AESGP

SELF-CARE AGENDA 2020

ESTABLISH EVIDENCE-BASED POLICIES

ENHANCE COOPERATION BETWEEN ALL STAKEHOLDERS

CREATE MORE INCENTIVES FOR INNOVATION IN SELF-CARE

GOALS 2020

- Proportionate regulation
- Improved availability of self-care products
- Facilitate product maintenance
- Constructive interaction between regulator and applicant
- Adequate environmental measures
- Recognition of well-established status of substances
- Proportionate decision-making everywhere
- Good visibility in a retail environment
- Advertising permitted in all media
- Build consumers' trust and confidence through brands
- Free pricing for self-care products
- Respect of approval timelines

REDUCE ADMINISTRATIVE BURDEN

USE PROCEDURES FOR MARKET ACCESS EFFICIENTLY

IMPLEMENT EU RULES REASONABLY

EXECUTIVE SUMMARY

TO FULLY REALISE THE PUBLIC HEALTH AND ECONOMIC BENEFITS OF SELF-CARE, THE AVAILABILITY OF SELF-CARE PRODUCTS NEEDS TO IMPROVE.

Non-prescription medicines, self-care medical devices and food supplements make an important contribution to the health and well-being of European citizens. People want to take responsibility for their own health and this, combined with demographic changes and the increasing cost of professional healthcare, means that more must be done to develop and support self-care. This document outlines how European citizens ability to self-care safely and effectively can be enhanced by improving the regulatory system for self-care products.

GENERAL PRINCIPLES

- The public health, economic and social benefits of self-care products should be recognised by all partners
- The implementation of legislation affecting the self-care sector needs to be appropriate and proportionate. Mechanisms need to be put in place to check whether legislation is still fit for purpose and lessons learnt should be used to improve the implementation.
- Policy-making should be evidence-based with meaningful cooperation/ dialogue between authorities, stakeholder representatives and industry partners.

NON-PRESCRIPTION MEDICINES

- The routes to market (centralised, mutual recognition, decentralised and national procedures) need to guarantee timely market access for non-prescription medicines including reclassification from prescription to non-prescription status (“switch”). The benefits of non-prescription medicines need to be taken into account in the evaluation process e.g. through the use of recognised risk-benefit decision making models.
- The implementation of the EU pharmacovigilance legislation should reduce unnecessary administrative burdens and avoid unjustified restrictions for non-prescription medicines.
- Advertising of non-prescription medicines to the general public in all media should be permitted in accordance with the EU legislation.
- Free pricing for manufacturers of non-prescription non-reimbursed medicines should be established everywhere.
- The value of brands including umbrella brand should be widely recognised.

MEDICAL DEVICES

- Medical devices composed of substances or combinations of substances should be classified according to their risk profile. The definition of a pharmacological, immunological and metabolic mode of action should be rational and proportionate.

FOOD SUPPLEMENTS

- Interactions between EFSA (the European Food Safety Authority) and applicants should be improved by permitting guidance and scientific advice e.g. with regard to health claims.
- The ongoing re-evaluation programme and reorganisation of the food supplements categories should lead to workable and sustainable conditions of use for food additives that reflect balanced judgement and robust science.

NON-PRESCRIPTION MEDICINES

ECONOMIC AND SOCIAL VALUE

The social and economic value of self-medication has been demonstrated in several studies, including the AESGP study on the Economic and Public Health Value of Self-Medication[1] the findings of which have been corroborated by more recent national studies. According to the AESGP study, the social and economic value of self-medication is realised by the fact that people manage common health problems themselves, with minimal or no intervention from their doctors. This way, public resources used for treating minor ailments are redirected towards more serious illnesses that have a large impact on individuals and public health. In light of this, growing support for self-medication has been observed from many official institutions, both inside and outside the European Union (e.g. the European Parliament, the European Commission, the EU's Council of Ministers, the World Health Organization, etc.). The study demonstrated the economic value of self-medication and the incremental benefits of an increase in the levels of self-medication using a conservative 5% substitution rate (from professional care to self-care). It estimated that the total annual savings in the enlarged European Union from the shift of care to self-medication by 5% would exceed €16 billion.

PROPORTIONATE REGULATION

In a fast-changing and global environment, it is imperative that the regulatory system be fit for purpose, efficient and risk-based whilst ensuring optimum public health protection. The so-called Escher study[2] recommended that periodic reassessments of the regulatory instrument take place to gauge whether or not regulations fulfil the original intent of the legislator. Any formal evaluation of a regulatory instrument should include the different actors involved (e.g. regulators, industry, patient organisations, healthcare professionals). Similarly addressing the lessons learnt should give rise to partnership with the industry at the earliest stage, for example the drafting of a concept paper, and until the final stage (roll-out of an IT system, final document). It should also include feedback loops to ensure that the instruments continue to operate well and remain fit for purpose.

