



Pictured at the AESGP Conference in Antwerp, Belgium, 26-27 October 2010 (from l):

Marc Gryseels, Director, Belgium Association of the Consumer Health Industry (BACHI);
Xavier DE CUYPER, Chief Executive Officer, Belgian Federal Agency for Medicines and Health Products;
Hubertus CRANZ, AESGP Director General;
Els GEERAAERTS, Directorate General for Medicinal Products, Ministry of Health, Belgium;
and **Marc VERLINDEN**, President, Belgium Association of the Consumer Health Industry (BACHI)

Conference Report

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The AESGP Conference **‘HOW CAN NON-PRESCRIPTION MEDICINES BEST CONTRIBUTE TO PUBLIC HEALTH?’** in Antwerp, Belgium, 26-27 October 2010, which was organised in cooperation with the *Belgian Federal agency for Medicines and Health Products* during the Belgian EU Presidency, was with more than 150 participants very well attended.

AESGP President **HANS REGENAUER** thanked the Belgian Federal Agency for Medicines and Health Products, and in particular its Chief Executive Officer Xavier De Cuyper, for the cooperation in the preparation of the event. He recalled that this was the fourth time AESGP had organised a conference in cooperation with the Heads of Medicines Agencies after London (November 2005), Dresden (February 2007) and Paris (November 2008). “Unfortunately,” said Regenauer, “the situation in our sector is still not ideal. Many issues are seen as problematic and with some improvements in the regulatory system – we like to call it ‘Smart Regulation’ – we believe that the contributions of non-prescription medicines to public health can be better explored. The Conference here in Antwerp will certainly provide the opportunity to do so,” said Regenauer.



A EUROPEAN PERSPECTIVE FOR SELF-MEDICATION

Opening the first session, chairperson **CRISTIAN SILVIU BUȘOI**, Member of the European Parliament, stressed the importance of policies to improve the quality of care while increasing efficiency. This should be even greater in an era of demographic change and financial austerity. According to Bușoi self-medication can provide a good solution for the growing healthcare needs as it presents advantages for patients by saving time and money in the treatment of minor ailments. Moreover, limited reimbursement of non-prescription medicines leads to savings for the healthcare system.



Initiatives by the European Commission

ANDRZEJ RYŚ, Director of Public Health and Risk Assessment in the European Commission’s Directorate-General ‘Health and Consumers’, praised the European pharmaceutical industry as a pillar of society and one of the engines of the economy making a major contribution to the health and well-being of citizens. Citing the fundamental approach of John DALLI, Member of the European Commission responsible for Health and Consumer Policy, to put patients and consumers first, Ryś identified delivering benefits to patients as the most essential elements of any future EU pharmaceutical policy. “The self-care industry plays a very important role in this respect. It contributes to empowering patients in taking care of their own health wherever possible, and offers important economic and social benefits. The impact of the sector on society as a whole must not be underestimated,” added Ryś.



Ryś presented the Commission’s initiative on the ‘Innovation Union’ as an example of the Commission’s vision to put innovation at Europe’s heart. New flagship *Innovation Partnerships* will be set up as part of this initiative to mobilise stakeholders ranging from the public and private sector to all layers of government. The first Partnerships will focus on active and healthy ageing, said Ryś;



this will improve the quality of life of Europeans, ease the strain on the workforce and have a positive impact on the competitiveness of the healthcare industry in Europe.

The importance of a robust regulatory framework to ensure the quality, efficacy and safety of medicines which would at the same time allow for a stronger European pharmaceutical industry was also stressed. Ryś informed the audience that discussions on the proposal on falsified medicines were progressing well. The issue of availability of and access to medicines was said to be in an early phase of reflection, while a step had recently been taken in the context of a new project on pricing and reimbursement. The project, launched by the Commission's DG Enterprise and Industry within the ***Process on Corporate Responsibility in the field of Pharmaceuticals***, will try to identify the necessary elements for an informed and adequate uptake of medicines after their switch from prescription to non-prescription medicines. Ryś also referred to the legislative proposal on pharmacovigilance and mentioned that issues and concerns raised by AESGP had been taken into account in the final text.

The DG SANCO Director confirmed that the Commission would continue to play its role in preparing properly for future challenges. He concluded by saying that only by working together with the self-medication industry could the common goals of public health protection and patient confidence in safe and high-quality medicines be achieved.

Initiatives under the Belgian Presidency

XAVIER DE CUYPER, the Chief Executive Officer of the Belgian Federal Agency for Medicines and Health Products, discussed some of the Belgian Council Presidency initiatives, in particular with respect to the need to ensure that European citizens have the right information on non-prescription medicines.



Referring to the legislative proposal for a ***Directive for the prevention of entry of falsified products into the legal supply chain of medicinal products***, De Cuyper mentioned that the Belgian Presidency had prioritised the issue as some cases of falsified products in the legal circuit were recorded over the past years. A dialogue is currently ongoing among the European Parliament, the Commission and the Council dealing, amongst other issues, with the scope of the safety features on which different opinions had been expressed so far concerning the elements to be taken in account and the associated risks and costs as well as the type of features and the possibility of a unique number and traceability characteristics.

Another important issue covered by the same legislative proposal is ***the sale of medicines at a distance*** (e.g. via the Internet) and the complications surrounding the sale of medicinal products in a different Member State than the country of origin. De Cuyper referred in this context to ***Pangea***¹, an international operation coordinated by INTERPOL to combat the online supply of counterfeit and illegal medicines. Forty-five countries had taken part in the October 2010 action, which resulted in 694 illegal Internet sites being identified of which 290 had so far been closed. Over one million illegal and counterfeit pills were seized, including antibiotics, steroids, anti-cancer drugs, antidepressants, anticonvulsants and slimming products and dietary supplements. The value of the seized counterfeit and illegal product was estimated at USD 2.6 million.

As part of its EU Presidency, Belgium had organised a ***Ministerial Conference on 'Innovation and Solidarity in Pharmaceuticals'*** in September 2010 to reflect on a European policy approach to stimulating, measuring and valorising innovation. Europe is faced with the challenge of improving

¹ <http://www.interpol.int/public/ICPO/PressReleases/PR2010/PR083.asp>

access to innovative medicines and guaranteeing equity and solidarity in meeting patient needs while keeping costs under control, said De Cuyper. The conference had made a valuable contribution in this respect.

Valorising self-care

ARTHUR TEN HAVE of Ecorys¹ presented a piece of research carried out for the Dutch association of the pharmaceutical industry for self-medication and health products Nprofarm entitled '*Healthcare savings by OTC drugs, the Dutch case*'. The study, which is still in progress, aims at establishing figures to measure the impact of self-medication in the Netherlands. It is performed in an environment of budgetary pressures, a health system with overloaded GPs and pharmacies facing commercial pressures.



