AESGP CONFERENCE A (RE)NEW(ED) AGENDA FOR SELF-CARE PRODUCTS | 9 October 2019, Brussels (Belgium)

The AESGP conference in Brussels brought together the self-care Industry, legislators and regulators as well as other key stakeholders with the aim to exchange on the current developments and to look into possibilities for further improving the regulatory framework for self-care products, notably non-prescription medicines, substance-based medical devices and food supplements.

As it stands at the crossroads of the three categories, AESGP has a unique insight into the regulatory landscape, which was conveyed throughout the conference. The first three sessions were dedicated to each respective category and their regulatory framework, while the last session examined the role of self-care, in particular from the perspective of stakeholders.

Changes and challenges pertaining to the regulatory framework of food supplements

The first session, chaired by **Maud Perrudin**, AESGP Deputy Director General, focused on food supplements, highlighting recently adopted changes to the EU General Food Law and touching upon issues of relevance for the Industry such as health claims, food additives and novel foods.

Alexandra Nikolakopoulou, Head of Food information and composition, food waste Unit, European Commission, stressed the importance of regular exchanges between the Commission and Industry in order to better understand its perspective. Giving an overview of the ongoing priorities, she noted the importance of the practical implementation of the revised General Food Law which introduces new transparency requirements in the food risk assessment process and significantly impacts the current functioning of the European Food Safety Authority (EFSA). Referring to the ongoing REFIT evaluation of the nutrition and health claims regulation with the main focus on the issue of botanicals, she explained that the Commission Staff Working document should be published by the end of 2019 following the approval by the new Commission. Stakeholders will not be able to comment on the document, but will later have the opportunity to engage in the process when the Commission starts working on the way forward. Nikolakopoulou further updated the audience on the procedure under Article 8 of the Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, which allows the Commission to ask the European Food Safety Authority (EFSA) for a safety assessment of a given substance when there is a potential harmful effect to consumers. The procedure has so far been triggered for five botanicals, namely hydroxyanthracene derivatives, monacolins, green tea catechins, yohimbe and ephedra, and has been concluded for the latter two, which are now prohibited for use in food supplements. While a public consultation on the risk management measure for hydroxyanthracene derivatives is expected soon, the risk management options are still under discussion for monacolins and green tea catechins.

Rafael Perez Berbejal, Policy Officer, Food processing technologies and novel foods Unit, European Commission, presented the implementation experience of the new novel food authorization procedure as well as of the notification of traditional foods from third countries, applicable since 2018. He provided some overall statistics on the authorization procedures, conveying that the Union list of novel foods has so far been amended 31 times and now includes 3 traditional foods and approximately 20 novel foods from botanical extracts. The issue of nanomaterials in novel food was pointed out as one of the challenges where it would be necessary for the Commission to update the definition in the novel food regulation once the Commission Recommendation 2011/698/EU on the definition of nanomaterial will be revised.

Camilla Smeraldi, Senior scientific officer, Food Ingredients and Packaging Unit, European Food Safety Authority (EFSA), presented the ongoing food additives risk assessment, focusing on those relevant for food supplements. As regards the re-evaluation, EFSA has still to assess more than half of the food additives due to a number of complexities and challenges during the process, such as the use in children aged less than 16 weeks to which the health-based guidance values (HBGV) such as acceptable daily intake (ADI) or tolerable daily intake (TDI) have traditionally not been considered applicable. One of the recent challenges in the assessment of food additives that EFSA needs to address is to derive health-based values for those food additives that are also nutrients, in particular on what the general approach would be and how this information should be conveyed to risk managers.

From left to right: Alexandra Nikolakopoulou, Head of Food information and composition, food waste Unit, European Commission; Rafael Perez Berbejal, Policy Officer, Food processing technologies and novel foods Unit, European Commission; Maud Perrudin, AESGP Deputy Director General; and Camilla Smeraldi, Senior scientific officer, Food Ingredients and Packaging Unit, European Food Safety Authority (EFSA)

The speakers agreed with the expectations that the changes to the General Food Law and specific sectorial legislation, including novel food and food additives, should improve trust in the risk assessment process and Member States' support for EFSA's work, ensure an increased scientific cooperation and a coherent risk communication throughout the risk assessment process as well as enable companies to seek pre-submission advice. There are however a significant number of practical questions to be answered by the Commission and EFSA until the application of the regulation in March 2021.

