AESGP ACTIVITY REPORT 2020

Self-care in times of pandemic and beyond

AESGP

Self-care in times of pandemic and beyond

The **Association of the European Self-Care 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.

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 healthcare systems.

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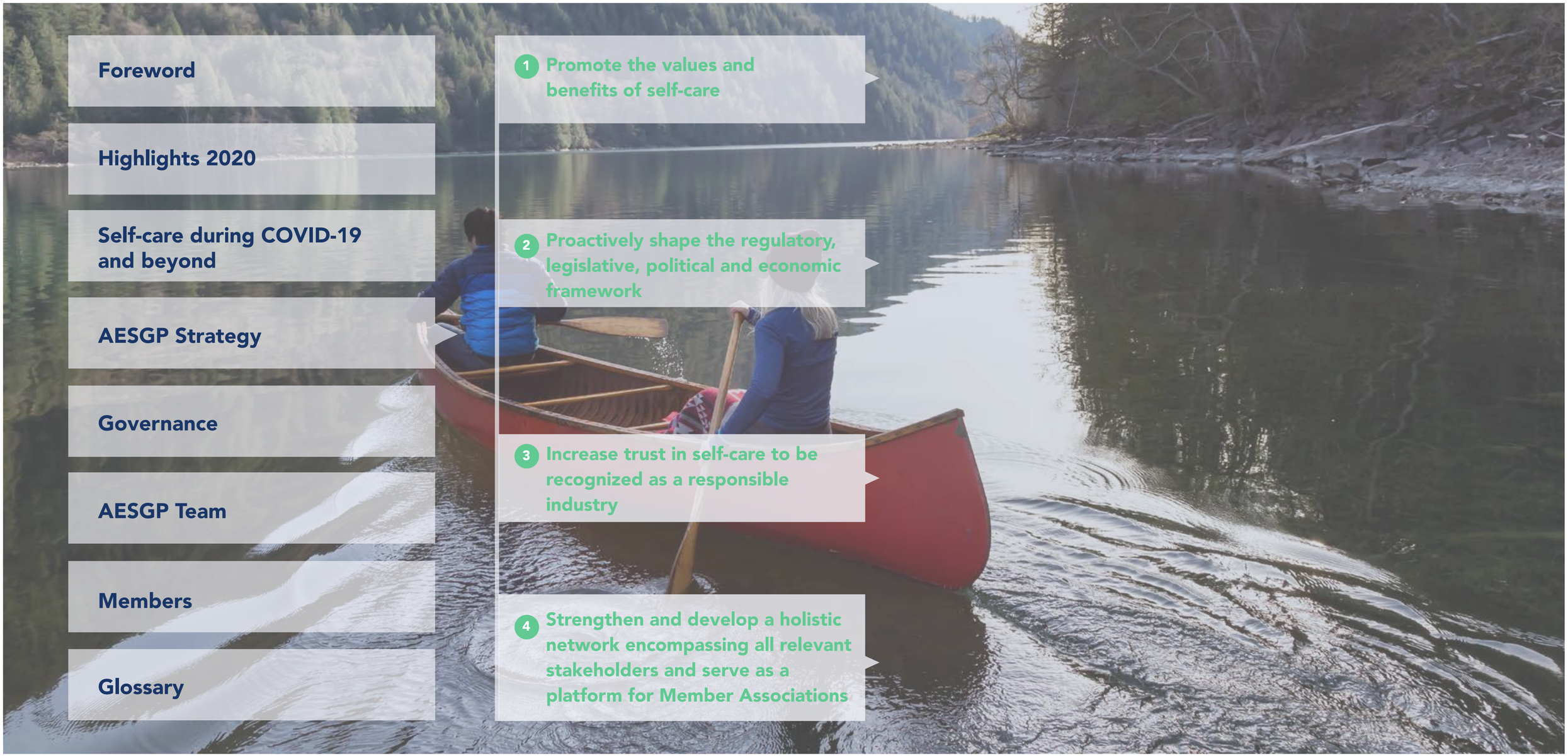

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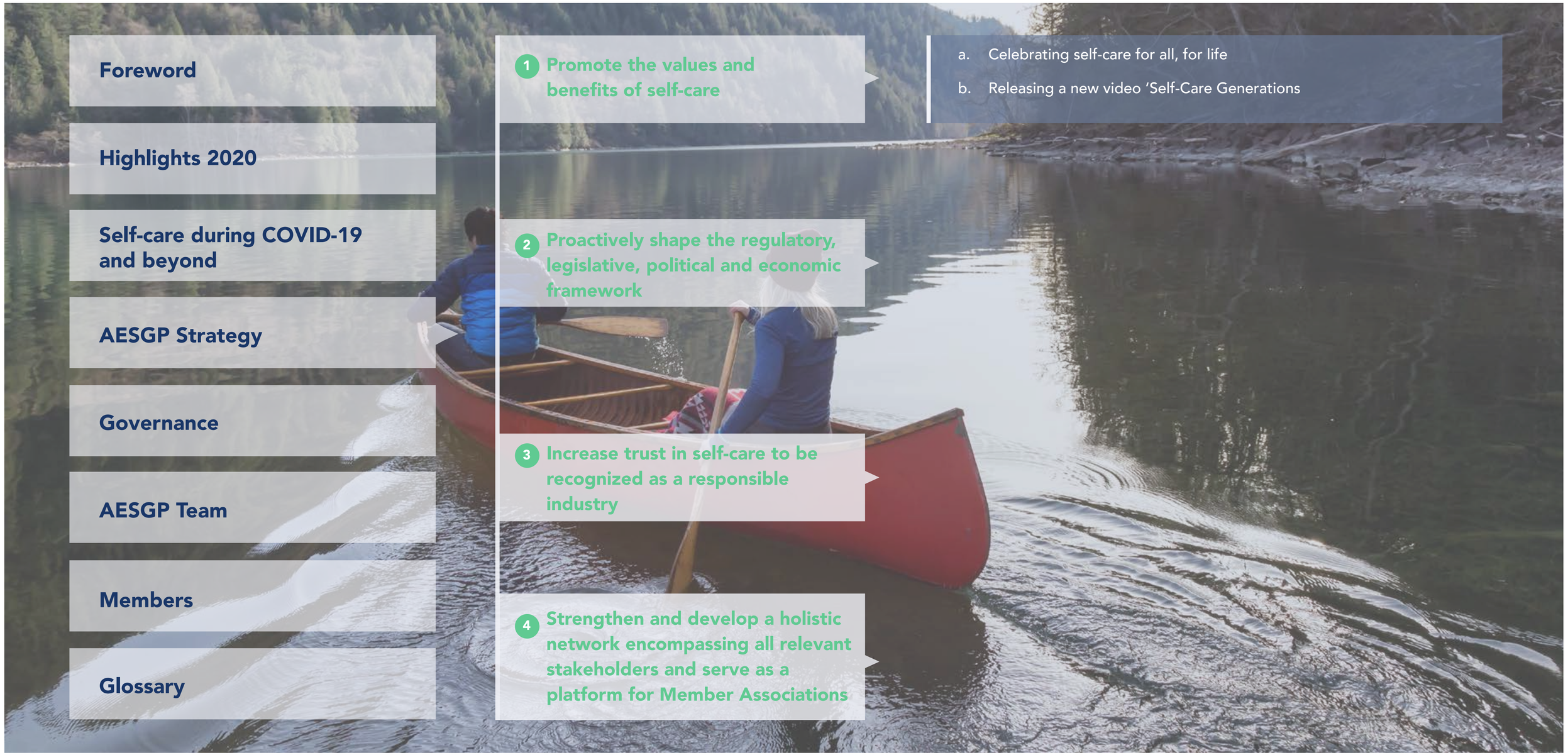