In the Netherlands, pharmacies and druggist stores have co-existed for a long time as distributors of non-prescription medicines. The Medicines Law of 2007 introduced a third OTC delivery mode, general sale. This means that three distribution categories exist for non-prescription medicines: one exclusively in pharmacies, one in pharmacies and druggist stores, and one through general sale (supermarket gas stations, etc.). Additionally, the latest reforms of the healthcare system have resulted non-prescription medicines being no longer reimbursed with the exception of certain medicines for the chronically ill.

Ten Have presented the methodology of the study's qualitative analysis, which included expert meetings with GPs, pharmacists and druggists as well as interviews with health insurers. The preliminary results demonstrated that GPs reported an unnecessary workload in connection with minor ailments while at the same time showing a reluctance to accept substitution of this workload towards pharmacists or druggists. GPs also acknowledged the importance of correct information on medicines being available. However, as patients seem to become more insecure with the information overload, the question arises of who should provide this information. Furthermore, differences observed in the quality of professional advice and patients' health literacy called for more attention on the issue of information noted Ten Have.

Health insurers participating in the study saw a potential for cost savings through self-medication but also perceived GP care as a cheap and cost-effective aspect of their commercial relationship with the insured.

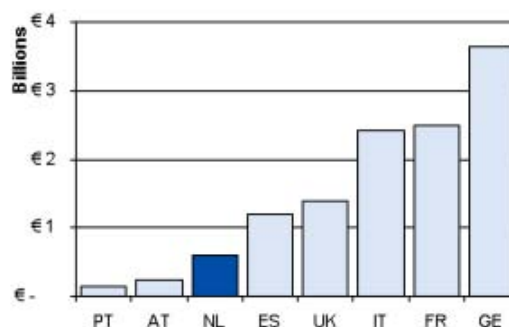
Participants in the study were also asked about the possibility of long-term reforms. In this context they identified 'assisted self-medication' - with a closer collaboration between pharmacists and druggists, incentives for health insurers and better inspections by the Healthcare Inspectorate.

Arthur ten Have also presented the preliminary quantitative results of the study, for which ECORYS followed the methodologies of two previous studies. The first was used by AESGP in 2004. It relied on the conservative assumption of a 5% switch of prescribed medication to self-medication. It made an estimation of the benefits resulting from reduced GP consultations, absenteeism and prescribed medication costs and co-payments (see graph on next page). The 2010 Dutch study found an annual outlay of approximately EUR 680 million for minor ailments on a total of EUR 5 billion allocated to GP care, and a per capita amount of EUR 41 for GP care. These findings

¹ Ecorys is a leading European research and consultancy company with approximately 560 staff and 16 permanent offices in 11 countries. Ecorys' work includes a study on the Competitiveness of the EU market and industry for pharmaceuticals (DG Enterprise and Industry), as well as Health Technology Assessment (HTA) methodology studies.



could be used to estimate public savings, said ten Have. The second methodology was used in a study conducted in 2008 for PAGB in the United Kingdom, where the IMS ‘disease analyser’ was used to select minor ailments related to GP contacts. This allowed a direct link between diagnosis and prescribed medication. The study results indicated potential savings of UK£ 2 billion per annum when minor ailments are addressed with self-medication. In preparation for the implementation of this method, GPs in the Netherlands were found to consider 29% of consultations as unnecessary, while the cost estimate for GP treatment of minor ailments reached EUR 57 per capita. In both methods, noted Ten Have, there is some uncertainty with regard to the definition of a ‘minor ailment’. Moreover, an effort needed to be made to find a better and stricter way of linking diagnosis to minor ailments and costs.



The potential for reduced insurance coverage when increased self-medication is implemented is an issue that could according to Ten Have be examined in the future. In the Netherlands a political window is presented by the fact that the new government supports individual responsibility and is planning significant cuts in public expenditure (EUR 18 billion). In this environment, concluded Ten Have, putting greater emphasis on self-medication may be advisable.

STRATEGIES FOR THE FUTURE

AESGP President **HANS REGENAUER**, who is Vice President of Consumer Health Care Europe and Global Development for Sanofi-Aventis, chaired the session *‘How to integrate the public health, social and economic value of non-prescription medicines in the decision-making of European Medicines Agencies’*. Introducing the speakers, Regenauer referred to AESGP’s proposals laid down in [‘Smart Regulation 2015’](#)¹ and expressed the hope that the plans to be revealed in the *HMA Strategy 2011-2015* and the *European Medicines Agency’s Roadmap to 2015* would present overlaps with the AESGP proposals.

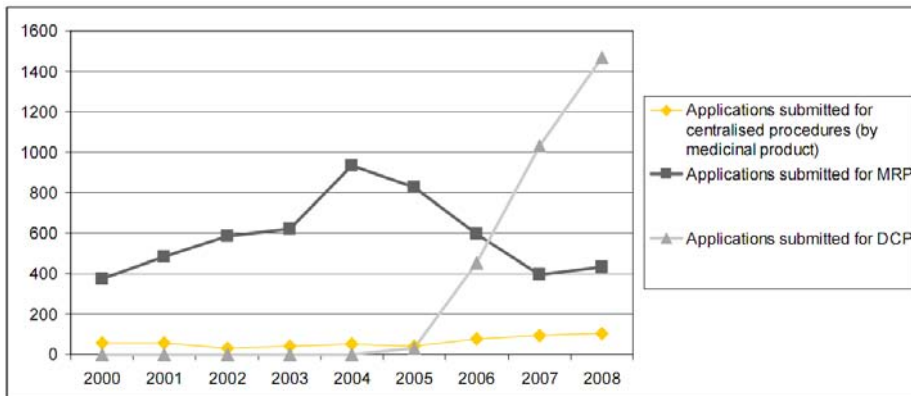
The HMA Strategy for 2011-2015

KENT WOODS, Chief Executive of the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) and Chair of the HMA Strategy II Task Force, discussed the development of the *Heads of Medicines Agencies Strategy for the years 2011-2015*. The strategy, said Woods, needed to be seen in the context of the architecture of the European medicines regulatory system which operates in three domains: the centralised authorisation activities which are the subject of the EMA Roadmap to 2015, multinational non-centralised activities which fall under the HMA Strategy, and national activities, laid out in the business plans of the national agencies. The ‘network’ as a whole delivers a diverse range of functions for which in particular the scientific resources are essentially the same.



