AESGP

Annual Report 2017-2018

HIGHLIGHTS OF THE YEAR

Campaigning for self-care

Explaining the value of self-care products to all relevant stakeholders is a key objective of AESGP. To contribute to this goal, AESGP organised three successful conferences – one of them preceeded by a well-attended evening event in the European Parliament hosted by Adina-Ioana Vălean, Chair of the Committee on the Environment, Public Health and Food Safety of the European Parliament, who cordially welcomed participants and underlined the importance of the self-care industry for offering product choices and for providing the necessary information.

At this occasion, EU Health Commissioner Vytenis Andriukaitis recognized the role of self-care, stating that "self-care and empowerment can make patients more autonomous and by extension less dependent on our health systems".

Two projects relating to self-care have been funded by the European Commission: PiSCE, a project of self-care systems in the EU, and PRO STEP, which promotes self-care in chronic diseases. "The PiSCE project developed guidelines and communication tools on how to promote self-care for chronic diseases. This can contribute to improved patient centred care." The Commissioner furthermore stated : "The project also provides recommendations for the implementation of non-prescription drugs and stresses the importance of early involvement of stakeholders, training of health professionals and improving

At the AESGP event in the European Parliament on 10 October 2017 (from left to right): Hubertus Cranz (AESGP Director General), Adina -Ioana Vălean (European Parliament), Vytenis Andriukaitis (European Commission), Renate Sommer (European Parliament), and Dirk Ossenberg-Engels (AESGP Vice-President, Bayer Consumer Care)

the knowledge and skills of citizens and patients. " It is important to note that those recommendations were developed under the lead of the European umbrella organization of medical doctors — the Comité Permanent des Médecins Européens (CPME), whose President Jacques de Haller presented the results of the PiSCE project in a much appreciated speech at the AESGP Annual Meeting 2017 in Vienna.

Mr Andriukaitis also focused on anti-microbial resistance (AMR), one of the major priorities for the European Commission (EC), which adopted in 2017 the EU One Health Action Plan against AMR. He outlined that in July 2017 the Commission published guidelines on the prudent use of antimicrobials in human medicine, which stress the importance of avoiding treatment with antibiotics when there is evidence of a viral infection. "Non-prescription medicines can play an important role in alleviating the symptoms of patients who do not require antibiotics to treat minor ailments and disorders", the Commissioner stated.

CPME President Jacques de Haller at the AESGP Annual Meeting in Vienna

Non-prescription medicines

Better regulation

How to improve the availability of self-care products by looking at the progress of the AESGP Self-Care Agenda 2020 was the key topic of the 9th Conference AESGP organized together with the Heads of EU Medicines Agencies (HMA). The meeting took place in Lisbon on 26/27 February 2018 and discussed the impact of the EU Medicines Agencies Network Strategy to 2020 and the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) strategy having as common objective to increase access to non-prescription medicines. The CMDh recently revived the Non-Prescription Medicinal Products Task Force. In order to support the CMDh task force's review of Member States practices, AESGP submitted the results of an internal survey on the national switch processes and practices. The survey clearly showed the diversity of processes and practices between EU countries.

In line with the continuous AESGP objective to promote switches as well as their timely access to the market independently of the procedure chosen, the association very much welcomed the conceptual proposal relative to multistakeholders scientific advice (MSSA) for non-prescription medicines. Together with the proposals related to regulatory optimization, this was discussed at a dedicated session at the Lisbon event and previous conferences. AESGP submitted its views and suggestions on the MSSA concept in a position paper and shared it with the EMA and the CMDh Task Force.

Pharmacovigilance

Non-prescription medicines have a well-known safety profile documented by their long use and presence on the market and AESGP continuously make the case for a proportionate risk-based approach for non-prescription medicines. In the past years, AESGP successfully led an industry initiative aiming at simplifying the EMA guidance on Risk Management Plans (RMP) and the related template. The European Medicines Agency (EMA) documents were revised taking into account the industry recommendation and AESGP is again leading an industry survey to gauge the uptake of those revised documents in practice. AESGP is also taking an active role in the CMDh-led initiative on RMP harmonization which has 2 streams: update of the RMP of innovative products soon, which means prior to their patent expiry, and harmonization of the numerous versions of RMPs existing for the same well-known substances.

AESGP has proposed paracetamol as the self-care sector's contribution to the RMP harmonization pilot.

