in the fight against antibiotic resistance.

February

- EU Public Affairs training for AESGP national associations to reinforce its internal network and explore best practices in advocacy.

March

- AESGP responds to the 10-year review of the European procedures (centralized, DCP and MRP) by the Network of medicines regulators.
- The AESGP Regulatory Conference is held in Amsterdam, the new home of the European Medicines Agency (EMA).
- AESGP welcomes a new company member: Perrigo.

April

- AESGP addresses the 42nd Annual Congress of the European Pharmaceutical Students' Association (EPSA) in Sofia, Bulgaria, on the topic of self-care in the case of non-communicable diseases.

2019 at a glance

May

- AESGP participates in the RAPS Regulatory Conference Europe 2019.
- AESGP addresses the Annual Conference of the European Association of Faculties of Pharmacy (EAFP) in Krakow, Poland.
- AESGP addresses the European Healthcare Distribution Association (GIRP)'s 60th Annual Meeting in Stockholm, Sweden.

June

- The 55th AESGP Annual Meeting «Evolving Self-Care Environment» – the annual gathering of the self-care sector in Europe – takes place in Geneva.
- The AESGP Action Plan 2019 – 2022 is adopted by the AESGP Board.
- AESGP celebrates PAGB's (UK consumer healthcare association) 100-year milestone in defending and promoting consumer healthcare.
- AESGP attends European Food Safety Authority (EFSA) 6th Roundtable with industry associations, dedicated to the revised General Food Law.

July

- AESGP celebrates International Self-Care Day and the vital role played by self-care 24/7.
- New video on self-care launched with the aim of sharing AESGP's vision for responsible self-care.

September

- AESGP attends the European community pharmacist's association's (PGEU) 60th Anniversary event.
- AESGP, together with the Global Self-Care Federation (GSCF), attends the International Federation of Pharmacists (FIP) 79th World Congress.

2019 at a glance

October

- AESGP relaunches its website with the aspiration to become a go-to source on self-care in Europe.
- AESGP holds a reception in the European Parliament to celebrate the European self-care industry's contribution to healthcare and wellbeing.
- The AESGP Regulatory Conference «A (re)new(ed) agenda for self-care products» takes place in Brussels.
- AESGP takes part in the 3rd EFSA Stakeholder Forum in Parma.
- AESGP addresses GSCF's 12th Asia-Pacific Regional Conference in Beijing, China.

November

- AESGP welcomes its first partner: IQVIA Consumer Health.
- AESGP attends a plenary meeting of the Co-ordination group for Mutual recognition and Decentralised procedures (CMDh).
- AESGP takes part in EMA's multi-stakeholder workshop on its Regulatory Science to 2025 strategy.
- AESGP holds a meeting with the European Directorate for the Quality of Medicines & HealthCare (EDQM).
- AESGP attends a bilateral hearing with the Working Party on European Union Monographs and European Union List (MLWP).
- AESGP attends the Joint EU Telematics Management Board and Industry Stakeholders Meeting.
- AESGP joins the communication campaign on the occasion of the World Antibiotic Awareness Week (WAAW) and attends the European Antibiotic Awareness Day (EAAD) launch event.
- AESGP takes part in the "Connecting Healthcare Debate" organized by the European Federation of Pharmaceutical Industries Association (EFPIA).
- AESGP addresses the 10th International Pharmaceutical Conference "Science and Practice" in Lithuania.

1 Promote the values and benefits of self-care

International Self-Care Day: celebrating the benefits of 24/7 self-care

On the occasion of the International Self-Care Day, held in July, the AESGP used its social media presence on LinkedIn and Twitter to celebrate the increasingly important role played by responsible self-care - 24 hours a day, 7 days a week. The continuous availability of self-care products allows individuals to have greater autonomy and personal engagement in their own and their families' health, which may contribute to the long-term sustainability of our healthcare systems.

Responsible self-care, coupled with timely and convenient access to a greater choice of self-care products, saves individuals time and effort, enabling them to manage health conditions themselves, or where necessary, in consultation with a pharmacist or doctor. Consequently, healthcare providers are able to serve a greater number of people and focus attention on more complex cases.

AESGP video 'What is self-care?'

AESGP published its new video on self-care. This video, first shown at the 55th AESGP Annual Meeting in Geneva, is a reminder that self-care is something we practice every day. The video aims to provide answers to questions such as what is responsible self-care, what are its benefits and how should we promote it?

#InternationalSelfCareDay

A new website and visual identity

AESGP has updated its look and redesigned its website. These changes accompany the Association's objective to become the go-to source for self-care in Europe.

The new website provides information for anyone interested in knowing more about AESGP and self-care product regulations. It also introduces the idea of responsible self-care as a benefit for individuals and society alike.

Thanks to an improved navigation and structure, the website is more user-friendly and now compatible with mobile devices. It is easy to access up-to-date and relevant information quickly.