¹ <http://www.aesgp.be/SmartRegulation/SmartRegulation2015.pdf>

The HMA Strategy II aims at identifying the key challenges for the next five years and how they can be addressed by the network. The draft Strategy was endorsed by HMA on 5 July 2010 and consultations were launched shortly afterwards.



AESGP, noted Woods, had made a thorough and thoughtful contribution to the consultation, stressing the distinctive nature of the non-prescription sector.

Key themes of the HMA Strategy II include safeguarding public and animal health, innovation, and further improvement of the operational efficiency of medicines' authorisation through the decentralised and mutual recognition procedures (DCP/MRP).

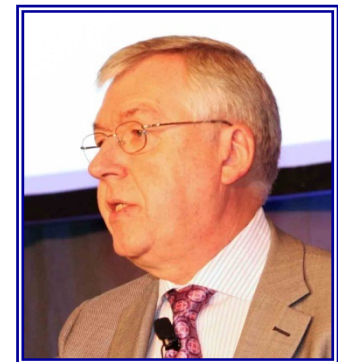
Woods referred to the dramatic increase in the number of DCPs, as indicated in the graph above (from a 2009 Ernst & Young report).

Woods concluded by laying out the future steps. Following the Strategy's adoption by the HMA on 25 October 2010, work on delivering the implementation plan was to commence in November/December 2010, in time for the Strategy to be rolled out in 2011.

The Agency's Roadmap to 2015

NOËL WATHION, Head of the Patient Health Protection Unit at the European Medicines Agency (EMA), presented the proposals for the Agency's long-term planning laid down in the '*Agency Roadmap to 2015*'¹. A priority for the Agency was the successful delivery of its core business in line with current and upcoming legislation. The EMA aims are strengthening efficiency and improving the quality of the work outcomes. Three strategic areas are covered by the Roadmap to 2015:

- Addressing public health needs: gaps in medicine development, new and emerging science, public health threats.
- Facilitating access to medicines: medicine development process - early assessment - continuing dialogue, benefit-risk assessment and communication, facilitation of the relative effectiveness assessment.
- Optimising the safe use of medicines: post-authorisation follow-up, patient safety, authoritative source of information, outcome research.



According to Wathion, various initiatives addressed in the strategic areas are also valid for non-prescription medicines, e.g. the scientific advice procedure, post-authorisation follow-up, patient safety, outcomes research and the move from a qualitative to a quantitative benefit-risk assessment methodology that would take account of patient values. Having received 70 contributions to the public consultation on the draft Roadmap, the review process had now been finalised.

¹ Final version to be published on http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000292.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac05800293a4

Wathion discussed in detail how the comments made by AESGP were addressed in the finalised strategy. In particular, the EMA revised what Wathion called ‘an oversight’, recognising the industry as a legitimate stakeholder whose involvement in some key aspects would be explicitly mentioned. Wathion also referred to other opportunities for interaction such as the EMA-AESGP platform where topics of mutual interest can be further discussed.

AESGP also requested that a specific reference be made to actions that further enhance the availability of and market access for non-prescription medicines. The EMA accepted the comment, mentioning that further actions will be listed in the ‘From Vision to Reality’ document to be published later. Responding to an AESGP comment that a ‘better regulation’ reference was absent from the draft Roadmap, he noted that initiatives had already been envisaged for the ‘Vision to reality’ document. At this point Wathion referred to recent Agency work to re-engineer the process for Type 1A variations. This should be seen as an example and other, more complex, processes may be re-engineered in the future.

A specific reference to herbal medicines and actions recently undertaken by the Agency in this area was also included following an AESGP request. Especially important was the Agency’s response to AESGP’s call to include benefits *and* risks, rather than risks alone, in the assessment of a medicine. Wathion noted that the rationale behind risk assessment had always included benefits as well as risks.

Another AESGP comment on the Roadmap concerned the results of clinical trials conducted in third countries. Wathion noted that this comment had also been accepted: a reference to a recently published guideline on this topic had been included in the strategy.

Finally, the implications on investment of “staggered” approvals or progressive licensing had been put forward by AESGP. The issue also raised questions among patients, mentioned Wathion, as they might have some safety concerns. The industry also had questions on the issue of patent protection. Provisions for ensuring early access, a continuing dialogue and interaction with HTA bodies effectively addressed this issue in the Road Map, said Wathion.

Pack design

Following the first switch through the centralised procedure in September 2009, the Quality Review of Documents group (QRD) agreed to obtain feedback and experience from Member States on OTC pack design. In parallel, AESGP gave a presentation at the EMA-AESGP Platform last Spring on its draft Guidance on pack design for non-prescription medicines. The AESGP contribution was very valuable, said Wathion. However, there was as yet no common view among the Member States on a number of issues, including the use of logos / pictograms and the inclusion of additional information, e.g. accepting the indication “new” for switched products or depicting children on packages. An attempt is being made to finalise discussions at Quality Review of Documents (QRD) level in November 2010 (or the first quarter of 2011). AESGP would be invited to a workshop in the context of the public consultation on the draft guideline, concluded Wathion.

The Coordination Group's perspective for the future

TRUUS JANSE-DE HOOG, staff member of the Medicines Evaluation Board (MEB) in the Netherlands and Chair of the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh), referred to the CMDh's work over the past 10 months and the creation of a new Working Party to discuss the future of the CMDh mandate. In this context an analysis was undertaken of the future scope of the CMDh's activities, taking into account existing tasks and the extended responsibilities foreseen in the new pharmacovigilance legislation. The Working Party also took the responsibility of presenting ideas on how the work of the CMDh could be improved and adapted to future legislation,



and made proposals which could be presented to the Heads of Medicines Agencies (HMA).

Topics of discussion within the Working Party included the future workload and competence of members, how to increase the CMDh's efficiency, how to avoid unnecessary referrals and optimise procedures, and whether the DCP would remain an attractive option in the future.

Janse-De Hoog acknowledged that MRP and DCP had so far been underutilised by the self-medication sector (see graphs).

This may be due to differences in the Member States' healthcare systems, meaning that arrangements for access to OTC products vary. The CMDh needs procedures that facilitate entry of OTC products to the market, that are proportionate, risk-based, with good patient information and clear and well understood processes, said Janse-de Hoog.