AESGP also participated in an EMA meeting on common data model in Europe and continues to follow the issue with interest as it is close to the debate on Real World Evidence. Related to this, AESGP was present at the 2-day Big Data workshop organised by the EMA-HMA Task Force on Big Data in June 2017 and is looking forward to participating to the follow-up conference scheduled early May 2018. Thomas Senderovitz, Director General, Danish Medicines Agency and Chair of this task force created in March 2017, shared his reflections at the AESGP Conference with the Heads of EU Medicines Agencies during the Bulgarian EU Council Presidency held in February 2018 in Lisbon. AESGP also responded to the EMA-HMA Big Data survey that closed in October 2017.

Telematics

AESGP is also a member of the joint EU Telematics Management Board and thereby strongly involved in all relevant debates in the given context. It also continues its active support through its three leading experts to the development of the SPOR/ISO IDMP database with the view to best support the regulatory system, making it more efficient and underpin digitalization of more activities. Via meetings and webinars, it strives to communicate and translate the technical information to its membership and establish the link with regulatory activities. AESGP also run a survey on PSOR preparedness and one on eCTD implementation, industry preparedness and upcoming national requirements always with the objective to gauge implementation readiness and allow the early detection of potential issues.

In a wider context, AESGP was happy to see a strong reference to the importance of citizens' empowerment in the Council conclusions on Health in the Digital Society, which were adopted on 8 December 2017 by the Employment, Social Policy, Health and Consumer Affairs Council. This is now a good basis for the upcoming European Commission communication on Digital Transformation of health and care in the context of the Digital Single Market.

International Council on Harmonisation (ICH)

AESGP supported the World Self-Medication Industry (WSMI) in its membership application to the Management Committee of the International Council on Harmonisation (ICH) which decision was delayed until June 2018. AESGP coordinated the work, expert representation and expert nomination to the ICH General Assembly. It participated to the November General Assembly meeting ensuring the self-care sector's voice is heard, particularly highlighting the issues experienced during implementation of the ICH guideline by smaller, local companies. The file has been transferred to WSMI at the end of 2017 in light of the newly acquired regulatory resources in WSMI.

How to improve the regulatory environment for non-prescription medicines was discussed at the AESGP-HMA conference in Lisbon (from left to right): Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, Association of the European Self-Medication Industry (AESGP) ; Zaide Frias, Head of Human Medicines Evaluation Division of the European Medicines Agency (EMA); Karl Broich, Director General of the Federal Institute for Drugs and Medical Devices (BfArM); Hugo Hurts, Director of the Medicines Evaluation Board (MEB); Ian Hudson, Chief Executive of the Medicines and Healthcare products Regulatory Agency (MHRA).

Discussing future challenges for the self-care sector at the AESGP-HMA conference in Lisbon (from left to right): Andrzej Rys, Director of Health Systems, Medical Products and Innovation, Directorate General Health and Food Safety of the European Commission; Thomas Senderovitz, Director General of the Danish Medicines Agency; Guido Rasi, Executive Director of the European Medicines Agency (EMA); Belén Crespo Sánchez-Eznarriaga, Director General of the Spanish National Agency for Medicines and Health Products.

Herbal and homeopathic medicinal products

At the occasion of its annual meeting with the EMA Working Party on European Union Monographs and European Union List (MLWP) of the Committee on Herbal Medicinal Products (HMPC) in March 2017, AESGP gave its views on the Polycyclic Aromatic Hydrocarbons (PAH) reflection paper recommending that a risk assessment should be first carried out; AESGP was pleased to see its approach taken up in the final statement from the HMPC. It also presented a position paper advocating for the downgrading of some variations specific to herbal medicines which before its presentation to the Regulatory Optimisation Group (ROG).

A number of quality topics primarily related to herbal and homeopathic medicines were also discussed with senior officials from the European Directorate for the Quality of Medicines (EDQM) during the annual AESGP-EDQM meeting at the EDQM premises on 14 December 2017.

E-leaflet

The European Commission report on the summary of product characteristics and package leaflet called by the legislation was published in March 2017 and later on complemented by the EMA Action Plan to improve the product information for EU medicines. As part of the action plan, the EMA is planning a stakeholder workshop in the autumn 2018 on electronic product information. In preparation for this event, the inter-association task force (IATF) on electronic product information, to which AESGP takes part, responded to the EMA consultation and sent an overview of national initiatives on electronic/digital leaflets. The IATF continues to explore making leaflets of EU medicinal products available on a digital, searchable format.

For the self-care sector, it is critical that, as the patient may have no or little interaction with a healthcare professional, paper leaflet continues to be provided directly with the pack but could be complemented by an e-leaflet.

