AESGP

Annual Report 2015-2016

HIGHLIGHTS OF THE YEAR

From left to right: Hubertus CRANZ, AESGP Director General; Vytenis ANDRIUKAITIS, EU Commissioner for Health; Giovanni LA VIA, Chairman of the European Parliament Committee on the Environment, Public Health and Food Safety; Roger SCARLETT-SMITH, AESGP President at the AESGP Annual Reception in the European Parliament on 14 October 2015

The new medical device legislation now expected to be an acceptable basis for the future of substance-based medical devices

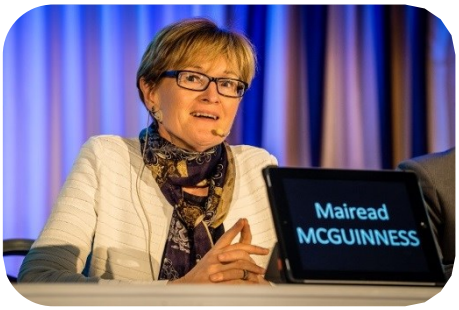
AESGP's primary interest is in "substance-based medical devices", which have become an important part of self-care. The new legislation envisages to define new classification criteria through a special "Rule 21". Originally, the European Commission proposed to put all substance-based medical devices in class III, the highest risk category. AESGP questioned this approach and started a far reaching campaign to secure a reasonable legal basis for these products.

Starting point of the process within AESGP was the formation of a AESGP committee on medical devices several years ago. This committee brings together representatives of the AESGP national associations and member companies with expertise in the area of medical devices. It prepared the positioning of AESGP in this sector and closely followed the numerous steps in the legislative procedure since the adoption of the European Commission's proposal in September 2012.

Establishing better regulation for self-care products was the guiding principle for AESGP during the course of the last 12 months. Well attended conferences and association meetings documented the strong interest in the work of AESGP.

A political highlight was the event in the European Parliament in October 2015, which allowed AESGP to explain its priorities to a wide range of decision makers of the European Institutions.

Top on the list of legislative issues was the new regulation on medical devices, which is expected to be finally agreed upon in 2016.



Shadow rapporteurs Michèle RIVASI (Greens/EFA) and Mairead McGUINNESS (European People's Party) expressing views on behalf of the European Parliament on the new medical devices legislation at the AESGP Conference

Further milestones in the process were the adoption of the first reading position of the European Parliament in April 2014 and the agreement of the Council on its negotiating position in June 2015.

This has been followed by the so-called trilogue - a discussion process between the European Parliament, the Council and the European Commission, which is expected to lead to an agreement on the new regulation by the end of the Dutch EU Presidency in June 2016.

It seems that this process will result in a new medical device legislation, which is an acceptable basis for the future of substance-based medical devices. Many concrete implications will however need to be sorted out once the new law is finally agreed.

This also holds true for many other parts of the new legislation, which are of high interest to AESGP, such as the classification of medical devices containing nanomaterials, the procedure for defining the regulatory status of a product, the Unique Device Identification (UDI) system and the transitional arrangements.

As the new legal provision will not be fully applicable immediately, AESGP continues to be strongly involved in the implementation of the medical devices directives considered at various working groups of the European Commission.

In particular, AESGP contributed to the review of the definitions of a pharmacological, metabolic and immunologic mode of action. In its effort to move towards recognition of the physical-chemical mode of action, the long-term work of AESGP is aimed at distinguishing mode of action and therapeutic effect. AESGP is also a member of the European Commission's expert groups in clinical investigation / evaluation, vigilance, new and emerging technologies, Unique Device Identification (UDI), software and the different working groups related to the new European database for medical devices ('Eudamed').

The increasing scale of the category facilitated the acceptance of a seat for AESGP at the market access meeting of the European Commission's Directorate General for Trade.

At the AESGP Conference on substance-based medical devices on 14-15 October 2015 in Brussels representing their national authorities from left to right: Judite NEVES (Portugal), Maria Grazia LEONE (Italy), Matthias NEUMANN (Germany).

DG GROW Director Carlo PETTINELLI explaining the European Commission's proposal for the new EU medical device legislation

John WILKINSON, MHRA, United Kingdom at the AESGP Conference in October 2015 in Brussels

Provisions and technical barriers to trade to third countries, such as China, Russia or the United States were at the heart of the yearly discussion with representatives from the European Ministries of Economy and Commerce, in which AESGP also participated.