- Following an invitation by the Heads of EU Medicines Agencies (HMA) and the European Medicines Agency (EMA), a discrete number of areas, where the administrative burden could be reduced, should be identified by the stakeholders. These topics should be subject to technical scrutiny by the relevant expert group of the network followed by consultation with stakeholders about concrete opportunities to reduce administrative burdens. Senior management in regulatory authorities should monitor the process ensuring that all arguments are carefully considered while not reducing the level of public health protection. Concrete examples of areas where such cooperation is needed are addressed in further details later in the document.
- With this in mind, AESGP supports the Benchmarking of European Medicines Agencies (BEMA); however, companies which use the system should also be invited to input into the survey. Furthermore, the results of the BEMA should be transparent to stakeholders and lessons learnt should be openly discussed with the industry.
- Transparency is key to a functioning and predictable regulatory environment. Non-prescription medicine manufacturers need to be consulted on any document that would introduce new requirements, modify existing ones or change the interpretation of relevant legislation. There was worrying precedence of Questions & Answers introducing a new interpretation of the legislation without proper notification of users, although these engendered significant changes for the industry.
- The main objective of the revision of the pharmacovigilance legislation[3] is to strengthen but also to rationalise

Self-care saves the European healthcare systems more than

16 Billion Euros

REGULATORY SYSTEMS NEED VALIDATION TO STAY FIT FOR PURPOSE

1 www.aesgp.eu/media/cms_page_media/68/2004study.pdf
2 Escher report: "Improving the EU system for the marketing authorisation of medicines – Learning from regulatory practice" http://escher.tipharma.com/fileadmin/media-archive/escher/Reports/Escher_report_IA.pdf
3 Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance & Regulation (EU) no 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) no 726/2004 as regards pharmacovigilance

"NETWORK OF EXPERTS IN RECLASSIFICATION SHOULD BE ESTABLISHED."

EUROPEAN COMMISSION REPORT ON PROMOTING GOOD GOVERNANCE OF NON-PRESCRIPTION MEDICINES

the existing pharmacovigilance requirements. Significant savings were anticipated for the pharmaceutical industry but also for regulators[4]. For the industry, the implementation was resource-intensive and costly. **A comprehensive and objective evaluation of the current pharmacovigilance system is needed to assess whether the original objectives have been addressed.**

- An efficient telematics system is the basis for a modern regulatory system enhancing the interoperability of systems at EU and international level. It is of the utmost importance that the EU network as a whole commits to such system and that all authorities fully embrace and implement it in a timely and transparent manner. It is essential that the partnership with industry remains active. **Roadmaps with clear timelines that account for sufficient transitional time for implementation should exist for all important telematics projects, including companies operating at local level and/or those with more resource constraints.** Maximising the value of the telematics system, in particular the Article 57 database, also has the potential to decrease variation and resource duplication.
- **Each Agency in Europe should have expertise in the field of self-care/non-prescription** medicines, either via its assessors or via a point of reference (for example the so-called "OTC champion").

AVAILABILITY OF NON-PRESCRIPTION MEDICINES

The recently published EU Medicines Agencies Network Strategy to 2020[5] recognises that the "*network also has a key role in improving patient access to well-established medicines including […] non-prescription medicines*".

This was further specified in the Heads of Medicines Agencies Multi-Annual Work Plan (MAWP) which counts amongst its priorities "*to facilitate medicines registration, including of non-prescription medicines*" and states that the "*HMA will continue searching for simplification, agreements and common ground between countries in relation to the requirements and procedures for the approval of medicines. The enhancement and improvement of existing tool such as the decentralised / mutual recognition 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. HMA considers that the work of CMDh is essential for the achievement of this goal.*"

Every second medicine
dispensed in Europe has non-prescription status.

But
only 5 molecules
are available in non-prescription medicines in the whole European Union

The final Strategy to 2020[7] of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) is in line with the above-mentioned documents, mentioning that the "*CMDh should investigate other ways/procedures to get a marketing authorisation in MSs 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*

4 http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/pharmacovigilance-ia-vol1_en.pdf, page 55
5 www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199060.pdf
6 http://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/01-HMA_MG_and_PS/2016_02_HMA_Joint_Mult_Annual_Work_Plan.pdf
7 http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/About_CMDh/CMDh_Activities/CMDh_335_2015_Rev00_2016_02.pdf

MRP/DCP procedures for OTC products (especially in procedures where legal status is different in MSs involved)."
The strategy adds that discussion should take place on the possibility for an applicant to ask scientific/regulatory advice from CMDh before submission of the application concerning the choice of legal basis and how to address/run DCPs with different legal status in MSs.

There is indeed an availability issue with non-prescription medicines in Europe. The report entitled "Promoting Good Governance of Non-Prescription Drugs"[8] of June 2013 showed that only five active pharmaceutical ingredients were available as non-prescription medicines in all Member States surveyed. Since then the situation has not really improved and there is still a huge inequality of access between countries in Europe with regard to non-prescription medicines.

Although the decision on legal status is a national prerogative, the definition and criteria underpinning such a legal status are fully harmonised in Europe… at least on paper. Non-prescription medicines are defined by default in the Community Code; however, in reality, the contrary principle applies. As a result, 'switching' from prescription to non-prescription is lengthy and difficult.