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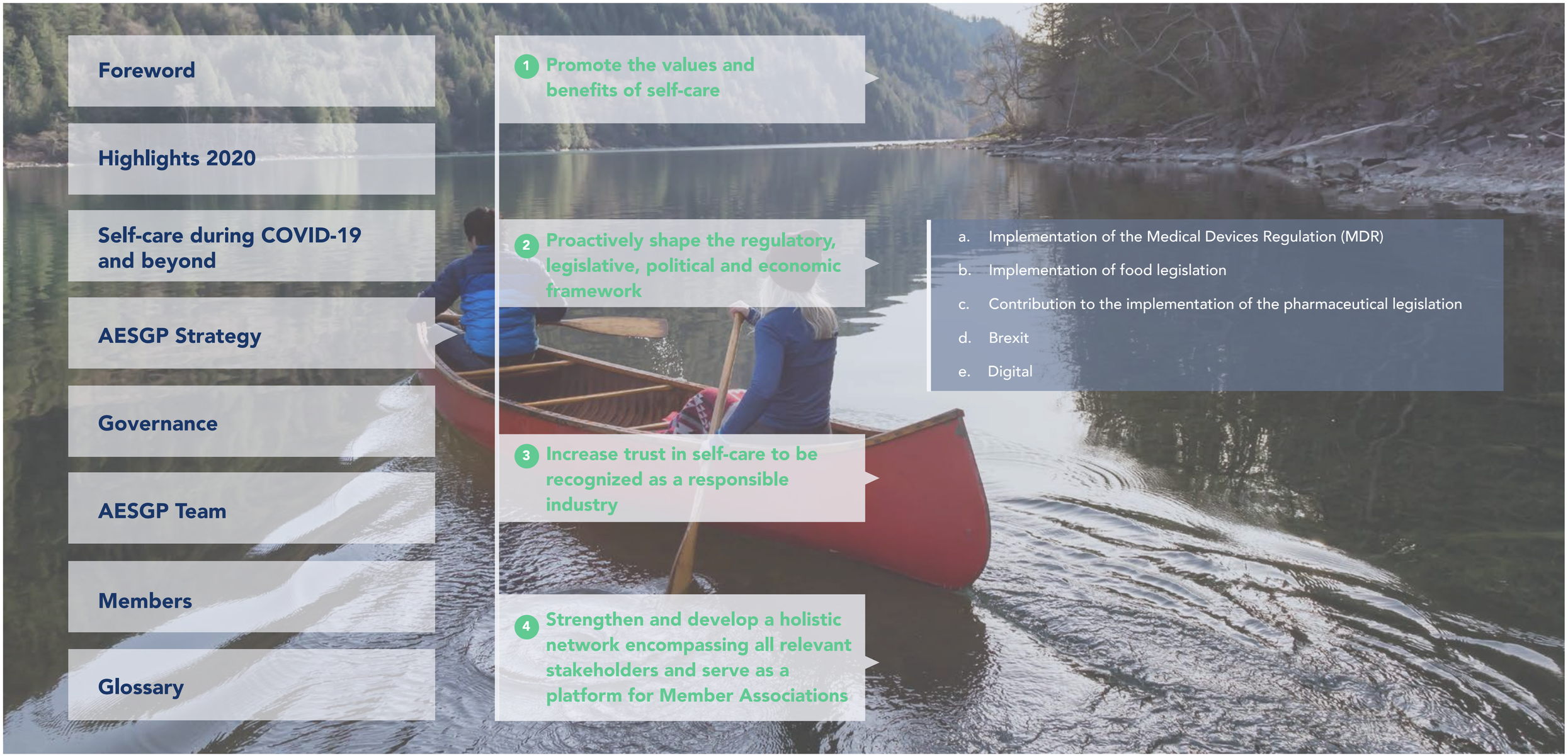

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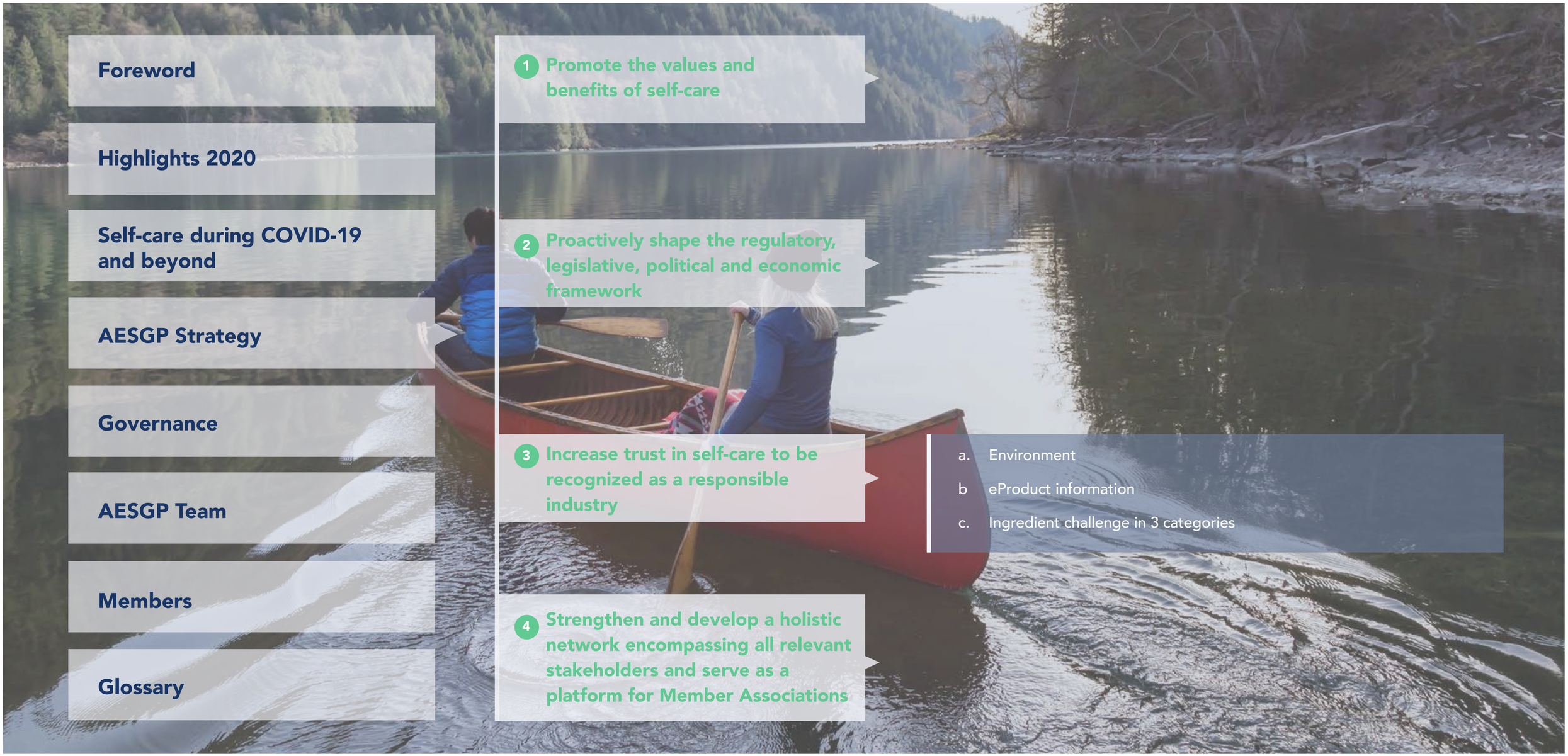