AESGP was also invited to the first meeting of the Competent Authorities for Medical Devices (CAMD) Executive with stakeholders, where AESGP presented its key priorities notably greater involvement of manufacturers during borderline discussions. The meeting was chaired by the Medical Devices Director at the UK's Medicines and Healthcare products Regulatory Agency (MHRA), John Wilkinson, who also spoke at several AESGP conferences.

Availability of non-prescription medicines: a priority for authorities for the years to come

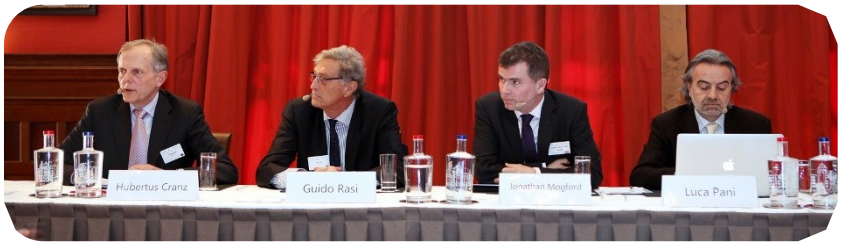
AESGP's efforts towards raising visibility of non-prescription medicines' issues in path to market have now paid off. A number of strategy documents issued by EU Authorities highlight the importance of the availability of non-prescription medicines. The final EU Medicines Agencies Network Strategy 2020 (also called High Level Strategy), which sets joint priorities for the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), emphasises that the "network has also a key role in improving patient access to well-established medicines including [….] non-prescription medicines".

The same objective is incorporated in the HMA Multi Annual Work Plan (MAWP) and the Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh) new strategy to 2020:
The MAWP, which describes how the authorities will take forward the High Level Strategy, states that the "enhancement and improvement of existing tools such as the mutual recognition / decentralised procedures (MRP / DCP) and the achievement of agreements on issues still unresolved as the common criteria for the authorisation of over-the-counter (OTC) products remain as HMA objectives." In addition, "the HMA will explore other ways to reach agreements between Member States regarding non-prescription products, to facilitate a greater number of product switches." A CMDh subgroup or workgroup aimed at exploring common agreements for individual active substances should be created to that effect.

The CMDh new Strategy to 2020 makes it clear that "CMDh should investigate other ways/procedures to get a marketing authorisation in Member States where the product is needed but not authorised in a more efficient way. There should be easier access to OTC-products and there is a need to explore (further) possibilities for MRP/DCP procedures for OTC products (especially in procedures where the legal status is different in the Member States involved)."

Also reflecting AESGP's campaigning for smart regulation and smart implementation, the notion of a proportionate risk-based approach and the need to tackle the complexity of the current regulatory systems are flagged high in all documents. Efforts will be directed on how to reduce administrative burdens and associated costs, taking into account best practices at the level of regulatory authorities.

Improving the availability of non-prescription medicines through simplified regulatory requirements was also the key issue of a well-attended conference with the Heads of the EU Medicines Agencies during the Dutch EU Presidency in the Royal Industrial Club in Amsterdam on 15-16 February 2016. In a distinguished and historical place, many Heads of Medicines Agencies, European Commission and European Medicines Agency representatives discussed ways forward with AESGP Members.



Discussing the new EU Heads of Medicines Agencies (HMA) Strategy document at the AESGP Conference with the HMA from left to right: Hubertus CRANZ, AESGP Director General; Guido RASI, EMA Executive Director; Jonathan MOGFORD, MHRA, United Kingdom; Luca PANI, AIFA Director General, Italy

Reflecting on ways to improve availability of non-prescription medicines at the AESGP Conference in Amsterdam, from left to right: Andrzej RYS, Director, Health Systems, Medical Products and Innovation, DG SANTE, European Commission; John BORG, Member of the CHMP, Malta; Christa WIRTHUMER-HOCHE, Head, Austrian Medicines and Medical Devices Agency (AGES MEA), Austria; Belén CRESPO, Executive Director, Agency for Medicines and Health Products (AEMPS), Spain

AESGP calls on efficient European procedures for non-prescription medicines

Before the adoption of the above mentioned documents, AESGP presented the results of its internal survey on mutual recognition and decentralised procedures (MRP / DCP) for non-prescription medicines at the interested party meeting of the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) in May 2015, which clearly showed the need for improvements. As part of possible solutions, AESGP spearheaded the idea of splitting MRP / DCP for non-prescription medicines so as to avoid procedures with mixed status and later on encouraged its members to take part in the pilot started by the CMDh. AESGP also participated to the first stakeholder platforms on centralised procedure, which addressed procedural aspects.