It is now important to put the general political orientations into real action:

- It is essential that each national authority and the EMA are committed to improving the system for non-prescription medicines. More medicines being classified as non-prescription should be seen as the key benchmark.
- In line with the recommendation of the report on promoting good governance of non-prescription medicines, "an EU network or Forum should be established for those within National Competent Authorities who are directly involved in the licensing and reclassification of medicines". It also recommends that "stakeholder platforms should be established at national level to share views and develop strategies to reach a common approach to supporting patient access to non-prescription medicines." Such platforms have been established in the UK, Ireland, Finland and Spain, for example. AESGP encourages the other European countries to set up similar discussion groups with all stakeholders.
- Beyond the commitment and political will, **Agencies should make sure they have the necessary expertise and resources for assessment of non-prescription medicines**. Visibility with regard to criterion used to evaluate products and changes in classification status ("switch") on the authorities' websites, specific switch guidance and openness to host pre-meetings are positive signals towards the self-care industry. Some authorities have gone a step further and published list of potential candidates for switch.
- The experiences of Member States where non-prescription experience is significant should be respected.
- In a reclassification process, the benefits of non-prescription medicines, such as the easier and more timely access for citizens, should be given equal weight to any possible risks.
- A balanced and proportionate approach to future submissions to change legal status should be put in place. The so-called **Brass et al. benefit-risk model and methodology**[9] **should become the**

8 http://ec.europa.eu/DocsRoom/documents/7623/attachments/1/translations/en/renditions/pdf
9 Brass EP, Lofstedt R, Renn O. Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit-Risk Assessment. Clin Pharmacol Ther, 2011. 90(6): p. 791-803.

"ACCESS TO WELL-ESTABLISHED INCLUDING NON-PRESCRIPTION MEDICINES NEEDS TO BE IMPROVED."

EU MEDICINES AGENCIES STRATEGY 2020

established standard for evaluating and deciding on switch applications in Europe.

- One year of data exclusivity is provided in EU legislation in case significant preclinical tests were carried out for a switch application. The exclusivity should be granted when the conditions outlined in the corresponding guideline are met. This additional year should be added at the end of the global exclusivity (when the product is still under market exclusivity). Educational material accompanying a switch should be subject to some intellectual protection as well.
- Taking into account that one year of exclusivity is too short to really stimulate innovation, it is important that additional measures are taken to encourage innovation wherever possible. In the longer term – which means in the context of the next revision of the pharmaceutical legislation after 2020 – the exclusivity should be extended to at least three years, as is the case in the United States and Japan.

CHOICE OF PROCEDURES

There are two procedures (European and national) which provide a route to market. It is vital that applicants continue to have the ability to choose which procedure they wish to use.

- Centralised procedure: since it became open to non-prescription medicinal products more than 10 years ago, four ingredients, orlistat, pantoprazole, esomeprazole and ulipristal, have been switched using the centralised procedure. This relatively low number does not encourage companies to apply through this route. AESGP has proposed the idea of a progressive centralised switch that starts with early dialogue between members of the EMA Committee for Medicinal Products for Human Use (CHMP) and other key stakeholders. **The EMA and the CHMP, together with the self-care industry, need find solutions to unleash the potential of the centralised procedure for non-prescription medicines.** A joint task force of the CHMP/EMA and AESGP should be created with that purpose.

- Decentralised procedure: this is the procedure more and more often used by the self-care sector. The most problematic issue for a non-prescription medicine manufacturer is the mixed legal status in a procedure which forces companies to withdraw application dossiers in the market in favour of prescription status. In order to prevent that issue, companies run parallel procedures. This is both costly and resource-intensive for both authorities and industry. Another concern relating to national implementation is the lack of respect for timelines.

AESGP offers the following potential solutions to address these issues:

- Where the Reference Member State (RMS) has non-prescription status, this should be the starting point for the assessment by the Concerned Member States (CMS); in line with the Community Code, prescription status should only be proposed where the criteria are clearly not met (and would hence be anticipated to be by exception only).
- Authorities should hold early discussions with companies on potential future applications to understand the availability of agencies to act as RMS. Follow-up discussions on the regulatory strategy approaches before the procedure is initiated should also be possible.
- Every regulatory authority should respect the timelines outlined in the legislation
- All parties involved should explore opportunities under Art 10(3) of Directive 2001/83/EC to consider applications for switching products authorised via the centralised procedure.
- All parties involved should continue to build on the practical approaches currently in place via parallel procedures to enable markets that would be expected to have similar views concerning e.g. legal status, to be grouped. This would enable real progress and avoid circular discussions when Member States cannot align.

successful centralised procedures for non-prescription medicines in 10 years

New pharmacovigilance legislation promised net cost savings for medicine manufacturers of

150,000,000 Euro per year

Regulatory authorities should consider further reflections on best practice and identify areas of improvement to avoid unnecessary duplication within this approach (for example in the review of module 3).
- All parties involved should explore the possibility of splitting a procedure during its evaluation while keeping the same RMS.
- Regulatory authorities should consider how changes of legal status can be accommodated for products within (established) procedures without reverting to national, independent applications, for example by using the blue box concept.

The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) plays a key role in the improvement of the Mutual Recognition and Decentralised Procedures (MRP and DCP). All parties involved including members of the CMDh:
- should maximise the value of the CMDh to reflect and comment on areas where progress is limited or the aims of harmonisation vs. access to products on the market may not align
- should continue the clear and consistent communications and opportunities for dialogue with stakeholders on a regular basis
- should ensure guidance and Questions and Answers (Q&A) documents are pragmatic and kept up-to-date
- should continue working towards the abolition of national measures that go beyond Community requirements

• National procedure:
- There shoud be no deprioritisation of national procedures;
- Companies must be able to retain the ability to use the national procedure for bibliographic applications whose Summary of Product Characteristics (SmPC) has not been harmonised in application of the Commission Communication on the Community marketing authorisation procedures for medicinal products of 1998[10].