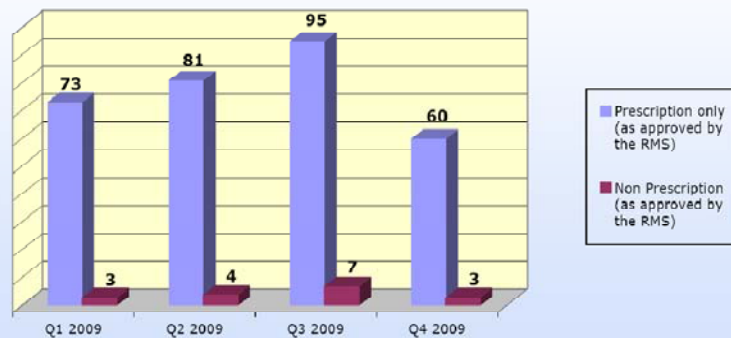
Trying to identify whether there was an inherent problem with the procedure, de Hoog cited a product index showing that for some substances the MRP/DCP procedure had been successful: Paracetamol-containing products (69 including line extensions); Xylometazoline-containing products (16 incl. line extensions); Nicotine-containing products (76 incl. line ext.). However, Janse-de Hoog noted that



MRP/DCP New applications 1st January to 31st December 2009

Started MRPs - Per Prescription Status*

Total: 326 MRPs (regarding 646 products)



MRP/DCP & Art.29 referral procedures - Statistics for 2009

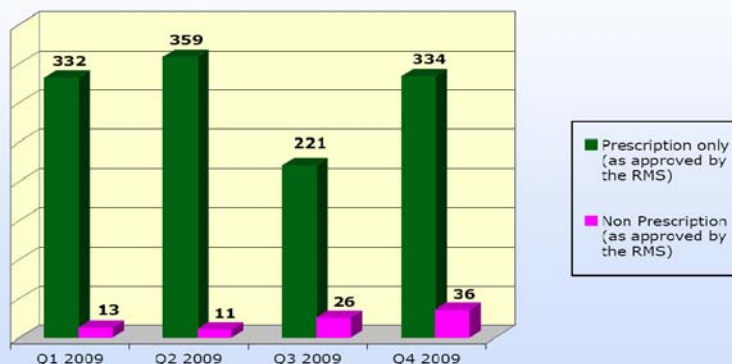
* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'.



MRP/DCP New applications 1st January to 31st December 2009

Started DCPs - Per Prescription Status*

Total: 1332 DCPs (regarding 2903 products)



MRP/DCP & Art.29 referral procedures - Statistics for 2009

* Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised'.



further discussion was required on MRP/DCP and OTC products, especially with regard to the differences in the legal classification in Member States and the extent to which these affect labelling and product information. Differences between Member States are also observed in the classification of borderline products (medicinal products / food supplements) and in switch procedures for medicines. Janse-de Hoog also mentioned additional differences concerning Member State requirements for product information with regard to contra-indications, posology and warnings. This leads to disharmony between products going through the MRP/DCP and existing products in the national market.

The MRP/DCP present strengths according to Janse-de Hoog insofar as they are flexible, allowing customisation to local practices and choice in Reference Member State and number of Concerned Member States. Repeat use of the procedures as well as worksharing in the assessment of new applications and the maintenance of dossiers are possible. Bringing national agencies close to patients and health professionals is an added value of the procedures, according to Janse-de Hoog, who supported the possibility of combining the long experience of national agencies with OTC products and that of the CMDh in dealing with the disharmony of requirements and procedures.

Janse-De Hoog mentioned the choice of legal classification within the procedures, of the Member States involved and of product name as possible solutions to maximise the procedural advantages of MRP and DCP. Noting that legal issues would need to be explored in this respect, she supported cooperation and expressed the wish to work with the industry to develop a future work programme that addresses the concerns of the self-medication sector. Other models for authorisation of recognised non-prescription active ingredients can also be considered in the longer term, always keeping an open-minded approach, added de Hoog.

Addressing the overarching question of how European Medicines Agencies can provide the adequate frame for the evaluation and authorisation of non-prescription medicines, Janse-de Hoog concluded by confirming that MRP/DCP do offer an adequate frame for all types of products. She repeated that CMDh is open to start a dialogue with the self-medication industry, and to discuss how the industry's concerns could be addressed, exploring possible scenarios for short-term and long-term solutions.

A training strategy for the European Regulatory Network

GRO RAMSTEN WESENBERG, Director General of the Norwegian Medicines Agency and Chair of the HMA/EMA Office of Training Steering Group, presented the HMA/EMA training strategy. She mentioned that in the past an educational background in pharmacy was dominant within regulatory authorities whereas nowadays there was clearly a need for all kinds of professions (pharmacists, medical doctors, veterinarians, biologists, chemists, biotechnologists, statisticians, civil engineers, lawyers, economists and communicators). There is also a need for continuous education, acknowledged Wesenberg, adding that this training should be adapted to the regulators' needs.



As drivers for change in education Wesenberg listed the HMA Strategy, the EMA Roadmap, BEMA (Benchmarking of European Medicines Agencies), the Innovative Medicines Initiative and the European Technology Platform for Global Animal Health (ETPGAH). The overall objective of the Training Strategy is improving the quality and consistency of the European Regulatory Network's activities. Moreover, the Strategy aims at fostering science-based, pragmatic and consistent assessment, inspection and laboratory control practices and decision making. It also aims at promoting harmonised interpretation of guidelines and operation of the regulatory frame-

work throughout the European Regulatory Network and providing continuous professional development for staff of regulatory agencies and possibly others involved in the regulation of medicines.

Key items in the Training Strategy are a coordinated approach, the development of core skills through specialised training and cooperation with non-profit organisations, said Wesenberg. “Blended” learning utilising different training models will be used for the core training. In-house training, distant learning, external courses and other methods are planned for a system that, according to Wesenberg, should be benchmarked or peer-reviewed. She also considered the possibility of joint training with industry which could even be desirable under two conditions: the agenda should be set by the regulators network and confidentiality should be fully respected.

A virtual central ‘EU Office of Training’ with the mandate of coordinating training within the ERN had been created and is being run in a similar manner to the HMA Permanent Secretariat. Additionally, a pilot project had been endorsed to examine the quality of chemical medicinal products. An expert group is also working on the topic of competence and knowledge for quality assessors, while gap analysis of needed and available training options will be performed at a later stage. Should the project succeed, it will be used as a model for other regulatory affairs, commented Wesenberg.