Environment

The year was particularly rich in environmental developments at EU level. The self-care, innovative and generic sectors working together on the 'Eco-Pharmaco-Stewardship (EPS)' initiative responded under that name to the consultations related to pharmaceuticals in the environment. The inter-association task force first replied to the consultation on the roadmap for the Commission's initiative on a strategic approach to pharmaceuticals in the environment by presenting their EPS initiative and called for a science-based response to the issue. EPS takes a life-cycle approach to the topic of pharmaceuticals in the en-

vironment. It includes initiatives on managing environmental risks post-authorization through an extended and publicly available Environmental Risk Assessment (eERA), providing tools to prioritize environmental testing of legacy pharmaceuticals, and improvements in manufacturing effluent management.

In their response to the EC consultation on the Water Framework Directive (WFD) fitness check roadmap, the industry reiterated its support to the objective of the WFD but underlined its concerns related to the implementation of the Directive with regards to pharmaceuticals and the potential to negatively affect patients.

The industry also commented on the Joint Research Center (JRC) Watch List Report calling for clear and transparent criteria for adding substances to the watch list but also for their removal.

Last, the industry responded to both the respective expert and the public EC consultations on pharmaceuticals in the environment. Under AESGP leadership, the three sectors were fully aligned against a back-switch proposal as possible mitigation measure in case of environmental risk caused by the Active Pharmaceutical Ingredient (API). The Commission strategy building on the responses to the consultations is expected soon.

AESGP also participated in the Innovative Medicine Initiative (IMI) iPiE Scientific Advisory Board meeting in October 2017. The IMI initiative has for aim to develop a predictive model to inform early of the environmental risk of new chemical entities but also of substances not having environmental data. One of the outputs of the initiative will be a public database showing substances and whether environmental data are available.

AESGP is a co-signatory to the medsdisposal campaign aiming at informing and educating the public about the proper disposal of expired or no longer used medicines. It endorsed the related joint declaration and actively supported the social media campaign.

Ingredient defense

AESGP's scope across self-care categories proved once against to be a clear advantage in navigating the safety re-evaluation by EFSA of iron oxide and titanium dioxide as food additives and the potential impact on the pharmaceutical sector. AESGP actively monitored and played an instrumental role in raising awareness and coordinating the sectors vis a vis the issue.

The CMDh under the lead of the UK authority raised the issue of the use of azo-dyes in medicinal products and asked for their phasing out following the example of the food sector. The AESGP link between the food and pharmaceutical sectors was again invaluable. Using its knowledge of the experience on the food side with azo-dyes, AESGP run an internal survey, coordinated with the other pharmaceutical sectors and lead the industry response to CMDh challenging the premises under which medicines would have to be reformulated.

Medical Devices

With the introduction of specific classification rules, the new legal provisions for medical devices recognise explicitly the existence of substance based medical devices. As the European voice for substance based medical devices' manufacturers, AESGP is actively involved in the implementation phase, participate in many working groups and subgroups of the European Commission (DG Grow) and calls for a proportionate implementation of these new rules so as to not prevent or slow innovative devices entering the market and to help its members to prepare smoothly for the application of the new framework. The implementation of the new legal provisions was discussed at the AESGP Annual Meeting in Vienna, but also in extensive sessions at a conference in Brussels in October 2017 and at the AESGP-HMA conference in Lisbon in February 2018. In implementing the new provisions, AESGP's key priorities include transitional measures, the regulatory status of products, the quality and safety evaluation of substance based medical devices, and the resource/capacity of notified bodies. In particular, the challenges relate to workload for all actors in

the regulatory system, including in particular medicines authorities with responsibility for medical devices and notified bodies. Particular attention was paid to borderline products and the classification of substance-based medical devices. In this context, clearer definitions for the terms "pharmacological", "immunological", and "metabolic" were regarded as necessary. The classification of a specific product will remain a case-by-case decision based on an assessment of the formulated products. It is critical for AESGP members that, at any time in the product lifetime, any process aiming at determining the regulatory classification of a product allows (1) the gathering of all the information necessary from the manufacturers for ensuring the consistent evaluation of a specific case and (2) the consultation of the appropriate scientific expertise to differentiate between the different modes of action in light of the whole formula of the product.

This holds also true for the classification of devices composed of substances or combination of substances. The implementation of Rule 21 should always be proportionate and risk-based. AESGP also reminded authorities that the requirement for notified bodies to consult the medicine authorities in the context of the conformity assessment under the MDR only applies to devices falling under the first indent of Rule 21. It is critical that a common understanding of this rule applies so that notified bodies do not consult medicine authorities in a disproportionate manner.

