AESGP

Annual Report 2016-2017

HIGHLIGHTS OF THE YEAR

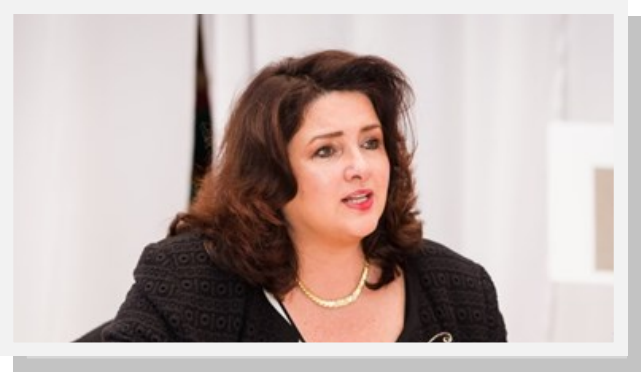
The 2016 AESGP Annual Meeting in Athens, Greece, was the perfect platform to launch the AESGP Self-Care Agenda 2020, which summarises the priorities for the self-care industry for the years to come. Overall, the legislation is fit for purpose but in many areas it is the implementation which is in need of improvement. More pragmatism, simplification and a risk-based approach taking fully into account the specificities of consumer care products are prerequisites to a well-functioning system.

Non-prescription medicines

AESGP was delighted to see an alignment of its considerations with the EU Medicines Agencies Network Strategy to 2020, which proposes changes for medicinal products including non-prescription medicines in the same direction as advocated by AESGP.

In line with AESGP input, reference to "improving patient access to well-established medicines including [....] non-prescription medicines" was included in the Network Strategy. This objective was converted into a clear action in the Heads of Medicines Agencies (HMA) Multi-Annual Work Plan (MAWP): "HMA will explore other ways to reach agreements between Member States regarding non-prescription products, to facilitate a greater number of product switches." Further, the "HMA considers that the work of CMDh is essential for the achievement of this goal. "

Discussing regulatory optimisation and better availability of non-prescription medicines at the AESGP Conference with the Heads of EU Medicines Agencies in Malta in February 2017, from LEFT to RIGHT: Hubertus Cranz, *Director General, AESGP;* Karl Broich, *Director General, Federal Institute for Drugs and Medical Devices (BfArM), Germany*; Catarina Andersson Forsman, *Director General, Medical Products Agency (MPA), Sweden*; Hugo Hurts, *Director, Medicines Evaluation Board (MEB), the Netherlands*; Ian Hudson, *Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom*; Birgit Schuhbauer, *President, AESGP*; Martin Seychell, *Deputy Director General DG SANTE, European Commission*



Helena Dalli, *Minister for Social Dialogue, Consumer Affairs and Civil Liberties, Malta*

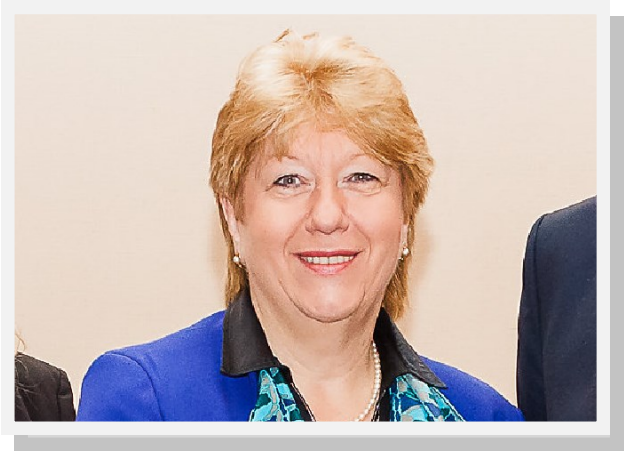
In turn, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) also made it an action point in its own work programme. In this context, AESGP was invited to a meeting in July 2016 to present its Self-Care Agenda 2020 and later on to provide clarification on specific issues encountered by the Self-Care sector in Mutual Recognition/Decentralised Procedures (MRP-DCP) and switching from prescription to non-prescription status. This had a favourable influence on the decision made by the CMDh to revive the Non-Prescription Medicinal Products Task Force, which explores new ways to improve convergence on evaluation and facilitate the access to safe and effective non-prescription medicinal products for EU citizens.

Again fully in time with the AESGP call for administrative simplifications, the Regulatory Optimisation Group (ROG) was set up by the Heads of Medicines Agencies and the IT Directors of the medicines agencies. It focuses on business optimisation and will first tackle type IA variations to see how many could be waived relying instead on their upload into databases. This could have considerable implications on the workload of non-prescription medicines manufacturers.

