



Conference Report

“HOW CAN THE AVAILABILITY OF NON-PRESCRIPTION MEDICINES BE IMPROVED?”

Welcoming the participants to the AESGP conference “*How can the availability of non-prescription medicines be improved?*” near the European Medicines Agency in Canary Wharf, London, on 18-19 October 2011, AESGP President **Hans REGENAUER** mentioned that when the last conference took place in the same location in January 2010, the first authorisations for non-prescription medicines in the centralised procedure had just been granted. At that moment many believed in a paradigm shift for non-prescription medicines, and expected a wave of new switch applications in the wake of the first authorisations. In the 19 months since that conference it has however become clear that this did not happen, and the reasons would be discussed at the conference, said Regenauer.



Pictured at the AESGP Reception in Canary Wharf, London on 18 October 2011 (from l):

Roger SCARLETT-SMITH, AESGP Vice-President and President, GlaxoSmithKline Consumer Healthcare Europe; **Tomas SALMONSON**, Vice-Chair of the CHMP and Director, Scientific and Regulatory Strategy, Medical Products Agency, Sweden; **Hans REGENAUER**, AESGP President, Merz Pharmaceuticals; **Eric ABADIE**, Chair, Committee for Medicinal Products for Human Use (CHMP); **Jörg OHLE**, AESGP Vice-President and Head Region Europe, Bayer Consumer Care; and **Hubertus CRANZ**, AESGP Director General

Eric ABADIE, the Chair of the Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency, confirmed this by providing some statistics about eligibility requests and application submissions since the opening up of the centralised procedure to non-prescription medicines in 2009. Of the 15 eligibility request submissions, eight received a positive opinion and seven were rejected. Only three requests were received in 2010 and 2011. As reasons for rejection, Abadie quoted that the products were already largely available without a prescription in European markets; the lack of convincing arguments; technical innovation not entirely proven; and medical indication not compatible with non-prescription status. Of the seven non-prescription applications



submitted since the opening up of the system, five received a positive and two received a negative opinion. In line with the legislation, the reasons for rejection were: the need for a medical diagnosis; safety concerns; the role of the pharmacist (distribution is not harmonised across the EU); and insufficient experience in some Member States.

Tomas SALMONSON, Vice-Chair of the CHMP and Director, Scientific and Regulatory Strategy at the Medical Products Agency, Sweden, said he was a “true believer in self-care as the way forward and as an important means for society to save financial resources. However, there is certainly room for improvement and we would like to receive more applications.” He also wanted to eliminate some myths. He asked for data to demonstrate whether there was really a lot of difference between a pharmacy and a supermarket in the distribution of non-prescription medicines. In his opinion the patient can very well decide for himself, and he even feared that the UK system might lead to a trap for newly switched medicines. He suggested that a solution could be found in switching a medicine to non-prescription status in only a few Member States to gain experience that could later be spread to the whole EU. The difficulty lies in devising a suitable reporting format to gather this experience.

Discussing benefits and risks is also a question of discussing uncertainties, said Salmonson, and the positive side of non-prescription medicines is often not sufficiently highlighted. “Keeping a medicine on prescription does not reduce the uncertainties that are inherent to it,” continued Salmonson, “as recent experience has shown.”

Abadie concluded by saying that the CHMP should not be blamed for lack of experience as there had only been a limited number of requests for eligibility and switch in the centralised procedure. Moreover, some CHMP members – although they officially only represent themselves - encountered a rather hostile environment towards switching and self-care in their home country, leading to fears that more switches may disrupt their national healthcare system.

Several solutions have been discussed within the CHMP: a choice of Rapporteur; a proposal for a “switch CHMP subgroup”; the (optional) use of Scientific Advice Groups (SAG) before the application is made, etc.

Hans Regenauer mentioned that some of these issues would be addressed in a project concerning a new approach for the benefit-risk assessment of non-prescription medicines. “Leading academic experts have put together their considerations in a peer-reviewed scientific article (see page 32 of this issue). We think that their proposals are very interesting, and we intend to discuss them with the Heads of EU Medicines Agencies (HMA) just before the start of their first meeting during the Danish EU Presidency in Copenhagen on 22 February 2012.”

The AESGP President further stressed the need to reduce administrative burdens for the non-prescription industry along the lines of the proposals put forward in the AESGP publication [Smart Regulation 2015](#)¹. Although considerable progress has been made in certain countries, especially in the switching of medicines for new indications, this trend is less evident in other European countries, and the question remains how to reach Europe-wide consensus in this respect.

Regenauer thanked the CHMP for its positive attitude towards the self-care industry and for the willingness expressed by its Chair and Vice-Chair for a continued constructive dialogue.

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

Has there been progress since December 2008?

Under the chair of AESGP President **Hans REGENAUER**, the conference looked at the implementation of the legislative provisions in the pharmaceutical sector adopted since the publication of the European Commission's communication of December 2008 entitled '*Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector*' and the three legislative proposals as well as at their implications for non-prescription medicines. According to Regenauer, the self medication industry in Europe continues to strive for innovation but is struggling to find the right kind of support for concrete innovative activities.