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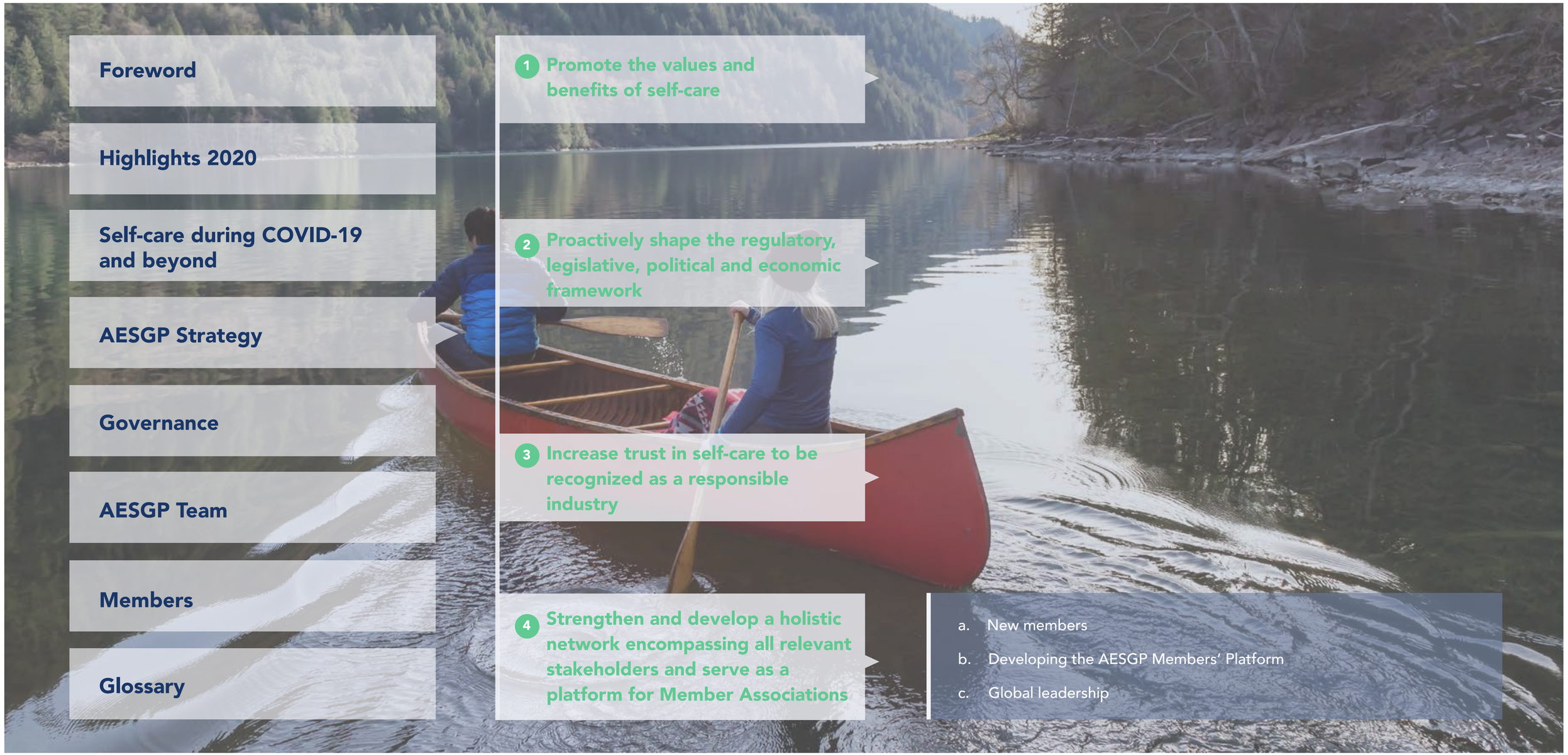


Foreword

By **Birgit Schuhbauer**, AESGP President

2020 is the year we will remember for the numerous disruptions that a global pandemic brought to our lives. COVID-19 created unprecedented challenges for our health systems, our economies and our social and mental well-being. Self-care has never been as important as in these circumstances. Even at the most critical of times, European community pharmacies have remained open and offered qualified advice as well as a number of self-care product options for the management of mild symptoms of COVID-19 and other common ailments, enabling us to practice self-care and spare health system resources for those in most need.

At the beginning of the pandemic in Europe, we saw unprecedented wave of panic buying, including of self-care products. At the same time, we saw Member States closing borders, usual transport routes disrupted due to fewer passenger flights, and we had to deal with other unanticipated challenges including export restrictions by EU trading partners. Still, our Industry, with the assistance of the regulators and legislators, was capable by and large to avoid shortages and ensure continuity of supply during this challenging period. At the same time, we have learnt lessons. We have stress-tested our supply chains. We have revised and updated contingency and risk management plans, etc. We are coming out of this stronger.

At the end of 2020, the Commission set out a vision for the future of the European pharmaceutical sector – The European Pharmaceutical Strategy. Europe hosts several global manufacturing facilities of non-prescription medicines. Medicines manufactured in Europe are supplied not only to the people in Europe, but to other continents as well, from the Americas to Australia. Hence it is important that when strengthening European production and procurement we ensure access to high-quality and affordable medicinal products globally.

We welcome in particular the Commission's commitment to regulatory and administrative simplification. It is crucial to pursue an agenda of better regulation for the pharmaceutical sector, to reduce red tape and improve the effectiveness of regulatory procedures. Some of the flexibility that was introduced during the pandemic hopefully is here to stay, so that the European regulatory system remains agile and future proof.

We believe that digitalisation of the pharmaceutical regulatory system should be recognised among the top strategic priorities by the regulatory network. We are committed to supporting the implementation of the EU Telematics Strategy so that common information-technology services are put in place and maintained to implement the European pharmaceutical policy and legislation.

I would like to conclude my review of 2020 by saying that we certainly live in unprecedented times. The pandemic has exposed many of our vulnerabilities, and the impact will be profound and long-lasting. But at the same time, it is amazing to see how fast we have adapted to this new reality, embraced digital technologies, adapted and found new ways of working and connecting to each other. It is important that while we are learning our lessons and future proofing our systems, we do not miss this opportunity to lay the ground for a sustainable "new normal".

Highlights 2020

4000 +

More than 4 000 different self-care products are available without prescription (OTC). Self-care products include medicines, e.g. painkillers, antihistamines etc.; food supplements, e.g. vitamins, probiotics etc.; and medical devices, e.g. nasal wash, wart removal gels, lubricant eye drops etc.

9.7 billions

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

Source: IQVIA Global OTC Insights

200 +

More than 200 active pharmaceutical ingredients (INN) in more than 4000 different products are available in Europe without prescription.

AESGP OTC Ingredients Directory (https://otc.aesgp.eu/)

2

Two new active pharmaceutical ingredients (INN) - desloratadine (antihistamine) and lidocaine + prilocaine formulation (premature ejaculation) have been reclassified centrally from **Rx to OTC** (switched) **in the EU in 2020**.

2000 +

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

Highlights 2020

60+

AESGP participated in 60+ high level meetings related to the pandemic response at the EU level, including:

15+ meetings with Commissioner for Health: S. Kyriakides and the Internal Market Commissioner: T. Breton

32 meetings set up by the Commission with Medical Devices Industry Associations to ensure a continuous exchange of information during the Covid-19 crisis with regard to demand and supply of medical devices and in vitro diagnostic devices as well as other related aspects.

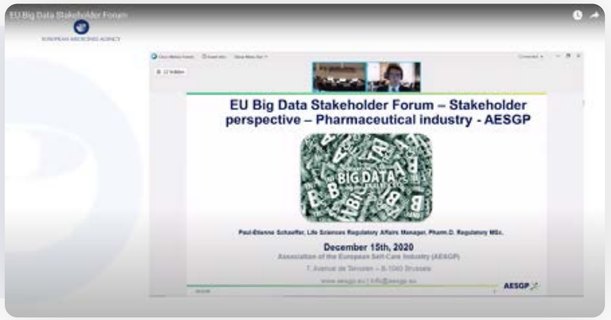
17 meetings with the EU Executive Steering Group on Shortages of Medicines Caused by Major Events (EMA, the European Commission (EC) and national competent authorities in the Member States)

Highlights 2020

External speaking engagements:

15+

Although many conferences and meetings were cancelled during the first part of the year because of the pandemic, AESGP delivered 15+ speeches in: the European Parliament, National members' events, healthcare professional association meetings, expert conferences etc.