Building upon a very successful series of meetings with the Heads of EU Medicines Agencies, AESGP hosted a well-attended conference during the Maltese EU Presidency in Malta on 20-21 February 2017. Availability of non-prescription medicines, regulatory optimisation, facilitating switches and the future of self-care in a connected world were the main themes of the conference debated by Heads of Medicines Agencies, representatives of the European Medicines Agency (EMA) and Commission representatives. The conference was opened by Helena Dalli, Minister for Social Dialogue, Consumer Affairs and Civil Liberties of Malta, who underscored the value of self-care in empowering people to take a more active role in their own healthcare, and Martin Seychell, Deputy Director General, DG SANTE, European Commission, who stressed that the development of self-care should be a key priority, highlighting it for economic reasons.

Ensuring timely access to non-prescription medicines, independently of the procedure chosen, remains one of the key issues for AESGP. At the AESGP-EMA bilateral meeting on 11 January 2017, both the Agency and the self-care industry reflected upon their experience with the centralised procedure for switch and discussed the way forward. Amongst other ideas, an inspiring new proposal from an EMA-CMDh multi-stakeholders scientific advice for non-prescription medicines was brought up. It was also the subject of a more extended debate at the AESGP conference in Malta.

AESGP presented the results of its internal survey on MRP-DCP for herbal medicines at the interested party meeting of the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) in November 2016 which showed a clear uptake of the European procedure in the herbal medicines sector and a respect of the timelines. However the national phase remains too long, by far exceeding the 30 days laid down in the legal provisions. Serious risks to public health are still often raised despite the well-known safety profiles of the botanicals used.



Christa Wirthumer-Hoche, *Chair of the EMA Management Board and Head of the Austrian Medicines and Medical Devices Agency (AGES MEA),* chairing the first session at the AESGP Conference in Malta dedicated to the availability of non-prescription medicines

Pharmacovigilance

Non-prescription medicines have a well-known safety profile documented by their long use and presence on the market and AESGP argues that this should lead to a proportionate risk-based approach for non-prescription medicines when commenting on pharmacovigilance documents and speaking at the joint stakeholders platform on pharmacovigilance regularly hosted by the EMA. Referral procedures and risk management plans have been two important areas where AESGP efforts have paid off. Constructive discussions have been ongoing with the Pharmacovigilance Risk Assessment Committee (PRAC), and June Raine, the Chair of the PRAC, attended both the 2016 AESGP Annual Meeting in Athens and the conference with the HMA in Malta.

AESGP also participated in an EMA meeting on patient registries 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 workshop on Big Data organised by the EMA in November 2016. This was followed by the establishment of a joint HMA/EMA Task Force on Big Data to explore how medicines regulators can use big data to support research, innovation and development of medicines. Thomas Senderovitz, Director General, Danish Medicines Agency and new Chair of this task force, shared his reflections at the AESGP Conference with the Heads of EU Medicines Agencies during the Maltese EU Council Presidency.

AESGP is also a member of the joint EU Telematics Management Board and the Cloud Security Consultative Group of the EMA and by that strongly involved in all relevant debates in the given context.

Thomas Senderovitz, *Director General, Danish Medicines Agency, Denmark*

International Council on Harmonisation

AESGP supported the World Self-Medication Industry (WSMI) in its membership application to the International Council on Harmonisation (ICH) which was successfully granted. AESGP continues to coordinate the work, expert representation and expert nomination to the ICH General Assembly, ensuring the self-care sector's voice is heard. This shall ensure adequate finalisation and implementation of key ICH guidelines such as the Q3D guideline on metal impurities.

Herbal and homeopathic medicinal products: keeping the choice for European consumers

AESGP met with the EMA Working Party on European Union Monographs and European Union List of the Committee on Herbal Medicinal Products (MLWP) for its yearly hearing and as usual had an open and constructive discussion on a variety of

issues pre-selected by the AESGP Herbal Medicines Committee with the objective to facilitate market access for herbal medicines around Europe.

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 in November 2016.

Modernisation of medicinal products leaflets

As called in the pharmaceutical legislation, the European Commission has now released its report on the current shortcomings in the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL). This will stimulate the inter-associations task force discussion around the improvement of the patient information and digital format in which AESGP takes part. 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.

Shortage and supply chain disruption

The issue of availability of medicines including shortages is a key priority of authorities in Europe. Some authorities at the AESGP/HMA conference in Malta showed that the issue was not limited to the prescription sector, particularly in small countries.

AESGP participates in the joint supply chain stakeholders' group on shortages which gathers representatives of the main European pharmaceutical trade associations, pharmacists, wholesalers and parallel traders. The group has finalised its statement on information and medicinal product shortages which provides recommendation for the set up of a transparent information system between supply chain operators at national level.