DECENTRALISED / MUTUAL RECOGNITION PROCEDURES NEED TO BETTER UNDERSTAND PARTICULARITIES OF NON-PRESCRIPTION MEDICINES

VARIATIONS

In line with existing EU legislation, variations allow minor changes to marketing authorisations already granted and are usually given as an illustration of 'better regulation' applied in practice. Although some improvements have been made to the system, for example, with the type IA 'do and tell' variations, the situation is still far from perfect. The following improvements should be put in place:
- All regulatory authorities should respect timelines and prioritise safety variations that will have a potentially high impact on public health
- As of 1 February 2016, for both centrally and nationally authorised medicines, companies will no longer be required to submit type IA variations in relation to the Qualified Person Responsible for Pharmacovigilance and Pharmacovigilance System Master File. The European Commission in cooperation with all stakeholders involved should **explore other variations that could be waived and replaced by an accurate and timely update of the Article 57 database.**
- There are increasing requirements concerning Good Manufacturing Practice (GMP) details to be added to the regulatory dossier; this generates a huge number of variations to be filed. GMP details should be maintained at manufacturing site level for scrutiny by GMP inspectors in order to reduce the number of variations.

PHARMACOVIGILANCE

Smart implementation of the revised pharmacovigilance legislation in line with the original legislative intention continues to be AESGP's key priority in that area. "*Ensure proactive and proportionate collection of high quality data on the safety of medicines*" was also a clear benchmark in the Impact Assessment. Risk management planning, adverse drug reaction case reports and Periodic Safety Update Reports (PSURs) in particular were considered for being made more risk-proportionate. In turn, important savings were foreseen for the pharmaceutical industry (in the range of €150 million)[11].

10 http://ec.europa.eu/health/files/eudralex/vol-1/com_1998/com_1998_en.pdf
11 Pharmacovigilance legislation – Impact Assessment SEC(2008) 2670 of 10 December 2008 http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/pharmacovigilance-ia-vol1_en.pdf

Up to now, the implementation of the new pharmacovigilance legislation has been resource-intensive and costly. The next step in the implementation should focus on the term 'simplification', which is particularly necessary in the following areas:

• Regulatory action to safeguard public health

Non-prescription medicines are in most cases well-established medicines with recognised efficacy and an acceptable level of safety which have been on the market for 10 years or more. Their safety profile is well-known due to their long-term experience and widespread use, which should make them of less interest to the Pharmacovigilance Risk Assessment Committee (PRAC).
Since the PRAC became operational in July 2012, a number of referrals on well-known substances were made. **AESGP believes that, due to its limited resources, the PRAC should focus on new/innovative substances and that there are better ways to deal with safety issues of well-known substances (e.g. increase of Periodic Safety Update Report (PSUR) frequency).**

• Improving EudraVigilance

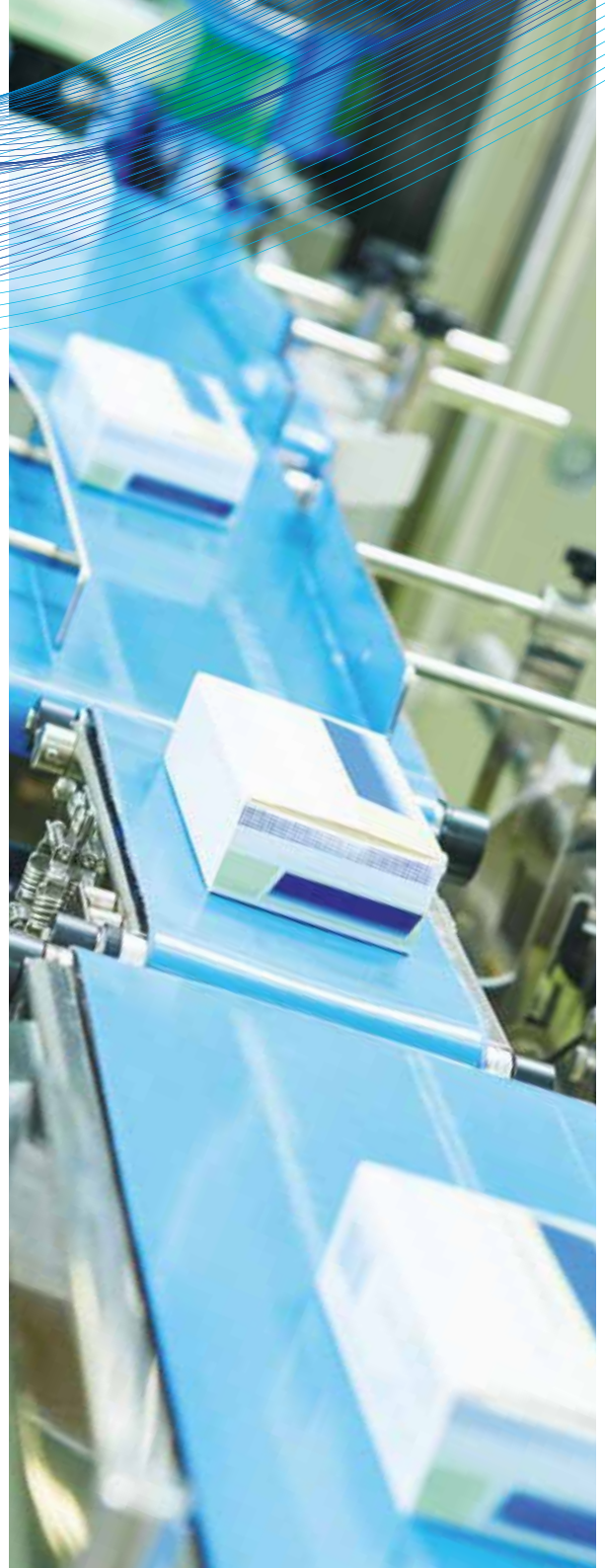
By centralising the notification of adverse reactions to one unique location in Europe, the EudraVigilance database responded to AESGP's request for simplification and elimination of unnecessary redundancies. **AESGP looks forward to EudraVigilance being deemed fully operational.**