33+

+33 Responses to public consultations by EC, ECHA, MDCG, EMA, HMA and EDQM.

Direct engagement with policy makers:
Together with BAH (German member), AESGP organised a high-level conference on the Future of Medicines under the German Council Presidency. This conference addressed what we have learned during the course of 2020 and discussed political conclusions for the pharmaceutical sector together with EMA, HMAs, European and German policy makers.

18+

+18 Industry Statements and Position Papers were published in relation to the European Pharmaceutical Strategy, Medicine Shortages (including lessons from the 1st wave of COVID-19), EU4Health Programme, Brexit, Pharmaceuticals in the Environment, the Medical Devices Regulation and Farm to Fork strategy.

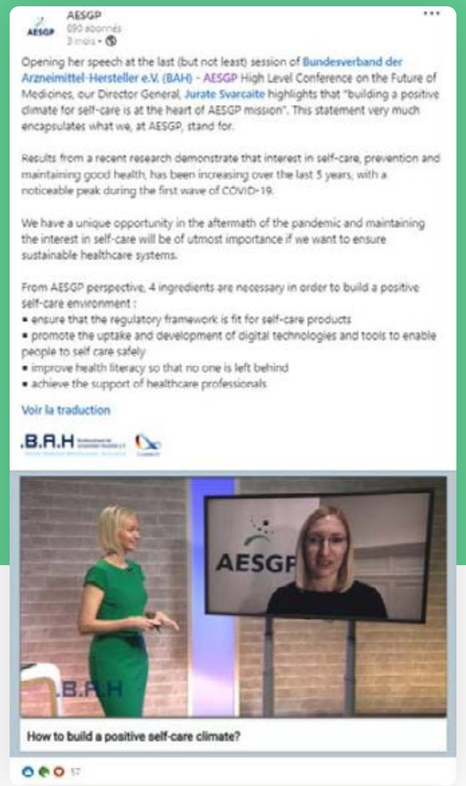
Highlights 2020

AESGP consistently increased its media profile throughout 2020:

428 new subscribers to our social media pages

+26K visits to the AESGP website

The most popular AESGP LinkedIn post achieved **2,077** impressions, while we collected **2,814** impressions on Twitter on the occasion of World Health Day 2020.



4

Blog posts on the occasion of the International Self-Care Day (24th July), including a guest blog post by Duarte Santos, PGEU President, 2020

1

1 new member:

UPSA has joined AESGP as an associated member company.

Self-care during COVID-19 and beyond

During the COVID-19 pandemic, health systems are facing an unprecedented number of patients requiring urgent and/or intensive care; it is apparent that material and human resources are scarce for the peaking demand. ***Optimizing the availability of healthcare professionals, infrastructure, equipment and therapeutics is essential both during pandemic and beyond.***

The European self-care industry prioritises the continuity of their supply chains to ensure that the availability of self-care products is never interrupted. It is important that citizens continue to have a regular access to self-care products, such as non-prescription medicines, medical devices and food supplements, through their regular suppliers (e.g., pharmacies). ***Responsible self-care, including use of self-care products enables us as individuals and as a society to reduce pressure on health systems and spare more limited resources for those most in need.***

The social listening exercise AESGP performed during the summer of 2020 in 3 major European languages (English, French and German) revealed that interest in self-care has been increasing consistently over the past 5 years and reached a peak during the first wave of the pandemic in Europe. ***It is apparent that more than ever before, self-care is central to how we live our lives today. At AESGP, we are doing everything we can to make that possible.***

AESGP works with the European Commission and the European network of medicines and medical devices regulators

In 2020, the AESGP worked alongside other European pharmaceutical and medical devices industry associations to inform, predict and resolve eventual problems to make sure that any potential shortages of healthcare products were prevented and/or mitigated.

AESGP believes that only through a coordinated approach of manufacturers, suppliers, healthcare professionals, governments and executive agencies, is it possible to overcome the crisis and achieve positive outcomes in a timely manner.

Dialogue with the European Commission

In 2020, AESGP and other trade associations representing the manufacturers of medicines, vaccines and medical devices had more than 15 joint meetings with the European Commissioners for Health, Stella Kyriakides, and the Internal Market, Thierry Breton. These were important in order to foresee any potential problems that might require political solutions or diplomatic interventions at the EU level in the early days of the pandemic.

AESGP provided information on behalf of its members on supply chain stability, both inside the EU and in third countries, described actual problematic episodes and suggested viable actions. In turn, the European Commissioners shared their concerns for healthcare provision across Europe and their political efforts to ensure that Member States act in a coordinated manner and had the appropriate tools to address the challenges of the pandemic.

This high-level dialogue has resulted in practical solutions such as green lanes for cross-border delivery of essential healthcare goods, guidelines on the optimal and rational supply of medicines, Q&A on regulatory exceptions and conformity assessment procedures, etc. This allowed the regulatory processes to foster timely access to the market, without delays from regulators and other parts of the regulatory system, flexibility, where appropriate, was applied temporarily, while upholding public health interests.

Dialogue with the European medicines regulatory network

In addition, the EMA, the European Commission and the national competent authorities of the Member States set up the EU Executive Steering Group on Shortages of Medicines Caused by Major Events to discuss measures aimed at addressing the impact of the COVID-19 outbreak on the supply of medicines in the EU.

The Steering Group has requested that AESGP and other EU pharmaceutical industry associations report any possible shortages to the EU authorities in a timely manner. In response, AESGP has asked its members to report their preparedness to prevent any possible shortages that may result from the pandemic back to the Steering Group.

Together with other EU pharmaceutical industry associations, AESGP suggested the creation of an Industry Single Point of Contact (iSPOC) system to improve coordination and reporting at the EU level. Once operational this system has led to better coordination of the reporting of shortages and allowed discussion of mitigation measures with no delay.

Dialogue with the European medical devices regulatory network

The European Commission, in close collaboration with Member States' competent authorities and relevant economic operators, has been working to set-up a joint procurement mechanism for Personal Protection Equipment (PPE) and also some essential medical devices.

AESGP has continuously collected feedback from its member companies regarding the impact of the COVID-19 crisis on the implementation of the Medical Devices Regulation (MDR) as well as the certification and availability of medical devices in Europe, and reported these issues back to the Commission.

Industry associations, including AESGP, indicated that companies were investing all their efforts to maintain the continuity of supply of medical devices in face COVID-19. It became apparent very early on that member companies could not prioritise the implementation of the new Medical Devices Regulation, scheduled to apply from 26th May 2020 during a pandemic. Hence the legislators' decision to postpone implementation for a year came as a welcome relief. Since then, the situation has stabilized, and pragmatic solutions have been found with regulators so that companies can again dedicate the resources needed to implement the new Regulations in a manageable way so as to ensure the continuity supply under the new system.

AESGP works closely with its members: addressing shortcomings and sourcing solutions

To prepare for exchanges with the Commission and the EMA, AESGP coordinated with its national industry associations and member companies on a daily basis to proactively collect relevant information and share it as quickly as possible. This facilitated the early reporting of supply bottlenecks which could have potentially affected the availability of self-care products in Europe, and with legislators and regulators enabled pragmatic solutions to be found together. This challenging period has brought the AESGP member network closer together, building on common industry interests and optimal use of the network resources to deliver tangible results when most needed.

Looking ahead

COVID-19 has stress-tested our supply chains. Especially at the beginning of the pandemic, when there were unprecedented spikes in demand for products such as PPE, hand sanitizer, medicinal products, etc., which in some cases, for a period of time, resulted in shortages. Strategies deployed to ensure supply availability included guidelines for the rational use of products, opening of transport routes within the EU, rapidly ramping-up production where possible and keeping the supply chains as "connected" as they safely can be – for example, continuing to allow cargo to be shipped between continents even if passengers were not accepted.