AESGP OTC ingredient directory undergoing major review

AESGP started to undertake a deep review of its OTC ingredient directory to ensure that it remains a credible and robust database. In addition, on behalf of WSMI, AESGP started to compile information on ingredient challenges in the world to later serve as knowledge and learning repository.

AESGP being the voice of the self-care industry in all telematics projects

AESGP provided comprehensive comments on the EU Telematics strategy and implementation roadmap 2015-2017. It also participated to the joint telematics Management Board – industry meeting and advocated for a good business case for the data to be entered into the database and be used in place of variations or other regulatory notification for example. Further on, the EMA is in the process of implementing the standards developed by ISO for the identification of medicinal products. AESGP has three permanent representatives taking an active part in the work of the joint EMA-industry task force and its sub-groups with the goal to ensure a smooth migration of the data currently in the so-called XEVMPD to IDMP, that the timelines are realistic and necessary EU guidance document available.

The development of the Clinical Trial Portal and database, outputs of the new Clinical Trial Regulation, has given rise to a joint working group, to which two AESGP experts contribute.

AESGP on API mix

A 2007 Q&A from the EMA quality working party is causing difficulties as it redefines the blending of the API with an excipient (so-called API mix) as the first step of manufacture towards the finished product. This has consequences in terms of GMP standards to be followed and shelf-life. AESGP raised those issues at numerous meetings and asked that the existing Q&A be revised. AESGP presented the issue to the authorities at the EMA Quality Working Party with interested parties meeting and the joint CMDh-industry meeting. As a follow-up to the meeting with the QWP, it ran a survey internally to gauge the extent of the issue and to underline important aspects. As a result the QWP has undertaken to issue a revised version of the Q&A to more precisely clarify in which conditions an API-mixture can exist.

AESGP coordinates ICH activities on behalf of WSMI

AESGP coordinates activities and expert representation on behalf of WSMI for the International Council on Harmonisation (ICH). AESGP develops preparatory and overview documents and teleconferences to ensure that WSMI members are up-to-date on the topics being discussed and of relevance to the self-care industry. Further to the reform of ICH, WSMI is eligible to become member the Council and AESGP supported WSMI in the preparation of the membership application.

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

AESGP met with the EMA Working Group on Lists and Monographs of the Herbal Medicines Committee (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. It presented its survey on herbal medicinal products and discussed amongst others the revision of monographs following the validation data of bronchitis severity scale, the consequence on herbal medicinal products of the draft question and answer on ethanol, the new standards for herbal combinations including herbal teas.

A number of quality topics were discussed with senior officials from the EDQM during the annual AESGP-EDQM meeting in November 2015.

Modernisation of medicinal products leaflets

As required by Directive 2010/84/EC, the European Commission is expected to produce an assessment report on the current shortcomings in the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL). AESGP is taking part in the industry reflection concerning the modernisation of the product information and in particular its electronic version. However, it is clear for the self-care sector that, as the patient may have no or little interaction with a healthcare professional, information provided directly with the pack will continue to be required but could be complemented by possibly a more user-friendly electronic information.

Pharmacovigilance

AESGP has closely been involved in the implementation of the new pharmacovigilance legislation adopted in 2012 and participated in numerous meetings to ensure that the specifics of non-prescription medicines are well taken into consideration.

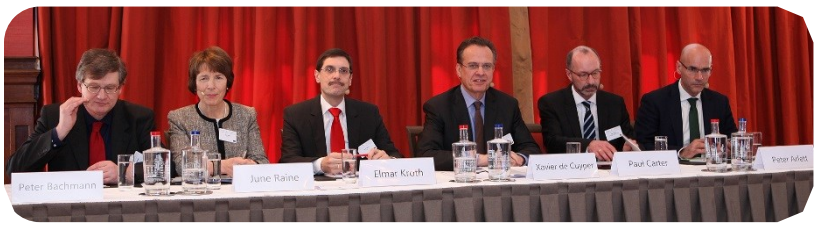
More specifically, the association has been addressing with highest attention the referral procedures related to well-known actives and suggested alternative procedures for this particular type of substances, with recent developments clearly going in the right direction. AESGP has also led important work around simplification of the Risk Management Plan (RMP) template, which will be finalised by the end of 2016.