Antimicrobial resistance: the role of the self-care industry

The rise of "super bugs" resistant to the most frequently used antibiotics is a major healthcare problem . Each year, 33 000 people die from infections caused by antimicrobial resistant bacteria[4].

One of the main reasons behind the rise of resistant microbes has been the incorrect use of antibiotics, particularly when prescribed for conditions that do not require them (e.g. common winter infections such as bronchitis, sinusitis, common cold and flu are viral in origin and therefore unaffected by antibiotics). European Antibiotic Awareness Day attempts to bring this to peoples' attention and AESGP was active in trying to communicate this important message.

Another factor linked to antimicrobial resistance is the incorrect disposal of expired or unused antibiotics. This leads to the presence of antibiotics in wastewater and landfill and the development of naturally occurring antibiotic-resistant bacteria in the environment. In Europe, most countries have collection systems in place for the correct disposal of medicines. Amongst the different projects overseen by the pharmaceutical industry, the #MedsDisposal campaign raises awareness and centralises the information on current European disposal schemes.

AESGP is committed to fight antimicrobial resistance and, to showcase the role played by the self-care industry to combat antibiotic resistance, it released a position paper on European Antibiotic Awareness Day (EAAD).

Throughout World Antibiotic Awareness Week, AESGP conducted a social media campaign, covering subjects such as health education, responsible use of antibiotics, safe disposal, sustainability of healthcare systems, etc. The campaign was coordinated with AESGP member-organisations, to allow the message to reach general public at the national level.

AESGP is committed to fight antimicrobial resistance and to showcase the role played by the self-care industry

[4] Source: European Antibiotic Awareness Day Portal (https://antibiotic.ecdc.europa.eu)

2 Proactively shape the regulatory, legislative, political and economic framework

Regulatory conferences

An essential part of AESGP's activities involves organising regulatory conferences. Members and stakeholders alike appreciate these conferences as they provide an opportunity for the self-care industry, stakeholders and regulators to interact and discuss.

The first of the year's regulatory conferences was held in Amsterdam in March. It covered two important topics in the area of self-care products: the digital transformation of regulatory science and healthcare, and the implementation the new Medical Device Regulation. Representatives from the European Commission, the EMA, and National Competent Authorities (NCAs) agreed that digitalisation provides unique opportunities. The advantages of digitalisation will improve operations, allow strategic regulatory innovation and, most importantly, enable person-centred care to be implemented. Another subject discussed was what had been learnt in the ten years since the first centralised switch (from prescription to non-prescription status) and how these findings could be used to plan future developments. The conference highlighted the self-care industry's readiness to participate in on-going developments especially during the digital transformation phase in order to implement the new regulations for medical devices and improve access to non-prescription medicines across Europe.

2 Proactively shape the regulatory, legislative, political and economic framework

The next of these regulatory conferences, in Brussels in October, brought the self-care industry, regulators and legislators together to debate current developments and consider the possibilities to further improve the regulatory framework for self-care products. This was also an opportunity to (re)introduce the self-care industry to the new European Parliament, explaining AESGP's cross-category expertise and its unique insight into the 3 regulatory framework that association is active.

The conference considered the main regulatory challenges concerning food supplements amongst these health claims, food additives and novel foods, which are of particular relevance to the self-care industry. The implementation of the Medical Device Regulation (MDR) was also discussed. This new regulation introduces substantial changes to existing regulatory framework and as such provides implementation challenges to Industry as well as regulators.

Additionally, a panel composed equally of regulators and industry members looked at the functioning of two of the most commonly used ways non-prescription medicines (including herbal medicinal products) obtain authorisation in Europe: the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP).

Finally, stakeholders gave their perspective as to the role of self-care. It was acknowledged that patient empowerment and health literacy are key enablers in self-care and these will also be necessary to provide the behavioural changes needed to improve antibiotic use.

Implementation of the Medical Devices Regulation (MDR)

The AESGP considers the correct, measured and sustainable implementation of the Medical Devices Regulation (MDR) to be a key objective of its mission. To this end, AESGP has had an active role in the working groups and task forces that the European Commission has been setting up under the umbrella of the new Medical Device Coordination Group (MDCG). The MDCG is responsible for developing guidance to ensure the effective and harmonised implementation of these important new regulations. The AESGP participates as an observer in the following MDCG working groups: Borderline and Classification (B&C); Clinical Investigation and Evaluation (CIE); New technologies; Unique Device Identification (UDI); International matters; Post-market Surveillance and Vigilance (PMSV); Standards; Nomenclature. Several of these working groups have established Task Forces on specific matters and Eudamed technical groups, in which AESGP also participates.

In 2019, AESGP took part in 24 physical meetings involving these eight working groups and Eudamed technical groups and numerous teleconferences with various task forces. In its role as observer, the AESGP coordinated and submitted comments and feedback for consultation and guidance on documents addressing specific provisions of the MDR brought up by the different working groups.