All this was possible because of the continuous dialogue between the Industry and regulators. Leadership and close coordination were proven to be key during this exceptional period, including flexibility of all stakeholders, to prevent and mitigate supply disruptions both within the EU and globally. Any interruptions to supply or surge in demand were swiftly pinpointed so as to reverse the potential threat and/or mitigate its impact. Political and diplomatic actions by the European Commission during COVID-19 proved to be effective in leveraging measures both within the European Union and at the international level.

Going ahead, the European Health Union Package and the European Pharmaceutical Strategy that were put forward by the European Commission in November 2020 could not be more timely. We expect the lessons learnt during the pandemic to be carefully considered and reflected upon during the implementation phase so that we are better equipped for the return to "normality" and any future crises. Regulatory agility and digitalisation of the regulatory processes should be at the heart of the strategy in order for the European region to remain competitive in the global pharmaceutical supply chain and continue to deliver affordable medicines in Europe and globally.

Going beyond supply chains and market access, people expect the healthcare system to be there when they need it. However, greater demands from events such as COVID-19 along with an ageing population and non-communicable diseases make this increasingly difficult. Our challenge as a society is to ensure equal access to care for all while minimising the burden on healthcare systems.

At AESGP, we see this challenge as an opportunity to promote responsible self-care as an integral part of a comprehensive health promotion and disease prevention strategy in Europe beyond the COVID-19 pandemic. A person-centred approach, which empowers and motivates each of us to play a greater part in our own health and wellbeing: an approach to healthcare that gives people more control, choice and confidence while helping reduce the pressure on the entire healthcare system.

1 Promote the values and benefits of self-care

Celebrating self-care for all, for life

The availability of self-care products and the continuous innovations of the consumer health industry allow everyone in Europe to have greater autonomy and personal engagement in their own and their families' health. This, in turn, contributes to the long-term sustainability of healthcare systems, allowing healthcare providers to focus their attention on more complex cases, a benefit that has become particularly evident during the global COVID-19 pandemic.

To reiterate its commitment to advancing responsible self-care, highlighting the role individuals can play day-to-day and the importance of health literacy, the AESGP ran an awareness campaign in the run-up to International Self-Care Day (24th July) across different channels, including its website and social media pages, LinkedIn and Twitter.

Under the theme "Self-Care Generations", the campaign celebrated "Self-care 24/7, for all, for life" and comprised animations, stories, blogs and other materials. It aimed to highlight the benefits of self-care products, focusing on their use throughout

"The COVID-19 pandemic was a good example of the role of self-care in both empowering individuals and supporting the resilience of health systems. We have all been asked to stay at home and practice self-care in order to flatten the curve of contagion and keep our health services running during the time of crisis."

AESGP Director General, **Jurate Svarcaite**.

different stages of consumers' lives, and their value to individuals, 24 hours a day, 7 days a week.

In addition to messages on the benefits of self-care for people, the campaign featured messages about the value of self-care for society and what will contribute to the success of self-care in supporting the sustainability, fairness and effectiveness of healthcare systems.

Releasing a new video 'Self-Care Generations'

As a highlight of the campaign for International Self-Care Day, the AESGP published a new animated video titled "Self-Care Generations". Structured around 5 generations from baby to senior, the video follows families as they practice self-care at home for minor ailments such as headaches and indigestion. Its main aim: to highlight the value of having self-care in our life.

The video was released together with five independent, but complementary video snippets, giving practical examples of how self-care is part of each generation's daily life (parenthood, healthy ageing, etc.).

View the video on YouTube >

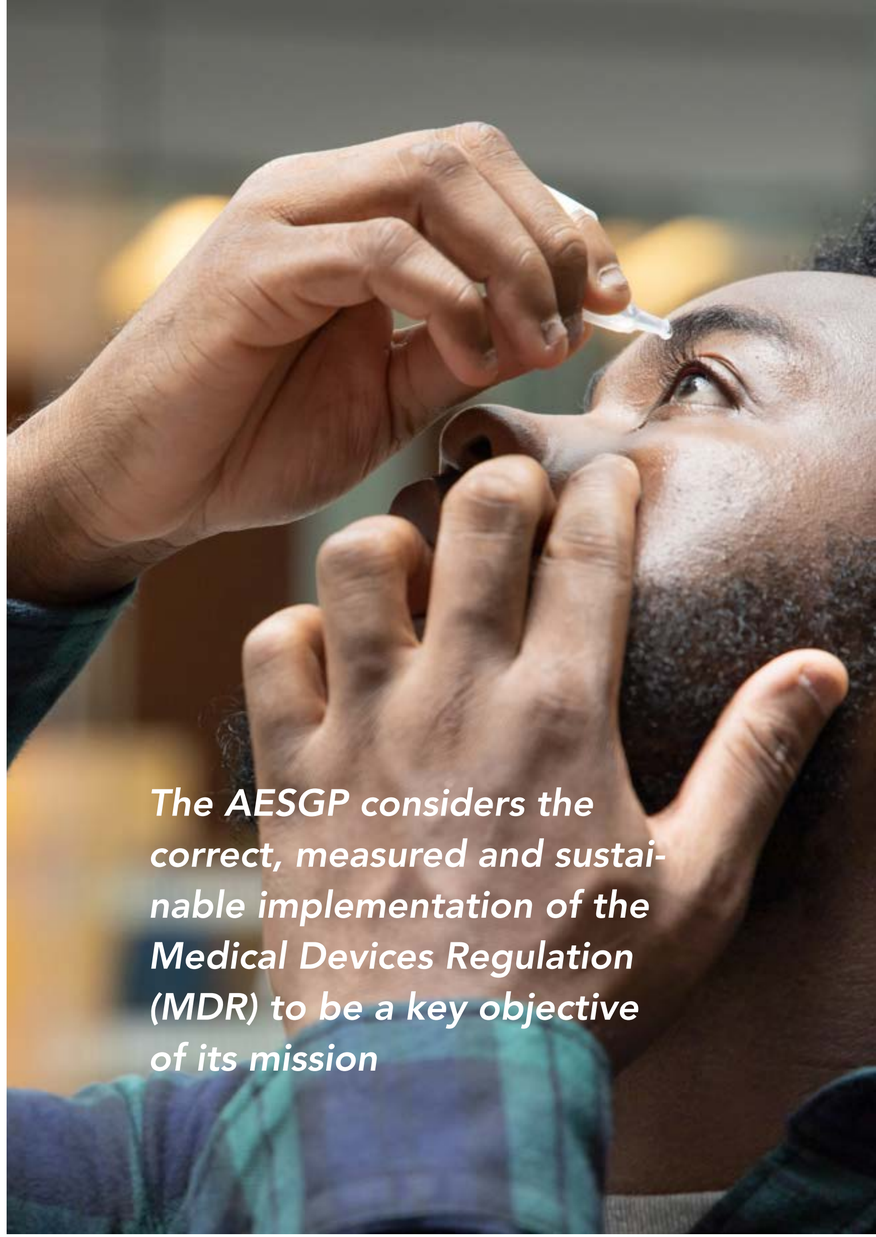
2 Proactively shape the regulatory, legislative, political and economic framework

Implementation of Medical Devices Regulation (MDR)

In 2020, new governance under the umbrella of the new Medical Device Coordination Group (MDCG) was established by the European Commission (EC) and project under the various MDCG working groups was launched.

One of its key objectives is to promote a correct, measured and sustainable implementation of the Medical Devices Regulation (MDR) in relation to self-care medical devices, especially substance-based medical devices which include products such as nasal sprays, cough syrups, wart removal gels etc., the AESGP actively contributed to the responsibilities in the MDCG working groups and related task forces. The main drive of the MDCG working groups was drafting guidance documents to ensure the effective and harmonised implementation of the MDR. In total, the AESGP provided input to approximately 14 consultations on various guidance documents that were under preparation in 2020.