In order to further strengthen the work of AESGP in this field, a new AESGP committee on pharmacovigilance was established. Committee members first met in the margin of the AESGP conference with EU Heads of Medicines Agencies in February 2016, where the working priorities of the new committee were defined.

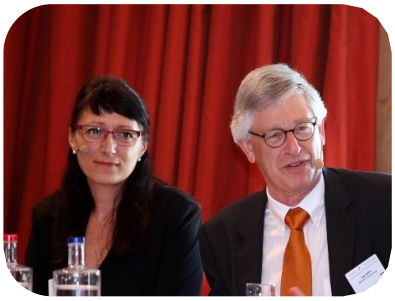
Shortage and supply chain disruption: dialogue with authorities continues

The EMA convened a stakeholder meeting bringing together national competent authorities, industry, patient and healthcare professional representatives to discuss recent initiatives and to reflect on possible further actions to proactively manage shortages. AESGP was part of the inter-association task force that developed the "harmonised communication principles between industry and authorities for quality- and manufacturing driven supply disruptions" which was actively discussed at the meeting. The paper advocates in favor of a harmonised and risk-based notification to Authorities. AESGP contends that publication of shortages should occur only after filtering by the Authorities in order to avoid hoarding and dilution of the information; shortages of non-prescription medicines do not need to be published as alternatives usually exist.

AESGP is also a full participant to the Joint supply chain stakeholders' group on shortages which gather representatives of the main European pharmaceutical trade associations, pharmacists, wholesalers and parallel traders. The group is working on a statement on information and medicinal product shortages.



Discussing pharmacovigilance issues at the AESGP Conference in Amsterdam from left to right: Peter BACHMANN, Chair of the Co-ordination Mutual Recognition and Decentralised procedures-human (CMDh); June RAINE, Chair of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC); Elmar KROTH, Director, German Medicines Manufacturers Association (BAH); Xavier DE CUYPER, Chief Executive Officer, Federal Agency for Medicines and Health Products (FAMHP), Belgium; Paul CARTER, Global Head Consumer Health Care, Development, Medicine and Regulatory Affairs, Boehringer Ingelheim, Peter ARLETT, Head of the Pharmacovigilance Department within the European Medicines Agency (EMA)



The opening of the AESGP Conference in Amsterdam focused on the need for reduction of administrative burden and ways to improve availability of medicines and avoid shortages. It was chaired by Hugo Hurts, Director, Medicines Evaluation Board (MEB), the Netherlands. A presentation was given by Kristin Raudsepp, Director General, State Agency Medicines, Estonia.

Environment

AESGP together with other EU associations launched in June 2015 a campaign entitled #medsdisposal on the appropriate disposal of medicines, designed to tackle effectively the potential negative impact of pharmaceuticals in the environment.

The #medsdisposal campaign aims to raise awareness among European citizens on how to best dispose of unused or expired medicine. The campaign has been presented at several events and was well received by the European institutions and other stakeholders.

Up to April 2016, the campaign had around 2 million impressions on Twitter where 195 organisations and individuals actively participated in the discussion, while the #medsdisposal website (www.medsdisposal.eu) has been frequently visited.

This campaign has been part of the overall AESGP activities in the field of 'Pharmaceuticals In the Environment' (PIE), which defines a set of collective actions aimed at reducing the potential impact of pharmaceutical actives in the environment, also known as the 'Eco-Pharmaco-Stewardship'.

In addition, AESGP continues to provide views of the non-prescription sector at meetings of the European Commission's working group on chemicals and specific meetings of the European Commission's Joint Research Centre (JRC).

In all instances, AESGP stands ready to dialogue with European policy-makers and external stakeholders in order to ensure that non-prescription medicinal products are not disproportionately impacted by new proposals.

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.

AESGP actively engaged with EFSA

As a member of EFSA Stakeholder Consultative Platform, AESGP continues to encourage improvement of EFSA services provided to applicants notably in the context of health claims and novel foods applications.