AESGP has been calling for a fair and risk-based implementation of the MDR requirements to self-care medical devices, especially substance-based medical devices which include products such as nasal sprays, lozenges or sprays to relieve sore throat, cough syrups, wart removal gels etc. In this context, AESGP has produced position papers on the classification rules 21 and 14 to ensure the consistent implementation of these rules by regulators and notified bodies.

In March and October 2019, AESGP organised conferences in Amsterdam and Brussels, respectively to discuss the key challenges from the on-going MDR implementation process from the

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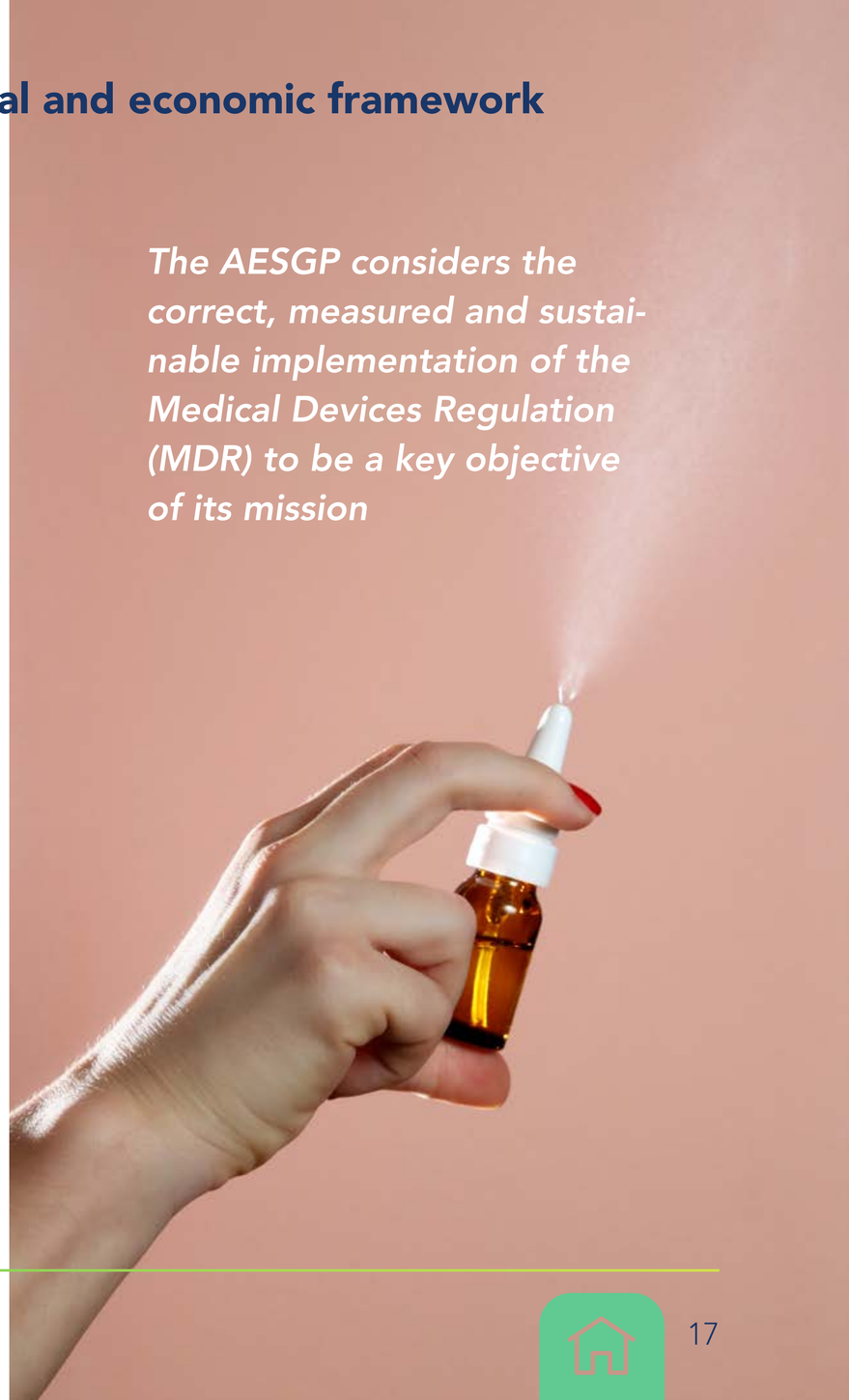


point of view of the self-care medical devices, with emphasis on substance-based medical devices. These discussions involved representatives from the European Commission, the Competent Authorities for Medical Devices (CAMD), the European Medicines Agency (EMA), the European Association of Medical Devices Notified Bodies (TEAM-NB) and industry. AESGP highlighted the need for appropriate expertise to assess substance-based devices. This is considered to be very important as regulators and notified bodies often consider these products automatically as medicines without carrying out a case-by-case assessment. AESGP also stressed the need for final guidance on the qualification and classification of substance-based medical devices as well as the need for more open discussions between regulators and industry stakeholders on borderline and classification issues. Key challenges of the on-going MDR implementation process that affect industry as a whole were also raised. These include the transitional periods provided under the MDR and the lack of availability and capacity of notified bodies. This latter is considered an obstacle to the timely certification of devices under the new MDR and to the renewal of certificates issued under the former Directives.