Following its application, the AESGP was granted observer status in two additional MDCG working groups that were created in 2020, namely the working group on Annex XVI covering products without an intended medical purpose and the working group on Eudamed (European database on medical devices). As a consequence, the AESGP now participates as an observer in 10 MDCG working groups, notably: 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; Annex XVI; Eudamed. AESGP also participates in Task Forces on specific matters and Eudamed technical group. In its role as observer, the AESGP coordinated and submitted comments for consideration in the development of Commission and MDCG Guidance documents that were and are under preparation, such as for example in the area of MDR classification rules. The effort of the Borderline and Classification working group has been a focal point in AESGP activities



under the MDCG governance structure. **As such the AESGP has stressed the need for proper guidelines in view of the MDR requirements addressing the qualification of borderline products in the classification of medical devices to ensure the proportionate and successful implementation of the MDR.**

To facilitate the timely availability of the medical supplies needed to fight the Coronavirus and overcome the public health crisis in the European Union, the Commission created the so-called "COVID-19 Clearing House" for medical equipment. Together with other recognized stakeholders, the AESGP actively contributed to the exchange of information with regard to supply and demand of medical and in vitro diagnostic devices as well as other related aspects during the COVID-19 crisis. In total, the AESGP participated at 32 Clearing House meetings in 2020.

To ensure continuation of the MDR implementation process and to allow the timely certification of devices under the new legal framework with COVID-19 restrictions in place, the AESGP highlighted the need for remote audits under the MDR.

The AESGP actively followed the EMA's developments and initiatives in relation to the implementation of Article 117 of the MDR which concerns so-called "drug-device combinations". As such the AESGP contributed to joint industry presentations on Article 117 of the MDR given during the EMA workshop on the implementation on Article 117 that took place on 27th November 2020 and EMA`s 5th Industry Stakeholder Platform on Research and Development Support that took place on 16th November 2020.

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 aims to ensure that the multiple applicable pieces of food legislation are implemented efficiently and pragmatically on food supplements, notably with regards to official controls (especially on online sales), the use of nutrition and health claims in their labelling and advertising, the use of food additives or the unintended presence of contaminants in the final formulations. To do so, the AESGP gathers and reports requested data to provide support to its member associations and companies and to assist regulators in their risk assessment and management efforts.

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

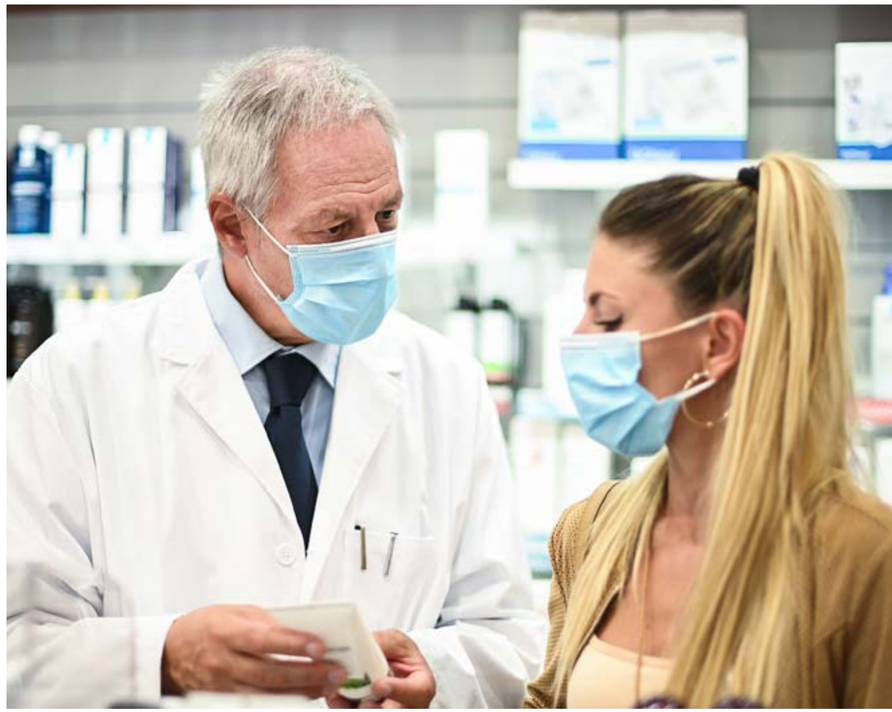
In the Summer 2020, AESGP welcomed the European Commission Farm to Fork Strategy, for a fair, healthy and environmentally-friendly food system, as well as the release of the long-awaited Staff Working Document on the REFIT evaluation of the EU legislation on nutrition and health claims on foods and how plant substances used in foods are regulated in the EU. AESGP will continue to collaborate with the European Commission in the implementation of the strategy and in the follow up process to the REFIT exercise.

Developments that may have an impact on innovation in food supplements are also followed by the AESGP, particularly the forthcoming implementation of new legislation on the transparency and sustainability of the risk assessment in the EU food chain in March 2021. AESGP, along with other stakeholders in the food sector, has been actively engaged in the implementation process and contributed to the various stakeholder consultations organised by the Commission and EFSA. **While AESGP has always expressed support for enhanced transparency and sustainability of the risk assessment process to improve citizens' trust. On many occasions it has raised its significant concerns regarding the practical impact of the new rules on Small and Medium-sized (SME) applicants and on the overall attractiveness of the EU as a leading region for change, an ambition of the European Green Deal / Farm to Fork Strategy. AESGP will continue to closely follow the application phase to ensure that the 'real life' implementation by the various actors of the system remain manageable for the self-care industry (including a significant number of SMEs).**

Contribution to the implementation of pharmaceutical legislation

COVID-19 regulatory flexibility

The AESGP along with other trade associations representing the pharmaceutical industry called for regulatory flexibility early on in the COVID-19 crises and participated in May 2020 at the joint webinar to discuss Questions and Answers on regulatory flexibility. The AESGP called for the scope of the Q&A document to be widened to include all medicinal products affected by COVID not just those critical to the treatment of COVID-19. **The AESGP surveyed its members twice on their experience with the implementation of regulatory flexibility in practice, which revealed that a number of national competent authorities (NCAs) have digitalised regulatory processes in response to obstacles relating to physical presence.** The results of the latest survey were presented to the EU Executive Steering Group on Shor-



tages of Medicines Caused by Major Events in November, 2020. **The AESGP continues to ask for all medicinal products that COVID-19 has impacted to be able to use regulatory flexibility after the pandemic to mitigate potential medicine shortages.**

CMDh and CMDh Task Force on non-prescription medicines

The AESGP participated at two CMDh meetings with Interested Parties in May and November 2020. **The AESGP presented the Industry's proposal, to split marketing authorisation procedures in specific cases, i.e. indication, age groups for administrative reasons, which would prevent clustering parallel procedures.**

Rx-OTC Switch

The AESGP's mission is to advance responsible self-care so that citizens may take better care of their health needs. Hence it welcomed the change of legal status, via two centralised procedures, of Fortacin (lidocaine/prilocaine) and desloratadine, approved by the European Commission in August and December 2020, respectively. These two products soon to be available in the community pharmacies of the 27 EU Member States will offer more choice for people suffering from erectile dysfunction or allergy.

Real-World Data – Real-World Evidence (RWD-RWE)

The AESGP presented the views of the self-care industry at the HMA-EMA Big Data Stakeholder Forum, held on 15th December 2020. Here it highlighted the potential of RWD-RWE in the self-care space, notably in supporting the change of legal status from prescription to non-prescription. The AESGP has been working on the value of RWD-RWE throughout the life cycle of non-prescription medicines, reviewing the latest literature and case studies.

Pharmaceutical Strategy

The AESGP welcomed the European Commission's Communication proposing a patient-centred Pharmaceutical Strategy ensuring the quality and safety of medicines, while boosting the sector's global competitiveness. **AESGP is looking forward to the dialogue with the Commission, European Parliament, Member States and European Medicines Regulators on the proposed actions. These involve implementing an ambitious Pharmaceutical Strategy that serves all citizens, while addressing current challenges with science-based, risk-balanced and proportional measures.**

Interaction with the EDQM

In February 2020, an EDQM representative was a guest at the AESGP Regulatory Affairs Committee (RAC) to present the work of the European Directorate for the Quality of Medicines and Healthcare (EDQM), in particular the MeIclass Database and the work of the Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO). The possibility of joining forces with the AESGP and exploring the use of the AESGP OTC Ingredients Directory, as the databases are complementary, were touched upon.