AESGP actively participated in meetings of EFSA Stakeholder Platform as well as the EFSA Stakeholder Consultative Platform Discussion Group on Food Chemical Occurrence Data which focuses on food additives related issues.

In the autumn of 2015, EFSA launched an open consultation on its draft Strategy 2020, which outlines EFSA's high-level strategic and operational objectives for the next five years as well as the initial practical steps that will be needed to turn these objectives into reality. AESGP welcomed the initiative and provided comments to EFSA supporting every improvement of the services provided by EFSA to applicants e.g. in the context of health claims.

In January 2016, AESGP participated in a meeting with the EFSA management to discuss further improvements in the quality, efficiency and timelines of EFSA processes and outputs as well as the future of the stakeholder engagement.

In March 2016, AESGP participated in an important study conducted within EFSA Transparency and Engagement in Risk Assessment project (TERA) to assess the potential impacts of measures that EFSA is considering in relation to increasing transparency and engagement in its risk assessment process. AESGP supported a greater involvement of stakeholders and other EU institutions in the framing and formulation of requests, in the development of risk assessment methodologies and a greater pre-submission engagement with applicants. While supporting improvement of accessibility and usability of information in EFSA's communication tools, AESGP strongly called for legal and practical certainty for economic operators with regard to the publication of their own data.

AESGP also contributed to a number of technical consultations and data collections such as data collection on isoflavones from kudzu root in food supplements.

AESGP attended as an observer the April 2015 open plenary meeting of EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA).

AESGP used these many opportunities to maintain its position as a key EFSA stakeholder representing a significant EU industry and to encourage a more intensified dialogue between EFSA and its applicants. This strong positioning allows AESGP to build up on its solid reputation as a reliable, stable and knowledgeable industry partner for EFSA beyond the activities of the Stakeholder Platform.

AESGP coordinates submission of food supplements industry data on food additives

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

In light of the ongoing discussions on food additives in food supplements, a dedicated AESGP Food Additives Task Force composed of technical experts was created to strengthen the responsiveness of the Food Supplements Committee on food additives related consultations.

In 2015 and 2016, AESGP has been engaged in a close dialogue with the European Commission on the future modification of the Regulation on food additives, in particular the creation of a category for food supplements for infants and young children (between 0 and 3 years). AESGP participated in a meeting with European Commission representatives in January 2016. The AESGP delegation actively contributed to the discussion on the scope of the food additives to be considered for authorisation in that category and on the data input from stakeholders. AESGP is currently collecting data supporting the safe use of additives in food supplements for this age range.

AESGP supportive of an evidence-based approach in the implementation of the Nutrition and Health Claims Regulation

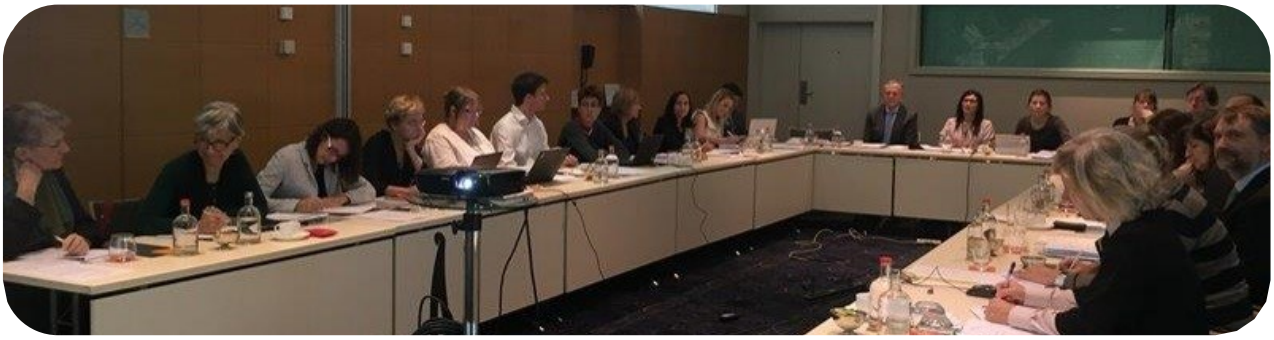
In 2015, AESGP welcomed the European Commission's initiative to carry out an evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims with a particular focus on nutrient profiles and health claims on plants and their preparations added to foods. AESGP has been supportive of an evidence-based approach in the scientific evaluation of all health claims, including claims made on botanical ingredients and will continue to do so by contributing to this evaluation and participating in the open consultation in the second half of 2016.