For all products on the market, it will be important to have a uniform interpretation of the rules and respect for the transition periods to ensure that medical devices remain on the European market in the interim period. These transition periods are particularly critical for substance-based medical devices currently falling under Class I, for which there are no existing certificates with defined periods for these products, which will be the first to have to fully meet the MDR requirements from 26 May 2020. In this allotted transition period, the industry is concerned that based on the current investment of resources, notified bodies may not be available and be able to certify the vast number of products early enough to avoid any disruption in the supply of medical devices to the market.

Looking at the implementation of the new medical device legislation (from left to right): Xavier de Cuyper, Chief Executive Officer of the Belgian Federal Agency for Medicines and Health Products (FAMHP); Lorraine Nolan, Chief Executive of the Irish Health Products Regulatory Authority (HPRA); Sinisa Tomic, Director of the Croatian Agency for Medicinal Products and Medical Devices; Oliver Bisazza, Director Regulations & Industrial Policy at MedTech Europe; Maud Perrudin, AESGP Deputy Director General; and John Wilkinson, Director of Medical Devices at the Medicines and Healthcare products Regulatory Agency (MHRA).

Brexit

The decision of the United Kingdom to leave the European Union by the end of March 2019 had numerous consequences for the work of AESGP in the last 12 months. Pharmaceutical policy is always part of a wider agenda, but here, even details depend a lot on overall politics with limited possibilities for specific arrangements in sectors. Evidently, AESGP follows the developments carefully and put out several position papers, some of them together with other associations in the healthcare sector (Life Science Industry Coalition Position Paper). AESGP favors the strongest possible integration of the United Kingdom to limit negative repercussions for all sides involved and above all for the European citizens.

Due to the high number of national authorizations and registrations, the self-care sector is somewhat less affected than other parts of the pharmaceutical industry, but AESGP remains concerned in light of the resources it takes and the risk of a lowering attention to non-prescription medicines in regulatory procedures.

Food related issues

As a key part of AESGP's activities is the representation of its members in all regulatory, legislative and political debates in relation to food supplements, AESGP is actively involved in many meetings of the European Food Safety Authority (EFSA) and the European Commission (DG Santé). For example, AESGP participated in the 15 years anniversary of the General Food Law event on 27 November 2017 and, In the context of the ongoing REFIT evaluation of the Nutrition and Health Claims Regulation, in the Advisory group ad hoc meeting on 27 October where the draft final report of the study by the contractor was presented and where AESGP could promote a proportionate interpretation of the results.

Bernhard Url, Executive Director, European Food Safety Authority (EFSA), at the AESGP Annual Meeting in Vienna

Sabine Jülicher, Director of Food and Feed Innovation, Directorate General Health and Food Safety, European Commission, at the AESGP Annual Meeting in Vienna

At the AESGP Annual Meeting in Vienna, AESGP was honored by the presence of two key officials out of the food sector: Sabine Jülicher, Director of Food and Feed Innovation, Directorate General Health and Food Safety of the European Commission; and Bernhard Url, Executive Director, European Food Safety Authority (EFSA). Both outlined the challenges they are facing both from a political and a scientific angle. Particular attention was paid to the ongoing debate around botanical claims, but also the upcoming change of the General Food Law, and by that, of new rules around governance, transparency and financing of the European Food Safety Authority (EFSA).

At the AESGP Conference in Brussels in October 2017, AESGP had the pleasure of discussing the current EU food law challenges of the food supplements sector with key actors of the political scene. As part of its commitment as a science-based industry, AESGP was notably keen to promote the ongoing control activities on internet sales and to support the ongoing work of EFSA in the safety assessment of certain other substances added to foods.

As part of its commitment to the evidence-based policy, AESGP coordinated various submissions of food supplements industry data to support Commission and EFSA work on the re-evaluation of the safety of food additives. All food additives permitted for use in food in the EU must undergo a safety re-evaluation by EFSA. This scientific assessment (exposure) needs to be supported by data submitted by the food industry that adequately reflect the current use levels of food additives in food. In 2017 and 2018, AESGP has also been actively engaged in a close dialogue with the European Commission and other stakeholders on the next steps to make sure that the necessary data in relation to key additives for the food supplements sector for which EFSA has identified issues that require a follow-up are collected and submitted in an appropriate manner. AESGP has been committed to provide timely and necessary support to its member associations and companies in relation to this follow-up process.

Membership service

Keep members updated on all relevant developments related to self-care products in a timely and understandable manner is an important part of the day-to-day work of AESGP. In addition, AESGP put together a comprehensive database covering both the economic and legal framework of self-care products and the classification status of around 250 ingredients (www.aesgp.eu). Building this evidence is also the basis for the political activities of AESGP.

Information services are complemented by the monthly newsletter — the AESGP Euro OTC News.