AESGP actively followed the EMA's developments and initiatives in relation to the implementation of the MDR. It is particularly interested in Article 117 which refers to so-called "drug-device combination products" and advocates that marketing authorisation applications for medicines with an integral medical device must include the results of the device's assessment of conformity by a notified body. In so-doing, AESGP contributed to the public consultations organised by the EMA concerning guidelines on the quality requirements for drug-device combinations.

Throughout the year, AESGP along with other stakeholders was also involved in the public consultation relating to the ECHA's restriction proposal on intentionally-added microplastics to consumer-use or professional-use products, which includes medical devices. During the public consultation period, AESGP expressed its concerns over the effect of the proposed restrictions on substance-based medical devices considering their high societal value in health terms compared with their negligible role in the release of microplastics into the environment.

Implementation of food legislation

Amongst its goals, AESGP would like to see the implementation of a balanced and fair legal and regulatory framework for easier market access for food supplements. The AESGP is collaborating with the EU authorities active in this area, namely the European Food Safety Authority (EFSA) and the European Commission (DG Santé).

The AESGP wants to ensure that the food legislation is implemented pragmatically particularly for food supplements. To create sustainable conditions for the use of food additives in food supplements, the AESGP and the Commission are working to reorganise the food supplement categories in which food additives are allowed and have introduced a separate category for supplements designated for infants and young children. The AESGP gathers and reports requested data to provide timely and necessary support to its member associations and companies. The added value of such a cross-category approach has been applied for example to the discussion on the maximum level of pyrrolizidine alkaloids, found in many medicinal herbs used in herbal medicinal products.

Developments that may have an impact on innovation in the food supplements area are also followed by the AESGP, particularly with regard to novel foods and the use of other substances e.g. chemical products in food.

The European Parliament and the Council of EU adopted new regulations on the transparency and sustainability of the risk assessment in the EU food chain in 2019. AESGP, along with other stakeholders in the food policy area, has been involved in this process. It has expressed support for enhancing the transparency and sustainability of the risk assessment process to improve citizens' trust while also providing effective protection of confidential business information. The next step will be the implementation of a regulation that introduces new rules around the governance, transparency and financing of EFSA. AESGP will remain involved in this implementation phase to ensure that the practicalities do not go beyond the intention of the legislator and remain manageable for the self-care industry.

Amongst its goals, AESGP would like to see the implementation of a balanced and fair legal and regulatory framework for easier market access for food supplements

Contribution to the implementation of the pharmaceutical legislation

AESGP and its members require that all the current routes to market (centralised, mutual recognition, decentralised and national procedures) guarantee timely market access for non-prescription medicines. The AESGP works with the medicine regulators to facilitate this while underlining the potential shortcomings and challenges of the different authorisation procedures. The AESGP submitted its response to the 10-year review following centralisation of two of the most commonly used routes for the authorisation of non-prescription medicines: the mutual recognition procedure (MRP) and the decentralised procedure (DCP). Following-up on past surveys, the AESGP conducted two surveys on manufacturers' experience with MRP and DCP for non-prescription medicines and herbal medicines, respectively. The results were presented at the AESGP conference in Brussels in October and provided an opportunity to review performance, from both the Industry's and from the national competent authorities' (NCAs) viewpoint. The timeline of the validation phase and the national phase were areas shown to be in need of further improvement. The results were also presented at the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) plenary meeting in November. At this later meeting, the AESGP was able to underline some of the specific challenges related to the authorisation of non-prescription medicines and continued to raise the possibility of splitting procedures as a potential solution to the problems. The AESGP presented its survey findings for herbal medicines at a bilateral hearing with the Committee on Herbal Medicinal Products (HMPC) which is the European Medicines Agency's (EMA) committee responsible for compiling and assessing scientific data on herbal substances, preparations and combinations, to support the harmonisation of the European market.

A major objective for AESGP is to promote switching from prescription-only to non-prescription status of medicines. This was discussed in depth in Amsterdam at the AESGP conference with the aim of creating an environment more open to innovation within the sector. One possibility would be to plan for this transition early in the life cycle of a medicine and combine it with the scientific advice and future real-world data/ real-world evidence that are required for any new medical product. The AESGP also participated at the "Regulatory Science to 2025" workshop organised by the EMA. It was a multi-stakeholder working session that the EMA has initiated to ensure that it has the regulatory tools to continue supporting the European medicines regulatory network and fulfil its on-going mission in light of upcoming scientific challenges. The AESGP contributed to the written consultation following the working session and among other points advocated for the application of real-world data (RWD) and real-world evidence (RWE) in regulatory decisions for well-known products.