The AESGP Annual Meeting in Barcelona in May 2015 provided an occasion to discuss the assessment of health claims. Valeriu Curtui, Head of the Nutrition Unit at EFSA, explained the role of EFSA in that regard and stressed that EFSA applies the highest standard of scientific evidence for all claims. Dr. Peter Liese, Member of the European Parliament, shared with the participants his views on the pending issues related to the Nutrition and Health Claims Regulation such as nutrient profiles and the scientific assessment of botanical health claims. According to Dr Liese all health claims, including botanicals, should be evaluated by EFSA.

AESGP also closely follows developments on pending claims, including the ones made for caffeine. Following publication of the EFSA safety assessment of caffeine in May 2015, the Commission proposed to authorise four out of five caffeine health claims (accompanied by warnings). Unless there is an objection from the European Parliament, the final adoption is scheduled to take place in the autumn of 2016.

Valeriu CURTUI, EFSA at the AESGP Annual Meeting in Barcelona

Pieter LIESE, Member of the European Parliament at the AESGP Annual Meeting in Barcelona



On 28 October 2015, the meeting of the AESGP Food Supplements Committee in Brussels provided an excellent occasion for the AESGP members to discuss the latest developments with regard to the implementation of the Nutrition and Health Claims Regulation, the Food Information to Consumers Regulation (FIC) and the Food for Special Groups (FSG) Regulation with Alexandra Nikolakopoulou, Head of Unit E1 'Food information and composition, food waste' at European Commission's DG Santé.

General Food Law (GFL)

In 2014, AESGP contributed to the consultation on REFIT Fitness Check of the GFL calling for increased transparency of public consultations, science-based risk management and improvement of the business environment by reduction of unnecessary regulatory cost and burdens.

AESGP participated in the September 2015 meeting of the Working Group on the Fitness Check of Regulation (EU) No 178/2002 on General Food Law. Presentation of the final outcome of this Fitness Check on General Food Law through the publication of the Commission Staff Working Document is foreseen for the first trimester of 2016.

AESGP contributes to technical consultations on Food Hygiene and Contaminants

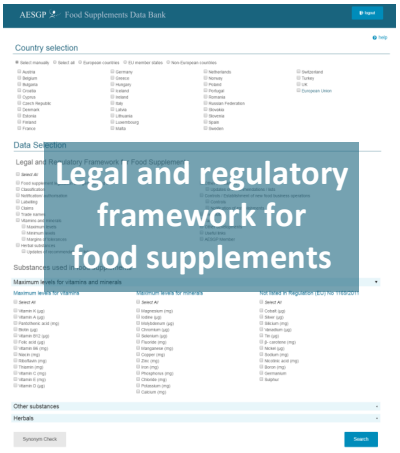
As part of its commitment to the evidence-based policy, AESGP coordinates submission of food supplements industry data to support Commission risk management work on food hygiene and contaminants. AESGP also remains an active member of the EFSA Discussion Group on 'Chemical Occurrence Data' where contaminants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

In 2015, AESGP submitted comments to a number of technical consultations such as maximum levels of benzo(a)pyrene in 'food supplements containing and/or derived from botanical ingredients, the revised guidance document on the implementation of HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses.

AESGP DataBank on food supplements now online

The new online AESGP Databank on food supplements was launched at the 2015 AESGP Annual meeting.

This comprehensive AESGP Databank should be a useful tool for companies to set market transparency and is in line with the AESGP commitment to provide evidence as part of its political activities. It complements the updated database on medicines and medical devices.



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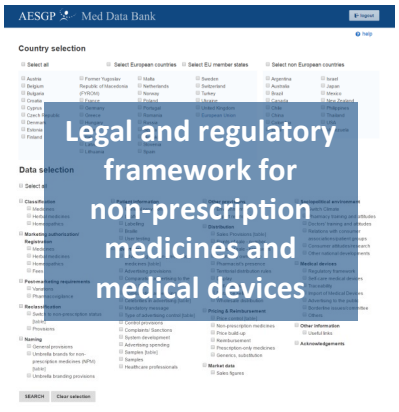

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