• Risk Management Plans (RMPs)

AESGP has initiated and led the work around simplification of the RMP template. It is essential that the implementation follows suit. In addition the same spirit should be applied to the PSUR/Periodic Benefit-Risk Evaluation Report (PBRER) format for well-established substances when the provision of such document is required. AESGP welcomes the initiative of the Coordination Group for Mutual recognition and decentralized procedures (CMDh) to publish safety concerns of nationally approved Risk Management Plans (RMPs). We hope that this will highlight situations where different safety concerns have been approved for different products. AESGP also welcomes the recent establishment of a forum between the CMDh and industry on initiatives related to RMP.

• Medical Literature Monitoring (MLM)

The MLM should benefit most of the non-prescription medicines industry and the **liability of the MAH should be clarified** so that industry does not have to run two systems in parallel.



INGREDIENT CHALLENGES

The above-mentioned activities are linked to the ongoing debates on the acceptance of well-established substances in the area of non-prescription medicines, in particular in the field of cough and cold medicines. AESGP is leading related data collection as part of a project within the World Self-Medication Industry (WSMI), which will contain the most comprehensive data collection in this area and contact points to provide further guidance, if needed.

Medical doctors and pharmacists play
a key role
in advising people on how to practice self-care

ELECTRONIC PRODUCT INFORMATION MAY COMPLEMENT THE LABEL AND LEAFLET INFORMATION.

ENVIRONMENT

AESGP acknowledges the concerns of stakeholders as to the emergence of pharmaceuticals in the environment and more specifically in water. It advocates the development of proportionate and evidence-based measures to protect the environment and supports the generation of greater knowledge and science on the topic.

In compliance with a recital of Directive 2010/84/EC on pharmacovigilance, the European Commission is expected to come up with a strategic approach on the pollution of waters and soils with pharmaceutical residues. **AESGP calls on the Commission to take its "Eco-Pharmaco-Stewardship", that was developed together with other trade associations in the pharmaceutical sector, into account as it develops its strategy.**

The "Eco-Pharmaco-Stewardship" consists of three important pillars:

- Reinforced research on the impact of pharmaceuticals on the environment
- Adequate management of productions sites
- Testing of an extended environmental risk assessment

In addition, proper disposal of unused or expired medicines should be promoted via the #medsdisposal campaign, and through information found in the medicine's product information. It should be recognised that appropriate disposal alone will not solve all environmental concerns, and should therefore be considered in combination with other measures and other stakeholders to be successful. National and local authorities should encourage the use of state-of-the-art waste water treatment, and processes, and systems to ensure incineration of waste containing active pharmaceutical ingredients.

SUPPORTING PROPER INFORMATION, SELECTION AND USE OF NON-PRESCRIPTION MEDICINES

Product information leaflet

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) on the basis of two study reports drafted by the Netherlands Institute for health services research (Nivel)[12].

AESGP recommends the development of electronic product information and its use alongside printed package information to inform and help people make a more informed decision by accessing detailed product information ahead of the purchase of a medicine.

Increased visibility

Distribution rules for non-prescription medicines in Europe are regulated at national level. Therefore differences can be observed in the possible points of sale for non-prescription products across Europe; some Member States only allow sales of non-prescription medicines in pharmacies while others permit other types of vendors (e.g. druggists, general sales stores). Some of them are also allowed to offer products for purchase at a distance (e.g. online) in certain Member States. The distribution methods adopted by Member States reflect the national traditions in relation

12 Feasibility and value of a possible "key information section" in patient information leaflets and summary of product characteristics of medicinal products for human use – The PILS-BOX study http://ec.europa.eu/health/files/committee/75meeting/pilbx.pdf
Study on the Package Leaflets and the Summary of Product Characteristics of Medicinal Products for Human Use – PIL-S study
http://ec.europa.eu/health/files/committee/75meeting/pil_s.pdf

to the provision of care, and are primarily defined by the needs and expectations of the population. As the organisation of their healthcare system remains a responsibility of the Member States, the regulation of distribution rules for non-prescription medicines at national level ensures that the sale of these products evolves in line with the overall healthcare environment. However, in all countries, it is important that customers can see non-prescription medicines e.g. in a pharmacy. **AESGP therefore advocates good visibility of non-prescription medicines in a retail environment**.

The role of pharmacists

The pharmacy is often the first place a person visits when faced with an ailment. Pharmacists are highly skilled and trained professionals with a vast knowledge about products and different conditions. It is important that they guide and advise individuals, helping them find the right product for their condition(s) and explaining how best to use it. To master this role, training on communication skills is important as part of the pharmacist's curriculum. Information and training on new "switches" is also key to support the advisory role of the pharmacist. The 'Charter of Collaboration'[13] signed by the European association of community pharmacists (PGEU) and AESGP underlines the role of pharmacists and their contribution to support self-care.