AESGP and its members require that all the current routes to market (centralised, mutual recognition, decentralised and national procedures) guarantee timely market access for non-prescription medicines

The EMA-HMA Task Force on Big Data published a draft report for public consultation in May 2019. The AESGP responded by highlighting some of the opportunities for regulatory use of Big Data and called for more involvement of Industry. It asked specifically for the Industry to be able to participate in subgroups, defined projects and/or in general governance.

AESGP has been calling for legislation on products that are well-known and have been marketed for a long time to be interpreted in a smart and impartial way. AESGP and a team of experts representing the Industry are advocating for modernisation of the EU Variations System. The AESGP contributed to a comprehensive position paper with suggestions for simplification of variations, removal of some administrative type variations and optimisation of variations system via digitalisation and telematics. This was submitted to the European Commission in December 2019.

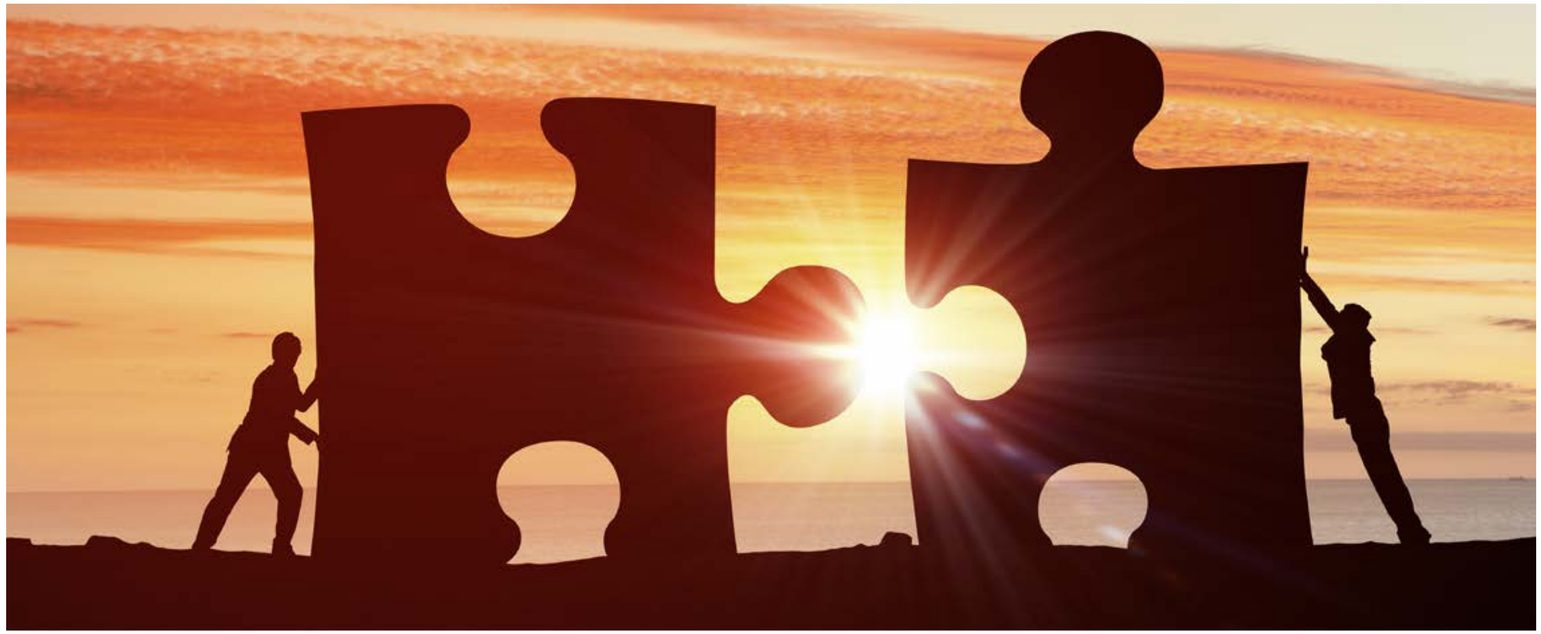
AESGP has been working with the European regulatory network on the availability of authorised medicines. AESGP would prefer a risk-based approach instead of the current reporting requirement of all potential shortages. Together with other industry partners, the AESGP has requested a pilot, before the full implementation of the "guidance and template for shortage notification to EMA and NCAs" that was published in July 2019.

In September, AESGP began coordination of the nitrosamine impurity concerns that require all marketing authorisation holders to review their entire portfolio for the potential presence of nitrosamine. This problem has become the centre of an article 5(3) procedure and a call by the EMA and CMDh to all marketing authorisation holders to review their entire portfolio for the potential presence of this substance. In November, the AESGP participated in a scientific workshop on the lessons learnt from the sartan case which acknowledged that, while the science is progressing, there are still a number of unknowns on the possible nitrosamine formation in products.

Brexit

Since the referendum in 2016, the Industry has worked to ensure minimal disruption to the supply of self-care products in both the European Union (EU) and the United Kingdom (UK), when the UK leaves the EU. The AESGP revised its position in March 2019.