In December, the AESGP had its annual bilateral meeting with the EDQM where the issues of semi- quantitative testing by HP-TLC, change of assay methods and consequences and CEP modernisation process were discussed.

Herbal medicinal products – Pyrrolizidine Alkaloids (PA)

The AESGP has been particularly concerned by the issue of pyrrolizidine alkaloids (from weeds) contaminating herbal materials and was addressed at the latest hearing the association had with the EMA Committee on Herbal Medicinal Products and the Monograph and List Entries WG in November 2020.

The AESGP presented the results of its 2020 annual data evaluation on the PA values in herbal drugs and extracts as collected annually by the German herbal industry. **The results of the database show that a limit of 1.0 µg PA/day is considered appropriate to guarantee sufficient stability. Hence, the new maximum recommended daily intake of 1.0 µg was very welcomed.**

Pharmacovigilance

The AESGP took part in the EMA pharmacovigilance stakeholder platform in October 2020 where it commented on the 2nd HaRP (Harmonisation of RMP Project) assessment, this aims to harmonise the safety concerns of any given active pharmaceutical ingredient (API) and align them with the latest version of GVP module V.

Nitrosamine

In September 2019, the AESGP began the 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.

The AESGP coordinated with an ad hoc group of experts, other pharmaceutical industry and suppliers representing associations to exchange updates and discuss issues arising during the course of the systematic review of the product portfolio and overall progress. It also ran a number of risk assessment preparedness surveys to gauge the progress to step 1 reporting. The AESGP has also been participating at dedicated workshop organised by the EMA and various calls that followed with the Agency. Given the stress in the supply chains due to COVID-19, the AESGP welcomed the postponement of the step 1 deadline to March 2021 and the revision of the Q&As.

The AESGP was also regularly in contact with its sister associations in Canada and the US. This spearheaded the creation of a nitrosamine group within the Global Self-Care Federation (GSCF) to make the case for the authorities' alignment on scientific and regulatory decisions in the future.

Brexit

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), following the UK leaving the EU. After the UK's withdrawal in February 2020 and the conclusion of the Withdrawal Agreement including Northern Ireland Protocol, the AESGP together with other Industry associations continued engaging with the European Commission and advocating for a Mutual Recognition Agreement (MRA) on batch testing and the introduction of flexibility with regard to the implementation of EU pharmaceutical acquis in Northern Ireland. AESGP members continued to invest in preparedness for every eventuality at the end of transition period on 31st December 2020.

The Industry welcomed the successful conclusion of negotiations and the EU-UK Trade and Cooperation Agreement including the Annex on medicinal products which allows for recognition of GMP inspection. The self-care industry however, continues to highlight the need to address some of outstanding issues affecting the supply of self-care products and calls for a mutual recognition agreement on batch testing.

Digital

Throughout 2020, AESGP has worked on a position paper on the self-care's sector digital transition. The goal of this paper was to present **a vision including the key industry asks and proposals for changes to the regulatory framework to allow for a successful digital transformation and advance responsible self-care.**

The position paper following a comprehensive consultation with Industry experts was released in March 2021. It covers 3 categories: medicines, food supplements and medical devices and is built around five key areas of interest to the Industry:

- Data, real-world-data and real-world evidence
- Artificial Intelligence
- Product and disease information
- Building the digital workforce
- e-Commerce

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

Environment

AESGP together with the Rx pharmaceutical industry, as the Inter-Associations Initiative (IAI) PiE Task Force, has been at the forefront of initiatives to increase knowledge of the environmental impacts of pharmaceuticals, including risk assessment and potential mitigation measures. AESGP experts are actively contributing to the pillars of the Extended Environmental Risk Assessment (eERA) and manufacturing effluent.

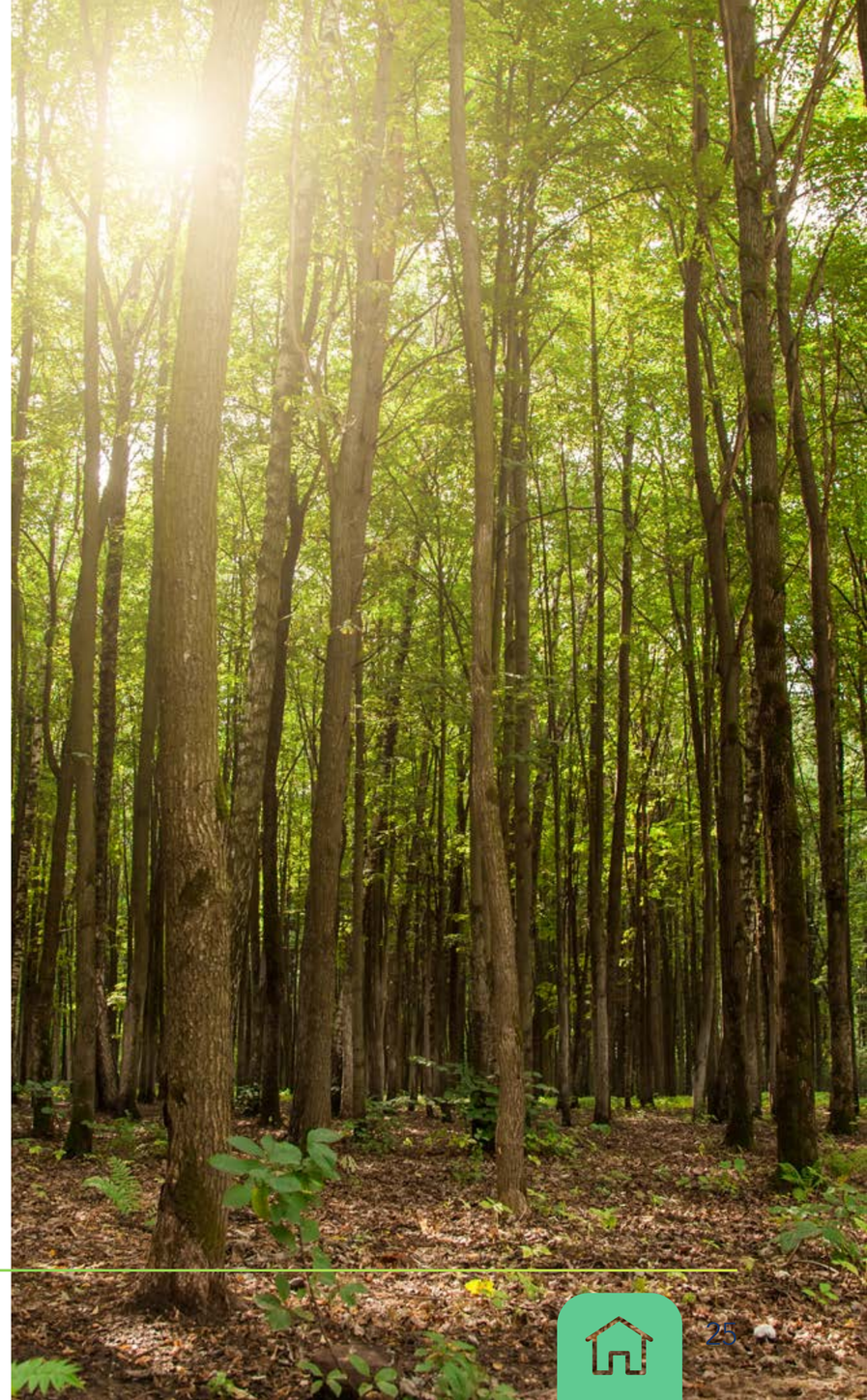
In November, the AESGP met with key officials of DG Environment for an informative exchange and update on the Eco-Pharmaco-Stewardship (EPS) initiatives of the Industry, notably on the Innovative Medicines Initiative (IMI) Premier that started on 1st September. Amongst its objectives, the project has to screen and test 25 legacy active pharmaceutical ingredients (APIs) for a tailored environmental assessment, test 25 prioritised APIs, develop tools and models to identify potential environmental hazards and risks associated with APIs earlier in development, and make relevant environmental data on APIs more visible and accessible to all stakeholders.