The role of medical doctors

Medical doctors continue to be highly influential when people make their choices in relation to health and disease issues. Therefore, the support of medical doctors in the context of self-care is important. More and more medicines should become available without prescription and some of them are used after an initial medical doctor's prescription or recommendation. Basic principles on the right use of self-care products are laid down in the brochure AESGP developed together with the European umbrella organisations of the medical profession[14].

THE IMPORTANCE OF PUBLIC ADVERTISING

Advertising represents an effective way of informing individuals about any non-prescription medicine including newly switched ones. In the short time or limited space of an advertisement, a consumer may receive information about a health condition, a product's availability and usefulness. This allows interested individuals to seek further information about a product or condition and to be better prepared should they become ill. EU legislation allows advertising and limits the conditions under which Member States may impose restrictions concerning the advertising of non-prescription medicines (Directive 2001/83/EC, Article 88). Different countries have also moved from primarily government-led systems to control the advertising of non-prescription medicines to a self-regulatory control environment. Self-regulatory bodies may review advertising before or after it is published or released. The adoption of a self-regulatory approach has proven to improve the quality of the control while at the same time reducing a costly administrative burden for governments. **The European legislation concerning the advertising of non-prescription medicines must be respected and, unless the product is reimbursed, advertising has to be allowed in all media.**

ADVERTISING
communicates the availability of a self-care solution

13 www.aesgp.eu/media/cms_page_media/68/PGEU-AESGP%2018-12_1.pdf
14 http://www.aesgp.eu/self-care/about-self-care/

FREE PRICING GUARANTEES A COMPETITIVE ENVIRONMENT AND IS THE BEST FOR THE PUBLIC.

THE USE OF BRANDS

Brands are a principal asset for the development and promotion of self-care. Brands in general and umbrella brands in particular can be critical to guiding consumers in selecting the appropriate self-care treatment. Brands can communicate the benefit, quality and promised experience a consumer can expect from the product. A consumer's ability to use a product safely and effectively can be enhanced by associating it with the brand name and image. Through repeated and appropriate use, brands can build consumers' trust and confidence in using self-care products.

As a way to encourage and reward investment, the legislation provides manufacturers with the option of applying for trademarks to protect their brands. These may last indefinitely, thus enabling and facilitating consumers to identify goods placed on the market for a long period of time. The value of brands means that manufacturers will strive to produce a consistently high quality product to protect the brand's reputation. When making choices, consumers set criteria that help them compare available products.

Moreover, consumers who know precisely what they are buying and where a product comes from are able to properly identify it when talking to their physician, pharmacist or family and friends.

Trademark legislation protects manufacturers and consumers against counterfeit products which confuse buyers into thinking that they emanate from the holder of the trademark when they do not. At the same time the law does not prevent others from selling identical goods unbranded or under their own brand, thereby stimulating competition and expanding consumer choice. By extending an established brand to other self-care products in the same or similar therapeutic area, manufacturers make people aware of the heritage of these products within an established range. To maintain consumer understanding in a market and as they travel from market to market, the original umbrella brand name should, where possible, be preserved. To the extent it is possible and appropriate, the use of prefixes and suffixes can be used to ensure sufficient differentiation and may indicate the target group or target indication for which products are meant without causing confusion and they should generally be permitted. In addition pack design helps people differentiate products with the same tradename.

BRANDING

helps communicate the value of a self-care product

FREE PRICING FOR NON-PRESCRIPTION MEDICINES

Pricing policy for non-prescription medicines is a determining factor for the functioning of a competitive market where manufacturers are incentivised to innovate and offer citizens the best value. A competitive market for self-care products is conditioned by the principle of free pricing for non-prescription medicines purchased by citizens. The European Commission also states:

"Price control is not necessary for non-reimbursed medicines. For these products, price competition can steer the price evolution sufficiently well. Therefore, Member States should abstain from price-control." EU Pharmaceutical Forum, 2007[15].

This principle must be adhered to in all Member States.

15 EU Pharmaceutical Forum, Second Progress Report, 26 June 2007 http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/pharma_forum_progres_report062007_en.pdf

HERBAL AND HOMEOPATHIC MEDICINES

More than 100 million EU citizens use herbal and homeopathic medicinal products. Given the fact that these medicinal products are widely used among EU citizens and provide alternative therapeutic choice, their availability should be improved.

More than
100 Million
EU citizens use herbal and homeopathic medicines

A study commissioned by the European Commission[16] states that there is a problem with the availability of herbal medicinal products and homeopathic products. The study highlights the divergence in national procedures and approaches for these products as one of the drivers of this problem. One issue is the incomplete and ineffective implementation of simplified registration procedures for herbal medicinal products and homeopathic medicines in the Member States.