Session Chair Etienne De LAROUILLIÈRE, AESGP Vice President, Nycomed (left) in discussion with Eric ABADIE, Chair of the European Medicines Agency's Committee for Medicinal Products for Human Use

OTHER REGULATORY ISSUES

An adequate framework for non-prescription medicines in the centralised procedure

ERIC ABADIE, the Chair of the Committee for Human Medicinal Products (CHMP) at the European Medicines Agency, addressed the current framework for the evaluation and authorisation of non-prescription medicines. Referring to the eligibility of non-prescription medicines for the centralised route, Abadie enumerated the criteria laid down in Regulation (EC) No. 2004/726, including optional access “in the interests of patient health at community level” (Article 3 para 2b under-



pinned by Recital 9). The common themes in the legislation for a prescription to non-prescription switch are, according to Abadie, safety, direct or indirect danger, medical supervision, incorrect use, and further investigation activity. Companies can address these issues by giving prominence to cumulative safety data from pre-existing non-prescription usage, including experience outside the EU. They can also identify co-morbidities and incorrect use and examine the role of the doctor in the product's use. Actual use studies (medicine utilisation studies) or surveys on patient behaviour patterns (not systematically linked to the use of a specific medicine) can also be used.

To decide on *eligibility of non-prescription medicines* for the centralised procedure the CHMP uses the [Guideline on changing the classification for the supply of a medicinal product for human use](#)¹ (last updated in January 2006) and the opinion of the Agency's Organisational Matters Drafting Group (DG ORGAM). These include:

- First in class: not available in any Member State or available in a very limited number of Member States
- Addition of a medicine of the same pharmacological class previously adopted (i.e. 2nd in class): more difficult to find an interest to 2nd substance once CHMP has expressed itself positively on the first
- Divergent non-prescription decisions amongst the Member States: depending on reason of divergence
- In any case: justifiable case that disease to be treated is suitable for non-prescription distribution: size of database, disharmony in SPC, specific risk-minimisation activities - to be discussed how this can be implemented in all Member States.

Abadie mentioned that the CHMP experience on examining eligibility included 13 applications, five of which were positive. Negative outcomes mostly concerned "old" products already available non-prescription in a number of Member States while arguments in favour might ultimately not be valid (mainly due to financial considerations).

The CHMP also has some experience with the assessment of the *benefit-risk balance of a switch*. The five applications had resulted in two positive and two negative opinions while one evaluation was still ongoing. Abadie mentioned that for most of these applications the CHMP was split. Regulators are faced with uncertainty when assessing benefits and risks and the CHMP opinion on risk may differ depending on the context of a healthcare system in a given Member State.

Abadie ended by stressing the role doctors and pharmacists play in informing patients as a factor in the risk assessment of a switch. Especially for pharmacists Abadie remarked that the type and quality of the information provided presented significant variations to an extent that it might hinder the assessment of the risk associated with non-prescription use. Abadie suggested that the central switch might therefore provoke a rethink of the traditional approaches to the role of the pharmacist.



The role of the pharmacist in self-care

The role of the pharmacist in healthcare - especially in relation to non-prescription medicines - was addressed by **John CHAVE**, the Secretary General of the Pharmaceutical Group of the European Union (PGEU) (standing in at the last minute for his President, Filip Babylon). Chave disagreed with Eric Abadie's position that significant variation in the quality of information provided in pharmacies around Europe obscures the possibility of factoring the role of pharmacists in the benefit-risk assessment of a

¹ http://ec.europa.eu/health/files/eudralex/vol-2/c/switchguide_160106_en.pdf

switch to non-prescription status. He argued that the education of pharmacists could not be disregarded and that a 5-year harmonised study programme is compulsory for pharmacists throughout Europe.

According to Chave, pharmacists can ensure the safe use of non-prescription medicines by advising on product selection, ensuring that patients are able to read and understand product labelling and helping them to avoid interactions. Moreover, pharmacists can warn patients about potential allergic reactions and side-effects and discuss appropriate storage and handling of non-prescription medicines, said Chave.

Time pressure on general practitioners (GPs) in Europe has led to pharmacists taking over some of the workload in some countries. Chave used the example of Scotland, where a move from GP consultation to pharmacist consultation has been observed for certain conditions. Self-care support provided by pharmacists should aim at increasing the capacity and confidence of the patient to practise responsible self-care, added Chave.

Some significant gaps are observed in patients' knowledge about the side-effects or risks of the non-prescription medicines they use. The need for objective and reliable information is likely to become more acute as self-care becomes more central to health strategies. It is therefore clear, said Chave, that pharmacists have a key role to play as for information and advice on non-prescription medicines and self-care.

John Chave also identified some challenges for pharmacists. Information provision on non-prescription medicines takes place in a different commercial context from prescription medicines; most patients are aware of and are being influenced by advertising. This sometimes requires different counselling strategies from pharmacists. At the same time, pharmacists in many European countries are under constant pressure to show 'added value' in the non-prescription context because of the threat that distribution channels will be liberalised. He agreed with Abadie that proactive approaches to self-care – for example after switching - may require a 'rethink' of traditional approaches to counselling and information provision.

Surveys suggest that patients would like more information about self-care and self-medication, said Chave. Therefore pharmacists must ensure that professional practice conforms to patient expectations. In this context one needed to ensure that pharmacy education and training were 'fit for purpose' in the self-care context. Pharmacists also needed to take full advantage of new technological opportunities, with the '*dossier pharmaceutique*' in France being a leading example.

There is no doubt about the key role pharmacists play in information provision in the self-medication and broader self-care context, concluded Chave. The profession cannot stand still – pharmacists needed to consolidate and evolve their role in the provision of self-care information.

How the licensing of medicines developed



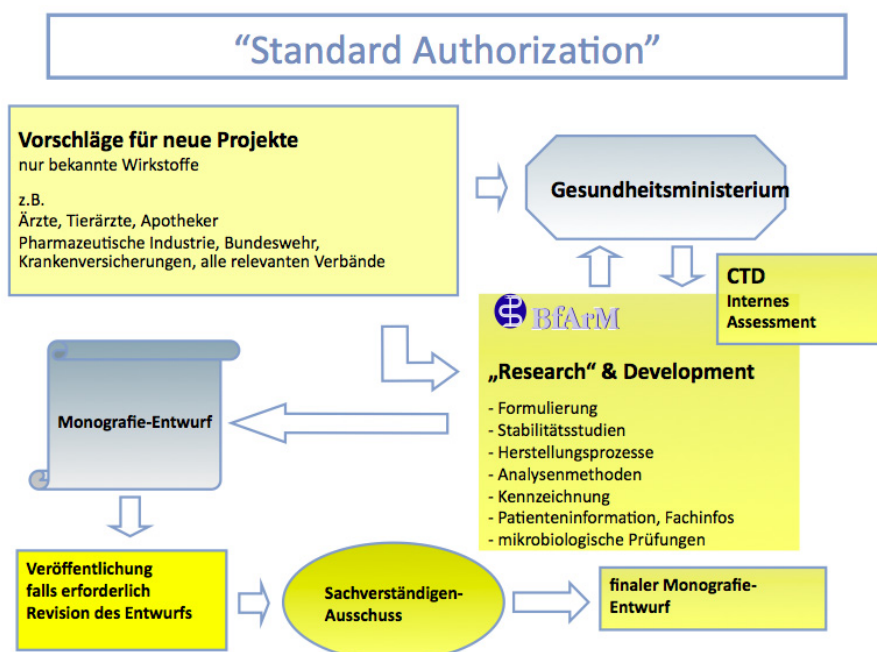
JOHANNES LÖWER, the President of the Federal Institute for Drugs and Medical Devices (BfArM) in Germany, gave a historical overview of the changes in philosophy concerning medicines regulation. Whereas historically all medicines were freely available without a prescription, this started to change in the first half of the 20th century with certain medicines being made subject to medical prescription. Only after the disaster with the sleeping aid Thalidomide in the late 1950s did the German Drug Law of 1961 for the first time stipulate that certain medicines which could directly or indirectly harm people's health even when used according to the instructions