In addition, 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 and the prioritisation of substances of concern.

Protecting the environment by promoting the safe disposal of medicines in Europe: the #MedsDisposal campaign

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 amongst the general public on the correct disposal 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 res-



ponsibility programmes. These take-back schemes prevent medicines from entering the environment through improper disposal in wastewater or landfill.

In 2020, pursuing its efforts to promote #MedsDisposal, the AESGP overhauled the visual identity of the campaign aiming to increase public awareness of the take-back schemes. The design of the logo was revamped with a strong and coherent look, that echoes what the #MedsDisposal Project is and what it stands for. Other actions led by the AESGP aiming to increase knowledge of the scheme include updating data and information regarding national take-back schemes as well as improving visibility throughout Europe.

eProduct information

The AESGP has been joint-leader of the Working Group Content of the Inter-Association Task Force (IATF) on eProduct Information (ePI) since 2016. The aim is to improve the content of product leaflets to better suit the needs of people using them. The WG Content is composed of 4 sub-groups looking in-depth into improving the readability guideline, the QRD templates and aiming to collect direct feedback from patients and carers through the organisation of dedicated workshops in various languages. A workshop with German patients in December yielded very rich insights, but unfortunately the pandemic has slowed down the organisation of other workshops in English, Spanish, Czech and Nordic language.

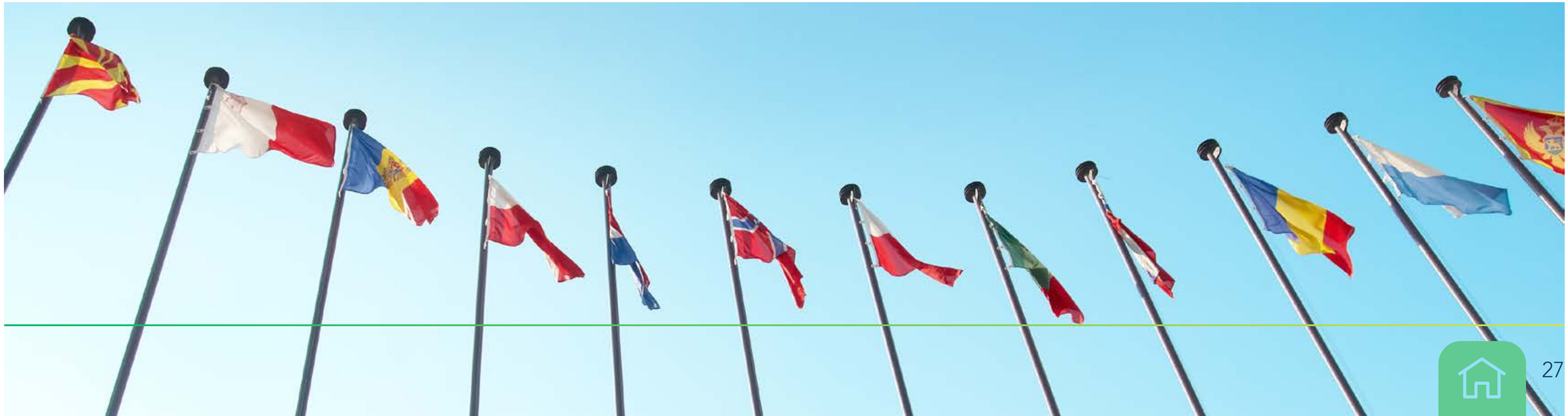
The AESGP is also co-lead of the WG Technical of the IATF on ePI. This working group is considering the proposals of EU Common Standards to assure that authorized product information is conveniently available to citizens in the EU/EEA in light of the EMA and NCAs proposal to establish a common EEA network for electronic product information (ePI).

At the steering group level, two major projects have started. Firstly, following the publication in January 2020 of the EMA key principles on electronic product information, the IATF extensively reflected on these key principles. Secondly, in collaboration with the European Association of Hospital Pharmacists (EAHP) a survey on the use of (electronic) patient leaflets and the future potential of electronic product information in the hospital setting is under construction.

Ingredient challenge in 3 categories

Following up on the 2019 reflexion around the impact of societal concerns for the self-care industry (see AESGP 55th Annual Meeting "Evolving the self-care environment" (June 2019) conference report), AESGP and its members have been working on strengthening their collaboration when it comes to ingredient challenges relevant to the self-care sector.

While the self-care products categories AESGP represents are highly regulated through the different EU legal frameworks applicable to non-prescription medicines, medical devices and food supplements, along with (notably in the absence of EU harmonisation) plenty of additional Member States' checks and balances, the general public is increasingly questioning the safety of ingredients and therefore, the regulators. **AESGP has been rethinking how to manage this as a sector comprising different product categories with different risk management approaches and has started to revise its own processes. Much can be achieved through better risk framing, appropriate risk communication, greater risk literacy, increased transparency and better governance.** Accordingly, any event with a sectorial dimension concerning an identified active (e.g. API or key nutrients) or inactive (e.g. excipients, additives, packaging material) ingredient relevant to marketed self-care products falls within AESGP's scope. Drawing regulators and/or the general public's attention at the European level requires a coordinated response from European industry. Building on its integrated network of companies at national, European and international level, AESGP has been developing a system to quicky identify and assess the challenges that require a coordinated European industry response. This can entail, as appropriate, close monitoring and information sharing activities between members through a global communication response (coordination through the global association – GSCF) to assistance in building inter-company consortia to generate the data needed. This development aims at building on the self-care industry's existing relationship with consumers to further promote their empowerment and acknowledging their expectations.



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

New members

In November 2020, the AESGP welcomed its newest associated member company, UPSA. UPSA is both a company and a brand with an international presence, employing 1500+ people worldwide. For more than 85 years, UPSA has developed strong expertise in the treatment of pain and fever, digestion, sleeping disorders and well-being categories through its range of self-medication products. UPSA's mission is to daily act in favour of the entire family health.

Developing the AESGP Members' Platform

As part of the strategy to strengthen its Network, the AESGP has worked on a dedicated members' platform. The platform launched at the beginning of 2021 provides a single resource point for member experts and committee members as well as a best practice platform for the national associations.

Inspiring and being inspired: towards a Best Practices Hub

The AESGP started to populate this platform by creating a **Consumer Education and Best Practices Hub**. By its members for its members, here they can share consumer education materials and other best practices, inspiring and being inspired in return. To compile the data and build the Consumer Education and Best Practices Hub, the AESGP carried-out a survey to assess and list materials already available amongst AESGP members. Both AESGP member companies and national associations have contributed to the Hub.

Global leadership

The AESGP is a member of the Global Self-Care Federation (GSCF), which brings together regional and national associations and manufacturers of non-prescription medicines. The AESGP significantly contributed to GSCF's missions throughout 2020. It has led the Federation's regulatory strategy as well as co-chairing its working group on the environment while also providing input for projects carried out under the Trust, Health System Sustainability and Health Data pillars.

Governance

The highest governing body is **the AESGP General Assembly,** to which of 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 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
Regulatory Affairs and Policy Manager

Oliver Hartmann
Legal and Regulatory Affairs Manager

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

ASSOCIATE MEMBERS

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

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

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

Eudamed: European database on medical devices

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

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

AESGP

Association of the European Self-Care Industry (AESGP)
Avenue de Tervuren, 7
1040 Brussels Belgium
+32-2-7355130
info@aesgp.eu

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