AESGP members continue to invest in preparedness for every eventuality until there is certainty of an orderly exit. This includes implementation of new regulatory requirements, adaptation of manufacturing and supply chains, including customs arrangements to ensure an uninterrupted supply of self-care products to the public. Nevertheless, the self-care industry calls for an explicit commitment of the EU27 and the UK to securing long-term, extensive cooperation in the field of health and medical technologies, in the best interests of citizens and public health.



3 Increase trust in self-care to be recognised as a responsible industry

Environment

Pharmaceuticals in the Environment

Over the past years, the presence of pharmaceuticals in water has become an emerging environmental concern. Good policy making in this area would aim to minimise the impact of pharmaceuticals in the environment (PiE) while maintaining timely access to effective treatments for patients and optimising health systems outcomes.

The pharmaceutical industry has been at the forefront of initiatives to increase knowledge of the environmental impacts of pharmaceuticals, including risk assessment and potential mitigation measures. The self-care industry is also committed to playing a leading role in addressing these concerns and is actively involved in managing the impact of PiE. This has led to the establishment of the Inter-Associations Initiative (IAI) PiE Task Force and the industry Eco-Pharmaco-Stewardship (EPS) initiative. As part of the IAI Task Force, the AESGP contributed to the industry's comments on the draft revised Environment Risk Assessment guideline. The AESGP has attended regular meetings of the Commission's Working Group on Chemicals, which focuses on a watch list of substances recognised by the Water Framework Directive, using effect-based modelling to enable these substances to be grouped by mode of action.

In March 2019, the European Commission released the communication "Strategic Approach to Pharmaceuticals in the Environment", which identified six action areas covering all stages of the pharmaceutical life cycle, where improvements can be made. The Commission, in conjunction with the Netherlands, organised a workshop with representatives and stakeholders from Member States, where the chair of the IAI PiE Task Force presented the industry's view on the communication. The Commission's strategy emphasises the sharing of national practices and the workshop provided an opportunity for representatives of Switzerland, the Netherlands, Sweden and Germany to present their national initiatives. As a result of this workshop, the pharmaceutical committee has formed a new environment group.

MedsDisposal

Since 2016, the MedsDisposal campaign has represented the combined efforts of the medicines supply chain (manufacturers, distributers, healthcare professionals and healthcare students). The aim of the initiative is to raise awareness among the general public on how to dispose correctly of unused and/or expired medicines. Current collection systems vary from one European country to another but in most cases are supported by the supply chain stakeholders, through their social or extended producer responsibility programmes. These take-back schemes prevent medicines entering the environment through disposal via wastewater or landfill. In 2019, the AESGP took over the leadership of the MedsDisposal campaign. Its actions include updating data and information as well as improving the schemes visibility throughout Europe demanding more input from other stakeholders to endorse the initiative.

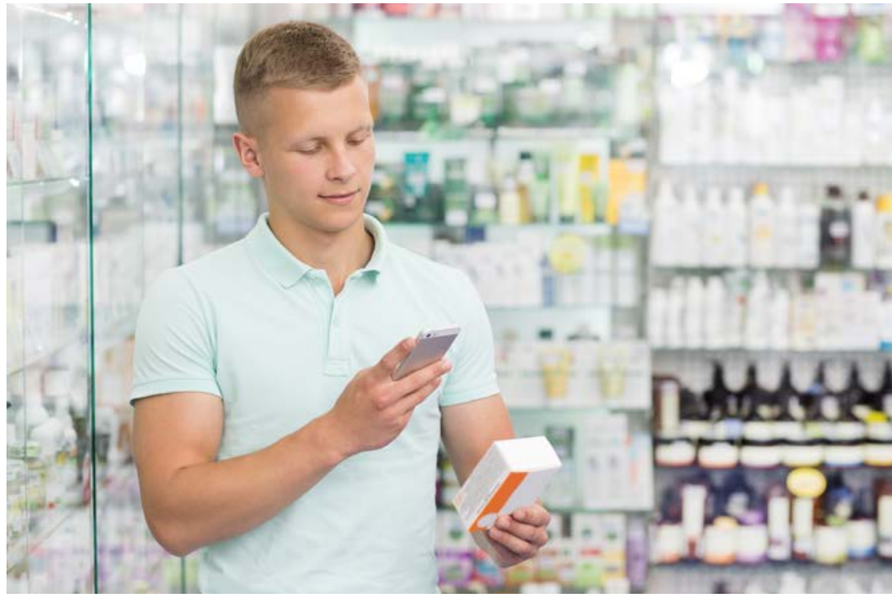
eProduct information

In 2019, the EMA released a six-month public consultation draft of the key principles to apply to electronic product information (ePi) for human medicines in the European Union. The Inter-Associations Task Force (IATF) set up specifically to oversee electronic information replied on behalf of the industry.

The AESGP is very much in support of having an e-leaflet available to complement the paper version of the information supplied with the product. This is of particular concern in the self-care sector, as the consumer may have little or no interaction with a healthcare professional before taking a non-prescription medicine. It is especially important, when treating symptoms from the contents of their home medicines cabinet, that packs continue to contain printed information that can be complemented by an e-leaflet.