Implementation of the Medical Devices Regulation

The second session, chaired by **MEP Claudia Gamon**, looked at the implementation of the Medical Devices Regulation (MDR) which will enter into application on 26 May 2020. Special attention was paid to self-care medical devices that are composed of substances or combination of substances.

From left to right: Salvatore D'Acunto, Head of Unit Health Technology and Cosmetics, European Commission; Maud Perrudin, AESGP Deputy Director General; Ivana Hayes, Regulatory Affairs Officer, Scientific and Regulatory Management Department, European Medicines Agency (EMA); and MEP Claudia Gamon

Salvatore D'Acunto, Head of Unit Health Technology and Cosmetics, European Commission, talked about the implementation status of the MDR, stressing that it remains a significant challenge not to be underestimated. After presenting the implementation tools delivered so far, he presented the key next steps of implementation which include, among others, the guidance on both qualification and classification rules for substance-based medical devices, for which there is a public consultation foreseen by the end of the year. Further, the Commission also intends to publish a corrigendum to the MDR to address some legal inconsistencies in the published text notably concerning the lack of transition period for low-risk medical devices while such period is foreseen for high-risk devices. Regarding the planned move of the Unit dealing with medical devices from DG Grow to DG Santé, it is expected that there will be no major impact on the work.

Ivana Hayes, Regulatory Affairs Officer, Scientific and Regulatory Management Department, European Medicines Agency (EMA), explained the future role of the EMA in the MDR. An update was provided on the ongoing EMA activities regarding

the borderline and classification work, with EMA being given a formal role in the discussions on borderline products. She further elaborated on the new classification Rule 21, which brings about new requirements applicable to substance-based medical devices and the related guidance, for which EMA would appreciate business case examples to get a better overview on the types of products they would be dealing with while acknowledging the useful feedback already provided by AESGP on the matter.

Françoise Schlemmer, Director, The European Association of Medical Devices Notified Bodies (TEAM-NB), addressed the conference via a video presentation. She shared the results of the recent TEAM-NB survey on the notified bodies' designation process under the MDR and IVDR, which indicated that majority of notified bodies are on a good path towards re-designation and willing to get more information to improve their capacity, yet would need more interaction with stakeholders. She however noted some discrepancy between the Commission and Team NB's forecast on the number of notified bodies to be designated in the coming months.

Maud Perrudin, AESGP Deputy Director General, speaking on behalf of the Industry, highlighted some of the key implementation concerns shared by the whole industry as well as key challenges specific to substance -based medical devices, which are still not getting the level of attention required from the regulators to address their complexity. She insisted that borderline and classification discussions would greatly benefit from dedicated and open discussion platforms among regulators and stakeholders.

Functioning of marketing authorisation procedures (MRP/DCP) for non-prescription medicines

The third session, chaired by **Christelle Anquez-Traxler**, Regulatory and Scientific Affairs Manager, AESGP, focused on the functioning of the mutual recognition procedure (MRP) and decentralized procedure (DCP), the two most commonly utilised European routes for authorization of non-prescription medicines. As both procedures are being increasingly used, the conference was a good opportunity to review how well they perform, not just from the Industry's but also from national competent authorities' (NCAs) viewpoint. To that purpose, AESGP conducted two surveys on the experience with MRP and DCP for non-prescription medicines and herbal medicines respectively.

Mark Griffiths, Vice President, Head of Consumer Regulatory EMEA, Johnson & Johnson Consumer Services EAME Ltd, presented the results of the survey for non-prescription medicines encompassing the period of the last five years and providing some comparisons with the previous AESGP surveys from 2012 and 2015. Timelines remain one of the major issues for companies, in particular for validation and national phase, which are usually extended beyond what is foreseen in the legislation. Companies are sometime unable to launch their products on time, which is of particular concern for seasonal self-care products (antihistaminics, cough and cold). It was suggested that national competent authorities (NCAs) could introduce a 'central slot availability' type system, allowing full visibility on all NCAs availabilities to act as a reference member state (RMS), which could also contribute to a wider variety of NCAs being chosen as RMS. Overall, companies increasingly value the role played by the NCA chosen as RMS. However, there is still a general lack of harmonization in the self-care arena and a great deal of diversity between different Member States on legal status which then may add some complexity in MRP-DCPs. For this reason, companies tend to cluster countries and run parallel DCPs; hence the industry regretted that the splitting pilot had been stopped by the CMDh as it could have provided a good alternative to the running of parallel procedures.