should be made subject to medical prescription. This resulted in 1964 in a general request for all new active substances to be subject to medical prescription. Recommendations on the classification of medicinal products are now made twice a year by the so-called *Expert Committee for Prescription Status (Sachverständigenausschuss für Apothekenpflicht)*.

Löwer also clarified the criteria for classifying a medicinal product as a non-prescription medicine. These are laid down in Directive 2001/83/EC as amended (Articles 71 and 72) and have been clarified in the [Switch Guideline](#) last updated by the European Commission in 2006¹. Harmonisation of legal status at the European level can only be achieved through the centralised procedure, added Löwer.

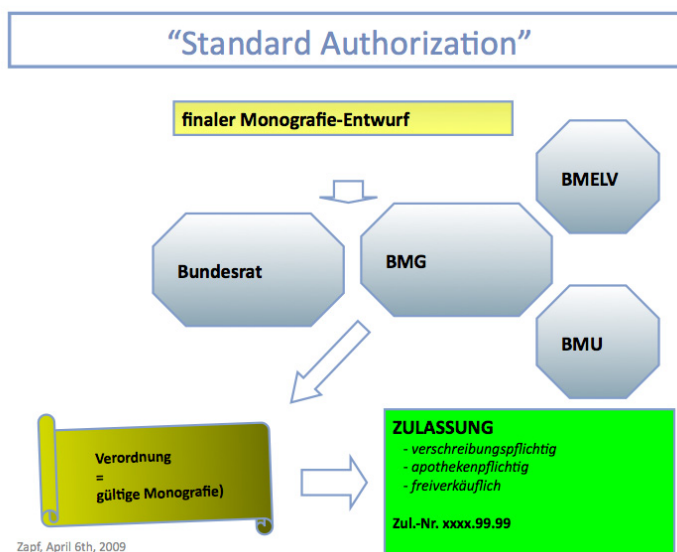
Could an existing German procedure lead to a general licensing procedure for non-prescription medicines?



Löwer then introduced the audience to an existing German licensing procedure, the so-called ‘Standardzulassung’ or ‘Standard authorisation’, which could theoretically be considered as an example for a standardised authorisation procedure for non-prescription medicines. This method, which is according to Löwer not currently supported by the German Ministry of Health, accepts that once a monograph on an active substance exists it can be used by all while the responsibility for the file remains with the Agency (see graphs). A large number of products with widely used ingredients (ASA, Paracetamol, Ibuprofen, Biscodyl, etc.) had been approved in this way in Germany, said Löwer.

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On a personal note, Löwer said his presentation marked his last official function as President of BfArM as he was to retire two days later - after a 30-year career in public service.



¹ Guideline on changing the classification for the supply of a medicinal product for human use - http://ec.europa.eu/health/files/eudralex/vol-2/c/switchguide_160106_en.pdf

Umbrella trade names in the Netherlands



AGINUS KALIS, the Executive Director of the Medicines Evaluation Board (MEB) in the Netherlands, presented on the rules for the use of umbrella trade names in his country. This issue was first discussed following a request from the pharmaceutical industry, said Kalis, which saw this as an opportunity of increasing people's familiarity with products within a particular therapeutic area. The subsequent introduction of the MEB policy document on 'Umbrella trademarks' in 1997 allowed the development of a group of products within the same therapeutic area that are recognisable as a group by name and pack design. At the same time confusion could be avoided.

Under the Dutch guideline of which the latest version was published in 2007¹, the use of an umbrella trade name is possible – however only for non-prescription medicines from a single therapeutic group. The ingredients or pharmaceutical form and indications may nevertheless differ.

Kalis mentioned the way in which the naming changes required under Directive 2004/27/EC had been implemented in the Netherlands. The Dutch Medicines Law stipulates that when a trade name is transformed into an umbrella trade name, its acceptability should be assessed in order to minimise the risk of confusion. A trade name may, said Kalis, not evoke any associations with active ingredients that are not incorporated in the product nor with therapeutic applications not accepted as indications by the MEB. When a specific product within an umbrella trade name is already approved, it is acceptable to add the addition as part of the product name (e.g. Otrivin Xylometazoline Menthol). However, an (abbreviated) indication not being allowed as part of the product name, it should be stated on the pack if approved by the Medicines Evaluation Board. The list of abbreviated indications ([MEB 21-5.1](#)²) had recently been updated, added Kalis. In order to distinguish between products within the same umbrella brand line, the Dutch Medicines Law requires the active ingredient to always be part of the name. Although such a provision is not obligatory under the law, it is also preferable for the strength to be part of the name, continued Kalis.



The layout of the product name within an umbrella trade name should be such that the name is read as one single unit and the product is recognisable as part of the umbrella brand, with attention paid to font size and type, colour and intensity (see the examples of the 'Otrivin' range). Although products under the same umbrella trademark having different active

ingredients may be a potential source of confusion, Kalis suggested that for confusion to be avoided, the active ingredient needed to be included in the products name and the (abbreviated) indication needed to appear on the package.

¹ See <http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/legislation-guidelines/umbrella+trademark/default.htm>

² See <http://www.cbg-meb.nl/CBG/nl/humane-geneesmiddelen/actueel/20101004-aangepaste-lijst-met-verkorte-indicaties-op-verpakking-OTC-middelen/default.htm>



New pharmacovigilance rules explained

CÉSAR HERNÁNDEZ GARCÍA, the Deputy Director for Human Medicines at the Spanish Medicines Agency, spoke about the features of the recent EU pharmacovigilance legislation. According to Hernandez, the objectives are to improve the efficiency of regulatory agencies as well as communication of decisions and their justification. It also aimed at providing a legal basis for the obligation to carry out a more proactive monitoring to detect, assess and prevent adverse reactions of medicinal products once they are on the market.