When replying to the consultation draft, the IATF suggested further work on content improvement, the implementation of the legislation and access to quality data. It also reiterated the need for close involvement of the industry to produce electronic information that is beneficial for patients.

The importance of delivering real-time electronic product information to advancing patient-centred access to medicines was discussed by Guido Rasi, the Executive Director of the EMA during the AESGP regulatory conference in Amsterdam. César



Hernández García, the Head of Department of Medicines for Human Use, also highlighted the importance of multi-stakeholder involvement in the development of product information to empower patients when he presented at EMA/HMA workshop on e-tools to improve accessibility to product information.

The IATF met with the ePI pioneering group from the EC/EMA/HMA in July and it was agreed that the Industry would be included in the ePI project in a collaborative manner in order to ensure its long-term success.

Engagement with 3 regulatory frameworks and stakeholders' networks

The AESGP plays an important role in discussions between all relevant EU institutions, regulatory bodies, agencies and stakeholders involved in determining the three frameworks in which the self-care/consumer health industry operates, namely: non-prescription medicines, substance-based medical devices and food supplements.

As science and technology advance, so regulatory science needs to keep pace in order that fit-for purpose regulatory standards and tools exist to inform the regulatory decision-making process for self-care products, in the best manner possible.

The AESGP promotes evidence-based regulation and legislation. However, this is constantly changing with the advancement of scientific evidence. Therefore, the AESGP has an important role in promoting a consistent approach towards regulatory science, classification and risk management across all regulatory frameworks at the EU level. AESGP was a pioneer in developing the collaborations needed across the European regulatory landscape to improve the environment for the innovation of safe and effective self-care products to enhance patient empowerment.

In 2019, the AESGP was included in workshops discussing the vision for the next EU Medicines Agencies Network Strategy (2020-2025) which includes recommendations for an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products (i.e. products having combined characteristics of medicines along with either foods, medical devices or cosmetics). Faced with an increasing number of complex health products, the EU regulatory networks know that they need to find new ways to collaborate with all the relevant stakeholders, particularly between medicines and medical devices regulators. These include the European medicines network, notified bodies and authorities responsible for regulating medical devices.

With the emergence of new health risks across product categories such as contaminants (e.g. nitrosamines), collaboration between the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) is increasingly needed to ensure trust in the regulatory systems. Here the AESGP continues to have an important role in the EFSA stakeholder engagement and workshops on various topics including: resolving scientific conflict, risk communication and the implementation of new transparency rules. These are all under the auspices of the development of EFSA's future strategy 2021-2027.

The AESGP continues to support collaborative efforts between EU regulatory networks and is actively engaged as a responsible stakeholder towards evidence-based and informed regulatory decision making throughout a product's lifecycle without unnecessary regulatory burden.

4 Strengthen and develop a holistic network encompassing all relevant stakeholders and serve as a platform for Member Associations

Annual Meeting

The 55th AESGP Annual Meeting – the annual gathering of the self-care sector in Europe – was held in Geneva, Switzerland, from 4th to 6th June 2019. The conference entitled 'Evolving the self-care environment' looked at the numerous challenges facing the self-care environment such as increasing societal concerns and the fragmented regulatory landscape. Ideas were considered as to how to turn these into opportunities e.g. building consumer trust, fostering socially conscious and transparent brands to make self-care the default option and, most importantly, making the environment consumer-centric.

The two-days of discussion consolidated a number of concepts and ideas to enable the industry to advance self-care for the benefit of individuals and health systems. While considering people to be at the heart of all debates, attention was paid to the need of health literacy for true empowerment. The rapid changes in digital technology offer an unprecedented opportunity to develop tools to enable individuals to self-diagnose and self-manage their health needs within clearly defined parameters of responsible self-care. An overarching theme of the conference was consumer trust. The industry's approach to environmental sustainability was identified as an important element to maintain relevance and build trust.

New members

In March 2019, AESGP welcomed its newest member company, Perrigo. Perrigo is a leading provider of branded self-care products throughout Europe. As a leading global healthcare company, it aims to provide value to consumers. This is demonstrated by the company vision 'to make lives better by bringing quality, affordable self-care products that consumers trust everywhere they are sold.'

Partners

In 2019, the AESGP created a new membership category, that of "Partners". This offers a partnership to companies that offer, or would be able to offer, services to AESGP or its members, such as: advertising agencies, PR consultancies, regulatory consultancies, marketing agencies, sales and distribution companies, and public affairs agencies.

The role of a Partner is to support the 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.

In November, the AESGP welcomed its first partner, IQVIA Consumer Health. IQVIA Consumer Health is a leading global provider of actionable insights, purpose-built technologies and exceptional market expertise to the consumer healthcare industry.