The latter was indeed acknowledged by **Martin Huber**, Chair of the CMDh Non-Prescription Medicinal Products Task Force, as the splitting led to (too much) disharmony in the common product information. It gave an overview on the work done by the CMDh Non-prescription Task Force and explained the recent revision of the best practice guide for authorisation of non-prescription medicines in the DCP and MRP to better delineate the place to put data substantiating the reclassification. He underlined that one of the challenges of the TF is to strive for a balance between national prerogative of Member States and harmonization. The current work of the TF on "core subset" is a good illustration.

From left to right: Christelle Anquez-Traxler, Regulatory and Scientific Affairs Manager, AESGP; Mark Griffiths, Vice President, Head of Consumer Regulatory EMEA, Johnson & Johnson Consumer Services EAME Ltd; Martin Huber, Chair of the CMDh Non-Prescription Medicinal Products Task Force; Frank Waimer, General Manager Operations, Dr. Willmar Schwabe GmbH & Co. KG; and Reinhard Laenger, Head of Department on Herbal, Homoeopathic and Veterinary Medicinal Products, Austrian Agency for Health and Food Safety.

Looking at the specificities of

herbal medicinal products, **Frank Waimer**, General Manager Operations, Dr. Willmar Schwabe GmbH & Co. KG, gave an overview of the results of the DCP-MRP survey highlighting that companies increasingly use European procedures to launch their products although they are still quite new to the sector. With regard to the timelines, the procedures appear to run faster; however, similarly to non-prescription medicines, the national phase needs improvement. The results showed that EU monographs play an important role, which was further confirmed by **Reinhard Laenger**, Head of Department on Herbal, Homoeopathic and Veterinary Medicinal Products, Austrian Agency for Health and Food Safety, who presented some additional data on MRP/DCP, indicating that the increased use of the European procedures reflects the work done by the EMA Herbal Medicinal Products Committee (HMPC). It also provided good advises to companies and added that deviation from monographs are possible on the basis of data from applicants. He also noted that if mutually agreed, the use of MRP-DCP is possible even if there is no monograph. All member states have now experience with MRP-DCP for herbal medicines and he encouraged companies to use scientific advice in case of questions and not to fear PSRPH being raised nor referrals.

The European Self-care Agenda - A Stakeholder Perspective

The fourth session was chaired by **Jurate Svarcaite**, AESGP Director General, who set the tone by giving an overview on the evolution of self-care throughout time and shared best practices of self-care initiatives implemented by AESGP member associations. The stakeholders' involvement was essential in the success of all the initiatives aiming to advancing self-care and contribute to sustainable health systems.

From left to right: Jurate Svarcaite, AESGP Director General; Ilaria Passarani, Secretary General, PGEU; Susanna Palkonen, Director, European Federation of Allergies and Airways Diseases Association (EFA); and Aurélien Perez, Policy Officer, Directorate Health and Food Safety, European Commission

Susanna Palkonen, Director, European Federation of Allergies and Airways Diseases Association (EFA), looked at the role of self-care in successful management of airway diseases. She noted that allergy was the most common chronic disease in Europe. She highlighted the importance of information and support as well as patient participation in decisions regarding their health in disease self-management. She called for the Industry to connect prevention, care, self-management and ultimately self-care. She said that this was currently done by patient organizations, but was not enough.

Ilaria Passarani, Secretary General, PGEU, presented the role of pharmacists in advancing self-care. She presented number of national examples of service-oriented pharmacy practice with a special focus on self-care empowerment. To illustrate the evolving role of pharmacists, Passarani pointed out that in seven countries, vaccines are now being administered by pharmacists in public pharmacies and this contributed significantly in improving vaccination coverage.

Aurélien Perez, Policy Officer, Directorate Health and Food Safety, European Commission, emphasized the significant burden of antimicrobial resistance (AMR) and presented the European One Health Action Plan against antimicrobial resistance. He shared the results of the latest Eurobarometer on AMR, which shows that too many Europeans did not have sufficient literacy on the topic. He noted the important role the self-care Industry can play through infection prevention, treatment for minor viral health conditions and by raising awareness about AMR.

Overall, the speakers acknowledged patient empowerment and health literacy as key enablers of self-care and necessary behavior change in use of antibiotics.