Environment

Since 2006, Environmental Risk Assessment (ERA) is a requirement that companies have to perform for their products, particularly new ones. The ERA is performed to evaluate potential risks of the active pharmaceutical ingredient (API) of the medicinal product on the environment and to ensure adequate precautions are taken where specific risks are identified. As part of its 'Eco-Pharmaco-Stewardship' initiative, an inter-industry task force representing the self-care, innovative and generic sectors has a pillar on extended environment risk assessment (eERA) which proposes a mechanism according to which new information that may affect the risk assessment can be accounted for. This mechanism will also reflect the cumulative effect of products containing the same API. In addition, possible review models for such an eERA were discussed and AESGP has advocated in favour of a network of regulatory and environment experts operating under the ownership of the HMA and EMA, following the example of existing structures.

Andrzej Rys, *Director, Health Systems, Medical Products and Innovation, DG SANTE, European Commission* and Guido Rasi, *Executive Director of the European Medicines Agency* at the AESGP Conference with the Heads of EU Medicines Agencies (HMA) in Malta in February 2017

Food Supplements

A key part of AESGP's activities is the representation of its members in all regulatory, legislative and political debates in relation to food supplements and the provision of comprehensive information services on European and national regulatory developments. This includes involvement in many meetings of the European Food Safety Authority (EFSA). For example, as a member of EFSA Stakeholder Consultative Platform, AESGP has been continuously encouraging improvement of EFSA services provided to applicants notably in the context of health claims and novel foods applications and will continue to do so within the new EFSA's Stakeholder Engagement Approach. Although individual pre-submission meetings with applicants can still not be introduced at the moment, EFSA confirmed its commitment to implement a more customer-oriented approach notably through its 'Catalogue of services for applicants' which includes services such as teleconferences and technical hearings where applicants can in person explain outstanding questions to the EFSA working groups.

AESGP coordinates submission of food supplements industry data on food additives and actively engages in the re-evaluation process

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. Compilation and submission of data are resource intensive and time consuming for companies and requires efficient coordination at the EU level.

As part of its commitment to the evidence-based policy, AESGP coordinates submission of food supplements industry data to support Commission and EFSA work on the re-evaluation of the safety of food additives. AESGP also remains an active member of the EFSA Discussion Group on 'Chemical Occurrence Data' where additives are discussed.

In 2016 and 2017, AESGP has been engaged in a close dialogue with the European Commission and other stakeholders on the next steps. Involved parties make sure that the necessary data in relation to key additives for the food supplements sector (notably iron oxides and titanium dioxide) 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.

Alexandra Nikolakopoulou, *Head of Unit at the European Commission's Directorate General Health and Food Safety*, providing an update on the regulatory framework applicable to food supplements and the state of play of the ongoing so-called REFIT exercise in relation to the Nutrition and Health Claim Regulation at the AESGP Annual Meeting in Athens in June 2016

Medical Devices

Being fully aware of the difficulties EU decision-makers faced in reaching a compromise in the given context, AESGP appreciated the recognition of substance-based medical devices in the new Medical Devices Regulation, approved by the European Parliament on 5 April 2017. This was the result of an intensive debate between the EU institutions following the proposal made by the European Commission in 2012. AESGP contributed at numerous occasions to the political debate. An adequate implementation phase is now essential to ensure that the Regulation has a positive impact for the EU citizens.

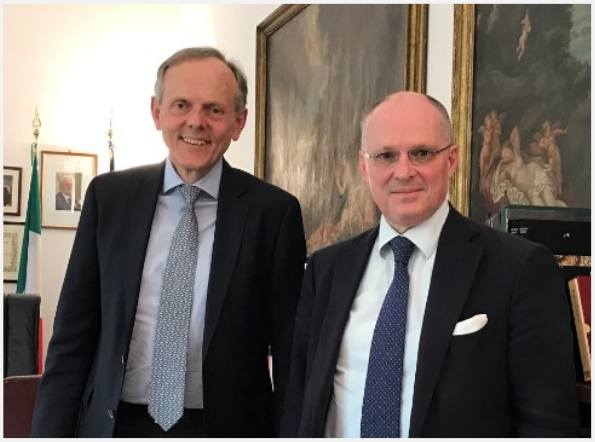
Discussing the new medical device legislation in the European Parliament in October 2015, from left to right: Hubertus CRANZ, *AESGP Director General;* Vytenis ANDRIUKAITIS, *EU Commissioner for Health*; Giovanni LA VIA, then *Chairman of the European Parliament Committee on the Environment, Public Health and Food Safety*; Roger SCARLETT-SMITH, *AESGP Past President*

In particular, a proportionate and risk-based implementation of the classification rule 21 is of critical importance for AESGP members, taking notably into account the long history of safe use of many low-risk substances.