Based on the revised legislation, a Pharmacovigilance Risk Assessment Committee (PRAC) is to be set up with the responsibility of issuing recommendations. These are then forwarded to the CHMP or to the Coordination Group. In case PRAC, CHMP or Coordination Group positions are not in accordance, the scientific grounds for the differences are to be made explicit, said Hernández García. The process was designed so that consistency is ensured in pharmacovigilance issues affecting the centralised, decentralised, mutual recognition and national procedures.

Worksharing among Member States is promoted by provisions of the pharmacovigilance legislation leading, amongst others, to a single EU-wide Periodic Safety Update Report (PSUR). A risk-based approach is to be followed with waivers from the routine PSUR obligation for certain products such as herbals or well-established use products. Additionally, the EMA will perform literature reviews for some products but the extent of the reviews is yet to be defined.

Package Information Leaflets (PILs) are the cornerstone for information provision to patients. In order to avoid confusion on the issue of patient access to information on medicines, the new pharmacovigilance legislation requires for the Summary of product characteristics (SPC), patient information leaflet (PIL) and Public Assessment Report (PAR) to be publicly accessible. Moreover, European and national web portals with this information will be linked, said Hernández García.

FOCUS ON MEMBER STATES

Belgium – informed patients

XAVIER DE CUYPER, the Chief Executive Officer of the Belgian Federal Agency for Medicines and Health products (FAMHP), noted in the context of self-medication and related information needs that patients wanted more autonomy when it comes to their health. “However, even though they receive more information they are not necessarily always better informed,” said De Cuyper. He stressed the key role of healthcare professionals, and in particular pharmacists, in providing information on self-medication. Moreover, he recognised that drug regulatory authorities needed to ensure that each citizen had all the information necessary for the proper use of medicines.

To guarantee that correct and adequate information for self-medication is provided to patients, the FAMHP exercises pre-control on the information disseminated to the general public through advertising. Guidelines specify the quality of the information in patient leaflets as described in the EU Directive.

Since January 2010, the SPCs and PILs of medicinal products authorised and marketed in Belgium are available on the FAMHP’s website¹. Moreover a partnership with pharmacists had been estab-

¹ [http://195.130.154.23/fagg/\(S\(efrlo555p04upeivf0vsqsfh\)\)/Fagg/FaggCompendium.aspx?compendiumType=H](http://195.130.154.23/fagg/(S(efrlo555p04upeivf0vsqsfh))/Fagg/FaggCompendium.aspx?compendiumType=H)

lished to boost the quality of pharmaceutical care, and Good Pharmacy Practices (GPP) rules apply since January 2010.

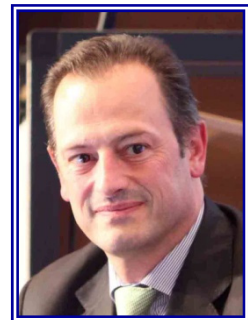
Following the development of the EU rules on switching a medicine from prescription to non-prescription use¹, Belgium adapted its own national guideline. The new recommendations were implemented starting from June 2009 and require some more data than the EU guideline to be submitted to the Belgian Agency, in particular some non-clinical data relating to eco-toxicity and pharmacokinetic data to assess potential interactions.

Offering medicinal products for sale on the Internet is allowed in Belgium but there are severe restrictions: only OTC products for human use can be sold, and this only via the Internet sites of authorised retail pharmacies. These websites have to publish all information needed for proper use, reproduce the complete approved leaflet and respect the legislation on advertising.

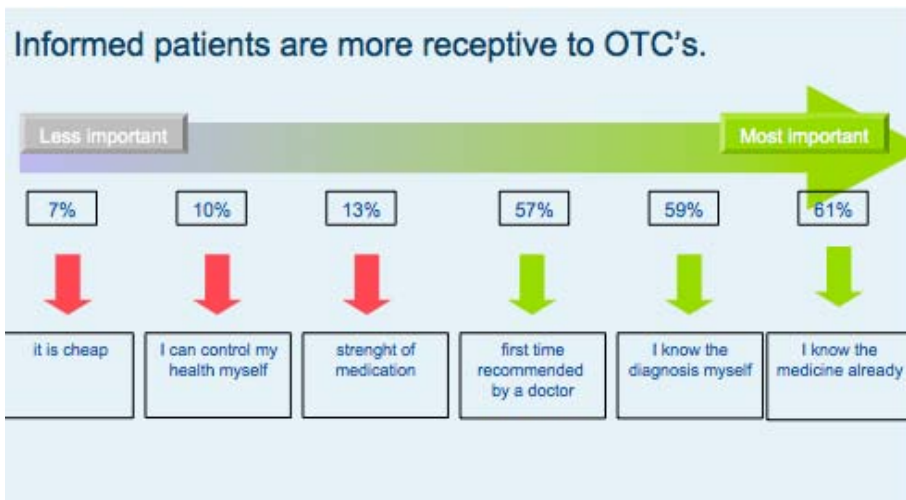
In general, Belgian initiatives to ensure that patients have the necessary information move on two axes: control and repressive actions on the one hand and awareness-raising and education of patients on the other. De Cuyper added that for 2011 another information campaign on the proper use of medicinal products is planned while a platform for “patients” will be created with patient /consumer representatives discussing all aspects of medicinal products including the characteristics of self-medication.

What consumers think of self-care in Belgium

MARC GRYSEELS, the Director of the Belgium Association of the Consumer Healthcare Industry (BACHI), presented the results of a study exploring the motivations and attitudes of Belgian consumers. The study was conducted on a sample of 2 000 individuals and tried to identify the place for OTCs in Belgian society, the drivers and barriers as well as patients’ preferences and opinions on healthcare services. 75% of respondents defined health as being active and productive at any moment. When asked to indicate common ailments, respondents overwhelmingly indicated conditions that can be treated by non-prescription medicines.



Informed patients are more receptive to OTCs as knowing a medicine ranks first in importance among the reasons for selecting a non-prescription medicine whereas price does not appear to be a significant factor in choosing an OTC medicine.



A medication previously prescribed / recommended is the leading driver for self medication, while uncertainty on diagnosis, posology and the risk of side effects rank high amongst the barriers for self-medication. GPs are by far the most important source of information for patients, with specialists and pharmacists coming next.