AESGP underlines the necessity of further developing the rules for herbal and homeopathic medicines so that this significant market in Europe remains competitive:

- **Stimulate research and innovation in the herbal and homeopathic sector by creating adequate rewards**
- EU Monographs accepted and respected for both medicines of traditional and well-established use.
- **No further restrictions when submission is in line with monograph**
- Acceptance of additional data, e.g. on indication, safety (genotoxicity, reprotoxicity), which may then lead to a modified, extended labelling
- Respect for the long-term use of some plants in children and reflect the principle in the corresponding monographs
- Allow plants commonly used in food for use in children, pregnant and lactating women
- Align national standard texts for medicinal plants with EU monographs
- **No further requirements concerning efficacy data for traditionally used herbal medicinal products**
- Leave flexibility for the choice of procedure (MRP-DCP vs national) taking into account the still diverging cultural and historical environment for herbals and homeopathic medicines as well as the different assessment approaches across Member States
- Respect traditional use (30 years) and therefore allow classification as non-prescription medicine with the ability to advertise to the general public
- Ensure availability of homeopathic medicinal products and therefore encourage Member States to implement Art. 16 (2) of the Directive 2001/83 EC in order to be able to authorize homeopathic medicinal products other than those referred in Art. 14 of the Directive

16 http://ec.europa.eu/health/files/committee/73meeting/73plus/study_report.pdf

MEDICAL DEVICES

IN 2015, THE EUROPEAN COMMISSION SELECTED AESGP TO BE ONE OF THE INDUSTRY REPRESENTATIVES ON THE EUDAMED STEERING COMMITTEE, WHICH WILL ACCOMPANY THE DEVELOPMENT OF A NEW EUROPEAN DATABASE FOR MEDICAL DEVICES

The wide availability of safe and effective self-care products enables people throughout the European Union to practice responsible self-care. These products do not only include non-prescription medicines, but also food supplements and medical devices used in a self-care context.

Self-care medical devices include a wide variety of products ranging from nasal sprays, primarily used for cold sufferers, to dentifrices for sensitive teeth, dental cleansers and adhesives, and products used for the reduction of bloating, as well as creams to treat or prevent minor skin irritations or acting by a chemico-physical mode of action. These are classified as medical devices in light of their mode of action which is not pharmacological, immunological or metabolic but relies on chemico-physical processes such as local pH changes, sequestering actions of molecules, or the formation of a physical barrier.

Faced with some scepticism from regulators, AESGP contributed to the recognition of the self-care medical device category. Nonetheless, there are still numerous challenges ahead.

A NEW LEGISLATIVE FRAMEWORK FOR SELF-CARE MEDICAL DEVICES

As part of a comprehensive review of the EU legislation for medical devices, the European Commission in 2012 proposed a new classification rule that would classify devices composed of substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally in the highest risk category, class III. In addition, it was suggested that these devices should comply with the relevant requirements of Annex I to Directive 2001/83/EC relating to medicinal products.

AESGP opposes these proposals and suggests an approach which recognises different risk levels of substance-based medical devices. This corresponds to "better regulation" principles and would avoid unnecessary new regulatory requirements.

DEFINING PHARMACOLOGICAL, IMMUNOLOGICAL AND METABOLIC MEANS

When delineating the borderline between medicines and medical devices, the definitions of pharmacological, immunological and metabolic mode of action are important. These are currently under revision within the European Commission guidance document on "Borderline products, drug-delivery products and medical devices incorporating as an integral part, an ancillary medicinal substance or an ancillary human blood derivative"1[7].

AESGP will continue to ensure that the views of manufacturers are fed into to the process by which these definitions will be finalised.

BORDERLINE CASES

In recent years, a consultation procedure – the Helsinki Procedure – was created to allow exchange of information and opinions between competent authorities over the classification of a product as a medical device or not. Outcomes of the non-binding procedure are published on the European Commission website.

AESGP is striving for a higher degree of integration of manufacturers' input in the discussions and a greater transparency of the procedure.

AESGP will continue to ensure that the specificities of the self-care medical devices sector are adequately taken into account at European Commission stakeholder meetings, notably those on borderline and classification, vigilance, clinical investigation and evaluation, new and emerging technologies, the Unique Device Identification (UDI) and on software/mHealth.

In 2015, the European Commission selected AESGP to be one of the industry representatives on the Eudamed Steering Committee, which will accompany the development of a new European database for medical devices (so-called 'Eudamed'). The particularities of substance-based medical devices should be fully taken into consideration in the development of the database. It is also important that lessons learnt from other sectors (e.g. the Article 57 database for human medicinal products) are taken into account.

Thousands
of self-care products are classified as medical device

17 http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

FOOD SUPPLEMENTS

ALL FOOD POLICYMAKING MAKING MUST BE EVIDENCE-BASED WITH COOPERATION/ DIALOGUE BETWEEN THE EU AUTHORITIES, THE MEMBER STATES AND INDUSTRY PARTNERS.

AN INTERACTIVE SCIENCE-BASED APPROACH DELIVERS BEST RESULTS TO THE PUBLIC

The EU food supplements market is shaped by the development and implementation of the various pieces of EU food law, including the Food Supplements Directive 2002/46/EC, Claims Regulation 1924/2006, Food Information Regulation 1169/2011, Food Additives Regulation 1333/2008, Novel foods as well as other relevant legislation.

AESGP has identified the following actions to promote the adoption and implementation of a balanced and proportionate legal and regulatory framework that facilitates innovation and rapid market access for food supplements in a consistent way across Europe:

Science
is a crucial element of food policy

A SCIENCE-BASED POLICY SYSTEM

One of the crucial activities of AESGP is fostering a fruitful collaboration with the European Commission, the European Food Safety Authority (EFSA), the European Parliament and Member States. AESGP represents the European food supplements manufacturers and their interests at the official EU forums such as the European Commission Advisory Group on the Food Chain and Animal and Plant Health and the EFSA Stakeholder Consultative Platform. Over the years, AESGP has built a solid reputation as a reliable, consistent and knowledgeable industry partner for the EU Institutions.