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 and chaired by the President:

AESGP President 2019-2021

Birgit Schuhbauer

Global Vice President OTC Franchise,
Johnson & Johnson

AESGP Vice-President 2019-2021

Traugott Ulrich

Traugott Ulrich, Executive Director,
Schwabe Pharma

AESGP Vice-President 2019-2021

Bernard Mauritz

Director General
Neprofarm, the Netherlands

AESGP Treasurer 2019-2021

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
Regulatory and Scientific Affairs Manager

Klavdija Kmetič
Junior Regulatory Affairs and Policy Manager

Oliver Hartmann
Regulatory Affairs Manager

Andrew Thornley
Health & Telematics Senior Adviser

Paul-Etienne Schaeffer
Life-Sciences Regulatory Affairs Manager

Luis Rhodes Baiao
Governmental and Public Affairs Manager

Lucy Gits
Events and Finance Administrator

Alix Marchal
Communication and Member Services Manager

Members

More than 2000 companies operate in the consumer healthcare sector in Europe.

They are affiliated with AESGP either directly, or through one of the **23 national associations**.

NATIONAL ASSOCIATIONS

anefp Autocuidado de la Salud
apifarma
ASSGP
BACHI
B.A.H
CASI The Croatian Association of the Self-Medication Industry
ΕΦΕΞ ΣΥΝΔΕΣΜΟΣ ΕΤΑΙΡΕΙΩΝ ΦΑΡΜΑΚΩΝ ΕΥΡΕΙΑΣ ΧΡΗΣΗΣ
IGEPHA The Austrian Self Care Association
ipha IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION
LIF
LMI LEGEMIDDELINDUSTRIEN
FEDERCHIMICA ASSOSALUTE
MAGYOSZ
Neprofarm
PAGB
PASMI
pharma.be
PHARMA INDUSTRY FINLAND
RASCI
afipa
SVOPL

INTERNATIONAL COMPANIES

BAYER
gsk do more feel better live longer
Johnson & Johnson
Perrigo
P&G Health
Reckitt Benckiser
SANOFI
SCHWABE

ASSOCIATED COMPANIES/ ASSOCIATIONS

Boots
Aboca
ALKALOID SKOPJE
Arkopharma
ASSOBIOMEDICA
ASSOERBE
BOIRON
GALDERMA
HRA Pharma
indena
IPSEN Innovation for patient care
medicalbrands
Pierre Fabre
SVKH ASMC

Glossary

AESGP: Association of the European Self-Care Industry

CAMD: Competent Authorities for Medical Devices

CMDh: Co-ordination group for Mutual recognition and Decentralised procedures – human

DCP: Decentralised Procedure

EAAD: European Antibiotic Awareness Day

EAFP: European Association of Faculties of Pharmacy

ECHA: European Chemicals Agency

EDQM: European Directorate for the Quality of Medicines & HealthCare

EFPIA: European Federation of Pharmaceutical Industries Association

EFSA: European Food Safety Authority

EMA: European Medicines Agency

ePi: Electronic product information

EPS: Eco-Pharmaco-Stewardship

EPSA: European Pharmaceutical Students' Association

Eudamed: European database on medical devices

FIP : International Federation of Pharmacists

GIRP: European Healthcare Distribution Association

GSCF: Global Self-Care Federation

HMA: Heads of Medicines Agencies

Inter-Associations Initiative (IAI) PiE Task Force

The Inter-Associations Task Force in response to the developing focus of pharmaceuticals in the environment (IAI PiE TF) is a collaboration between the AESGP, EFPIA and Medicines for Europe.

The IAI PiE TF has developed three major strategic areas:

- Addressing an improved regulatory framework for the environmental risk assessment of human medicinal products in context with the requirements of the authorization for human medicines
- Developing research-based methodology for prioritization of legacy compounds for environmental risk assessment
- Providing guidance for the effluent management for production and formulation sites

Inter-Associations Task Force (IATF) on ePi

The Inter-Associations Task Force (IATF) on electronic product information is a collaboration between the AESGP, EFPIA and Medicines for Europe. It provides a representative cross-EEA industry forum, which can partner with stakeholders. It focuses on:

- Creating proposals for improved product information content, layout and readability within the current legislation
- Applying (digital) health literacy principles
- The concurrent development of electronic product information formats

MDCG: Medical Device Coordination Group

MDR: Medical Devices Regulation

MLWP: Working Party on European Union Monographs and European Union List

MRP: Mutual Recognition Procedure

NCA: National Competent Authority

PGEU: Pharmaceutical Group of the European Union

PiE: Pharmaceuticals in the environment

RWD: Real-world data. RWD are defined as routinely collected data relating to a patient's health status or the delivery of health care from a variety of sources other than traditional clinical trials.

RWE: Real-world evidence. RWE is defined as the evidence derived from the analysis and/or synthesis of real-world data (RWD).

Switch: Regulatory medicine's status change from prescription to non-prescription status, and vice versa.

TEAM-NB: European Association of Medical Devices Notified Bodies

WAAW: World Antibiotic Awareness Week

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