Further on, AESGP calls for greater transparency and stakeholder engagement at an early stage in the procedure foreseen for deciding on the regulatory status of products in borderline cases. Past experience with the so-called Helsinki procedure points at the need to avoid decisions, which are not based on a robust scientific assessment.

AESGP also encourages the EU institutions and Member States to adequately and uniformly implement the agreed transitional provisions. This way, substance-based medical devices that are lawfully placed on the market pursuant to the current Medical Devices Directive can continue to be made available on the EU market until 5 years after the entry into application of the new framework.

A crucial element for making the new legislation a success is the provision of sufficient capacities of notified bodies. For substance-based medical devices, Italy has developed a certain leadership role. In order to discuss how future capacity building can be done in an adequate manner AESGP Director General, Dr Hubertus Cranz, met Professor Walter Ricciardi, the President for the Italian National Institute of Health, on 30 March 2017 in his offices at the Istituto Superiore di Sanita (ISS) in Rome.



Hubertus Cranz, *AESGP Director General* & Walter Ricciardi, *President for the Italian National Institute of Health*

Promoting self-care

In addition to the involvement in the numerous legal and regulatory debates relevant for the consumer health industry, AESGP contributed to many discussions of general importance for the development of self-care. This included for example the participation in the European Commission eHealth Stakeholder Group but also a contribution to the pilot project on the promotion of self-care systems in the European Union (PiSCE). At the final PiSCE conference on 17 March 2017, important policy recommendations were shared. Those were developed under the leadership of the Standing Committee of European Doctors (CPME), the umbrella organisation of all medical doctors in Europe, and call for the:

- Establishment of a framework to exchange best practices related to self-care
- Improvement of education at school and university on self-care related issues
- Integration of self-care in healthcare initiatives and in new technologies supporting people's self-care

AESGP will be involved in the implementation of the recommendations in close collaboration with other stakeholder organisations.

The 2016 AESGP Annual Meeting in Athens provided industry leaders the occasion to show their willingness to lead in the process of enabling more citizens to take care of their health. Consumer care companies were encouraged to reflect on ways to optimise public service to the customers by embracing new opportunities in the "digital space".

Recent developments related to Merger and Acquisitions should be seen as an opportunity to improve the service of the industry.

Erica Mann, *Member of the Board of Management of Bayer AG and Head of the Consumer Health Division* at the 2016 AESGP Annual Meeting in Athens

George Dokios, Director General of the Greek Proprietary Association (EFEX) explained the outstanding progress made in Greece. Most important is the abandoning of price control for non-reimbursed, non-prescription medicines. The economic and social benefits of more self-care for the Greek society are tremendous and are getting more and more recognised by policy makers.

George Dokios, *Director General of the Greek Proprietary Association (EFEX),* at the 2016 AESGP Annual Meeting in Athens

Membership support

Comprehensive support to member associations is an important part of the day to day work of AESGP. Due to recent developments, particular attention was paid to Romania, where a new association - the Romanian Association of the Self-Care Industry (RASCI) - was established in mid 2016. An international symposium organised by AESGP confirmed the need to further support good health education and citizens information on self-care products. Participants appreciated that the proposal to ban public advertising for non-prescription medicines in Romania was definitely rejected.

Building evidence is the basis for the political activities of AESGP and for membership support

The AESGP OTC Ingredients Directory compares the classification status (prescription or non-prescription) of key active pharmaceutical ingredients used in self-care in 39 countries (25 European and 14 non-European).

It is based on information provided by WSMI and AESGP member associations and is widely recognised as the most comprehensive analysis in this context. In addition to the publication, there is a OTC ingredients useful search.

AESGP Databanks

The online AESGP databanks on medicines, medical devices and food supplements were updated in mid-2016 and continue to provide transparency on the regulatory and economic environment of consumer health products.

Speaking at the AESGP conference in Bucharest on 19 October 2016 from left to right: Razvan Bosinceanu, *RASCI President*; Dirk Ossenberg-Engels, *AESGP Vice-President*; Iulia Rosian, *RASCI Vice-President*; Hubertus Cranz, *AESGP Director General*; Pete Smith, *Co-Chair, Self-Care Forum, United Kingdom*; Raymond Anderson, *President, Commonwealth Pharmacists Association*; Diana Loreta Paun, *State Adviser for the Department of Public Health, Presidential Administration, Romania*; Doina Draganescu, *President of the Electoral Commission, Romanian College of Pharmacists, Romania*; Oana Cociasu, *President, Romanian Advertising Council, Romania*; Diana Mereu, *RASCI Executive Director*