It is critical that in the future the evidence, science and policy-making on food supplements in the EU remain integrated. AESGP stands for a policy-making system that is evidence-based with cooperation/dialogue between the EU authorities, the Member States and industry partners.

AESGP IS FOSTERING A FRUITFUL COLLABORATION WITH THE EUROPEAN COMMISSION, THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA), THE EUROPEAN PARLIAMENT AND MEMBER STATES

PRAGMATIC IMPLEMENTATION OF THE FOOD ADDITIVES REGULATION

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 is resource intensive and time consuming for companies and requires efficient coordination at the EU level.

AESGP acts as the EU coordinator for data submission on the additives usage levels in food supplements for EFSA. AESGP will continue to provide all necessary support to its member associations and companies in data submission to EFSA in order to ensure that evidence-based policy-making on food additives in the EU continues to be robust.

Furthermore, the European Commission is working on a reorganisation of the food supplements categories in which food additives are allowed, with the aim of providing more clarity on each category such as chewable forms, syrup forms and dissolvable forms.

The Commission also intends to create a separate category of food supplements for infants and young children. This work has led to questions over the levels of additives used in food supplements and highlighted some mistrust from the authorities towards additives, regardless of the scientific basis for such concerns.

AESGP will ensure that the ongoing re-evaluation programme and reorganisation of the food supplements categories lead to workable and sustainable conditions of use for food additives that reflect balanced judgement and robust science.

Labelling plays a substantial role in informed

consumer choice

A WORKABLE AND UNIFORM IMPLEMENTATION OF THE FOOD LABELLING AND HEALTH CLAIMS RULES

The lack of harmonised interpretation of certain aspects of the Nutrition and Health Claims Regulation (NHCR) 1924/2006 (flexibility of wording, beauty claims, communication to healthcare professionals vs consumers, the use of pending claims) makes it difficult for food supplements manufacturers to correctly apply the Regulation. The lack of harmonised interpretation is also an issue for certain labelling aspects of the Food Information to Consumers (FIC) Regulation 1169/2011.

Regular reporting on the implementation issues of these regulations at national level is essential to guarantee a uniform interpretation at EU level.
For the sake of legal-certainty and the functioning of the EU internal market, AESGP calls on the European Commission to ensure EU acts are implemented in a uniform way throughout the EU.

GREATER SCIENTIFIC DIALOGUE AND TRANSPARENCY BETWEEN EFSA AND APPLICANTS

The lack of formal scientific dialogue with EFSA prior to submission of a health claim application creates difficulties for the industry in understanding EFSA scientific requirements.

AESGP believes that improved scientific dialogue between EFSA and the industry would significantly improve the quality of applications and would also increase the efficiency of the application assessment process at EFSA in terms of time and resources saved on the assessment of unsuccessful applications.

AESGP will therefore continue to advocate in favour of the set up by EFSA and the European Commission of effective services for the applicants.

REFIT/FITNESS-CHECK OF THE FOOD LEGISLATION

AESGP will actively monitor and contribute to the ongoing REFIT/Fitness-Check of the food legislation and will support any feasible initiatives which would improve the business environment in the EU by removing unnecessary burdens and simplifying food law rules.

As a second step of this REFIT, in its Better Regulation Communication of 19 May 2015[18], the Commission announced the planned REFIT of the Health Claims Regulation 1924/2006. This evaluation, due to be completed by the end of 2017, is expected to focus on nutrient profiles and health claims on plants and their preparations added to foods. It will also consider the more general regulatory framework for the use of such substances in foods since it is closely related to the use of health claims. As the voice of the evidence-based industry, AESGP will contribute to the consultation and will continue to actively support and defend a scientific and evidence-based regulatory framework ensuring a stable business environment for companies. The REFIT/Fitness-check of the food legislation should lead to initiatives that reflect balanced judgement and robust science.

IMPLEMENTATION OF THE TOLERANCES FOR NUTRIENT VALUES DECLARED ON THE LABEL

The European Commission guidance document on tolerances for nutrient values declared on the label raises questions in the food industry sector as to whether it is possible to comply with the proposed values. The Guidance document became applicable as of December 2014.

AESGP supports the Commission in collecting meaningful feedback on the implementation of the tolerances for nutrient values declared on the label. AESGP continues to monitor the implementation of the Guidance document by national competent authorities and to report any possible issues with tolerances faced by companies during the official controls by authorities.

A SCIENTIFIC AND EVIDENCE-BASED REGULATORY FRAMEWORK ENSURES **A STABLE BUSINESS ENVIRONMENT FOR COMPANIES.**

18 COM(2015) 215 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Better regulation for better results - An EU agenda. http://ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf

AESGP

Association of the European
Self-Medication Industry
Association Européenne des Spécialités
Pharmaceutiques Grand Public
Europäischer Verband
der Arzneimittel-Hersteller

7 avenue de Tervuren
1040 Brussels
Belgium
Tel: + 32 2 735 51 30
Email: info@aesgp.eu

aesgp.eu

AESGP *is the umbrella organisation of the European self-care product manufacturers. It has 24 national associations in membership and represents both small and medium size as well as multinational companies.*

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