¹ http://ec.europa.eu/health/files/eudralex/vol-2/c/switchguide_160106_en.pdf



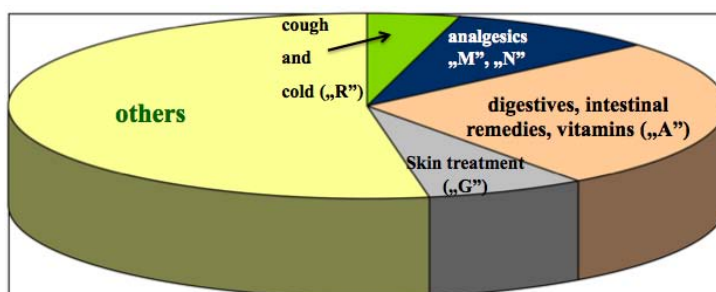
The important role of the pharmacist in OTC recommendation was demonstrated both by the high level of loyalty to a single pharmacist (81% of respondents compared to 96% of patient loyalty to a single doctor) and the high percentage of respondents in favour of receiving advice from pharmacists on the appropriate use of a medicine (69% and 77%, respectively). An effort was also made to identify the economic impact of OTCs. Half of the respondents reported having been absent from work due to illness for at least one day in the previous 12 months.



In summary, said Gryseels, self-medication can be a solution to avoid absenteeism. It can lead to a decrease in unnecessary doctor visits, thereby allowing doctors to concentrate on more important illnesses. A model used in the study to examine the budgetary impact of a switch to OTC status of a medicine against lower back pain had indicated savings of approximately EUR 170 million over a five-year period.

Hungary

ZSUZSANNA SZEPEZDI, the Director General of the Hungarian National Institute of Pharmacy, provided information on developments in the non-prescription sector in Hungary. In 2009 16% of the Hungarian medicinal products had non-prescription status. The non-prescription market (homeopathics, herbals and paramedicines excluded) increased by 9.1% in value compared with 2008 while the prescription market saw an increase of 3.6% during the same period. The figure below shows the main self-medication product groups sold in Hungarian pharmacies in 2009.



With regard to the regulatory environment Szepezdi referred to the main factors influencing the switch from prescription to non-prescription status in her country. These are the type of application, safety issues and the information available. Moreover factors such as changes in the healthcare system (e.g. restructuring, GP shortage), availability, self-medication needs and patient perceptions are also integrated in the decision making.

Slovenia

MARTINA CVELBAR, the Director of the Slovenian Agency for Medicinal Products and Medical Devices, discussed patient interest and need for information. Patients, said Cvelbar, are increasingly interested in their health and wish to be involved more actively in health-related processes. They wish accurate and unbiased information on healthy lifestyle, the prevention of illness and specific diseases, and various treatment options.



There should be a clear distinction between information and advertising for OTCs, argued Cvelbar, as advertising seldom includes contra-indications and safety information. In Slovenia, a public-private partnership and co-operation of the authorities with non-governmental organisations and professional associations has ensured the delivery of balanced and high quality information for patients.

HOW TO GET MEN TO TAKE BETTER CARE OF THEIR HEALTH

IAN BANKS, the President of the European Men's Health Forum, gave a lively presentation on gender differences and healthcare. The presentation focused on the differences between men and women in seeking and utilising the health services. In general, women are more likely to consult a doctor for 'non-serious' categories of health problems compared to men. When it comes to more serious conditions though, men are more likely to consult the doctor than women. However, men often tend to postpone visiting the doctor until it is too late.



The availability of products to treat conditions affecting men's health should be improved, said Banks. If these products cannot be purchased from reliable sources, men are bound to turn to Internet pharmacies, where many counterfeit products are circulating. It is therefore important to get men (and also women) into doctors' surgeries and into pharmacies. Banks underlined the critical role of medical doctors and pharmacists in informing people about their afflictions. At the same time, maintained Banks, it is important to guarantee patient confidentiality when people are consulting on diseases - for instance on a sexually transmitted disease such as chlamydia or on an enlarged prostate - for which non-prescription medicines are available.

Banks concluded by stressing the need to design targeted strategies to involve men in health-related programmes.

CONCLUDING REMARKS

HUBERTUS CRANZ, the Director General of AESGP, closed the conference by summarising the most important topics covered. He referred to the work of AESGP in establishing the socio-economic benefits deriving from self-medication and in proposing the way forward for more effective and efficient regulation, the former in the study on the '[Economic and Public Health Value of Self-Medication](http://www.aesgp.be/ephv/2004study.pdf)'¹ and the latter in the '[Smart Regulation 2015](http://www.aesgp.be/SmartRegulation/SmartRegulation2015.pdf)'² document.

¹ <http://www.aesgp.be/ephv/2004study.pdf>

² <http://www.aesgp.be/SmartRegulation/SmartRegulation2015.pdf>



The upcoming strategic documents of the Heads of Medicines Agencies and the European Medicines Agency offer the possibility of an improved regulatory climate for non-prescription medicines, and a number of concrete improvements should be put in place without any further delay. These refer in particular to the functioning of the mutual recognition / decentralised procedures but also to the adequate interpretation of the existing rules with regard to non-prescription medicines. The particularities of well-established substances really need to be taken into account.

“After the successful process leading to the adoption of the revised EMA guidance document on invented names, it is now time to establish a well-balanced guideline for the pack design of non-prescription medicines,” said Cranz. Concrete progress should be possible with a good leadership from the EMA. This issue will also be on the agenda of the next EMA-AESGP platform in January 2011.

The AESGP Director General also took the occasion to respond to the presentations made in the context of the so-called “pharma package”. Concerning the new provisions on pharmacovigilance, Cranz said that while the amendments in relation to the abandoning of the periodic safety update reports for well-established substances were very welcome, other legal provisions such as that on literature searches still needed fine-tuning during the implementation process. AESGP will follow the establishment of guidance on post-authorisation efficacy studies with particular interest. The possibility of a major review of the current leaflet system also offers interesting perspectives.



Finally, Cranz drew the government authorities’ attention to AESGP’s concerns in relation to the possible extension to non-prescription medicines of the mandatory use of safety features in the framework of the ongoing debate on the new legal provisions on falsified medicines. All measures in relation to additional control of APIs and excipients coming from countries outside the European Union should stay proportionate, added Cranz.

At the end of the conference, an invitation was extended to all participants to attend future AESGP events - in particular the AESGP Conference [What regulation for food supplements and herbal medicinal products in Europe?](#)¹ (Brussels, 1-2 February 2011) and the 47th AESGP Annual Meeting (Rome, 8-10 June 2011).

AESGP Conference

What regulation for food supplements and herbal medicinal products in Europe?

Brussels, Belgium
1-2 February 2011

Full programme available at www.aesgp.be



¹ <http://www.aesgp.be/Brussels2011/Brussels2011Programme.pdf>