Pictured at the AESGP Conference in Canary Wharf, London on 19 October 2011 (from l):

Fergus SWEENEY, Head of Sector 'Compliance and Inspection', European Medicines Agency; **Lidia RETKOWSKA-MIKA**, Head of Legal Unit, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland (Country of the EU Council Presidency in the 2nd semester of 2011); **Hans REGENAUER**, AESGP President; **Dagmar STARÁ**, 'Pharmaceuticals' Unit, Directorate-General Health and Consumers, European Commission; and **Peter ARLETT**, Head of Sector 'Pharmacovigilance and Risk Management', European Medicines Agency

This was underpinned by a recent Parliamentary question addressed to the European Commission by Member of the European Parliament **Françoise GROSSETÊTE** (Group of the European People's Party, France):

In its communication entitled '*Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector*' of December 2008 (COM(2008)0666) the Commission states that "non-prescription medicines play [...] an important role since they offer financial as well as social advantages. Self-medication allows patients to treat or prevent short-term or chronic illnesses which they do not consider as serious enough to require consulting a doctor or which they may treat themselves after an initial diagnosis. Consequently, access to and availability of these medicinal products requires particular attention". In the same document, the Commission com-



mits itself to examining the best means of “guaranteeing the availability and market access [...] of non-prescription medicines by 2011”.

Could the Commission say what action has been taken on this matter since the above document appeared? Does it intend to propose in the near future new legislative guidelines or incentives to facilitate access to European markets for non-prescription medicines - including a change in classification from prescription to non-prescription?

Dagmar STARÁ, Policy Officer at the *Pharmaceuticals Unit* of the European Commission’s Directorate-General Health and Consumers, presented the state of play with regard to the implementation of the pharmacovigilance legislation (one part of the package of three proposals put forward by the Commission in December 2008 which had since been finally adopted).

With regard to the new provisions on *medicines safety* (pharmacovigilance), Stará gave an overview of the key achievements and the main deadlines. A [concept paper](#)¹ on implementing measures for the performance of activities related to pharmacovigilance was released by the European Commission for public consultation until 7 November 2011, and a call has been published for members of the new Pharmacovigilance Risk Assessment Committee (PRAC) which should become operational from July 2012. A further stakeholder consultation concerning the concept paper is scheduled for 22 November 2011. The Commission will then proceed with finalisation of the guidance after consulting the Member States in the Standing Committee.

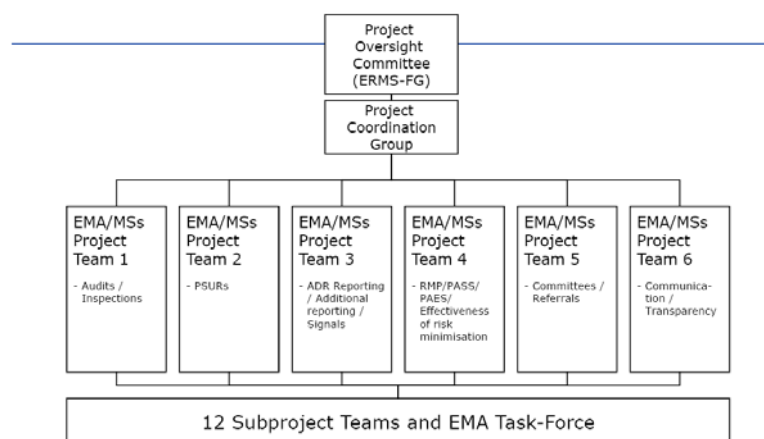
Stará advised marketing authorisation holders (MAHs) in particular to:

- Consider transitional provisions to clarify the application of new obligations to existing marketing authorisations
- Consider new rules for applications for Marketing authorisations in the coming months
- Integrate new rules in pharmacovigilance planning and management.

The Commission is envisaging a further tightening of the pharmacovigilance legislation through the recently released amended proposals on information to patients. These foresee in particular (a) an automatic referral at European level in case of specific serious safety issues with nationally authorised products so that these can be assessed and addressed in all Member States where the medicinal product is authorised and (b) to avoid that the voluntary withdrawal of a marketing authorisation or product by the holder could lead to safety issues not being addressed in the EU.

Peter ARLETT, who heads the Sector ‘Pharmacovigilance and Risk Management’ at the EMA, provided some background as to the reasons for adoption of the new pharmacovigilance provisions. 5% of all hospital admissions are for Adverse Drug Reactions (ADRs), and the societal cost of ADRs amounts to €79 billion per year in the European Union. Arlett called the new provisions on medicines safety “the biggest change to the legal framework for human medicines since 1995”. For the EMA, the lack of human and financial resources is the big-

How to implement? – Governance structure



¹ http://ec.europa.eu/health/files/pharmacovigilance/2011-09_concept-paper.pdf



gest risk to the implementation and operation of the new legislation, and Arlett demonstrated the

AESGP Questions / points

- Coordination / lists of medicines
- Authorisation requirements
- Risk Management Plans – modular approach, additional risk minimisation
- Post-Authorisation Studies (Safety and Efficacy) – guidance on efficacy
- Effectiveness of risk minimisation
- Adverse Drug Reactions reporting – literature reporting guide / non-serious
- Signal detection
- Periodic Safety Update Reports – not routine for WEM, traditional herbal, registered homeopathics
- Scientific Committees / decision-making
- Transparency and communication
- Coordination of inspections
- Pharmacovigilance Audits - PSMF
- Fees charged and payments for assessments / services - proportionate

governance structure implications put into place by the new legislation.

Arlett also addressed each of the questions / points raised by AESGP in connection with the new pharmacovigilance legislation and its implementation (see slide).

Fergus SWEENEY, who heads the Sector ‘Compliance and Inspection’ at the EMA, explained

the background and details of the *new provisions on falsified medicines*. Apart from the three sections originally foreseen (safety features, supply chain and good distribution practices, and active ingredients), the European Parliament had added a section on Internet sale of medicinal products. As mentioned previously, non-prescription would not normally have to appose any safety features unless they were entered into a special list. Asked whether non-prescription medicines would be allowed to apply safety features voluntarily, Sweeney said he did not see why this would not be possible but in that case they would need the cooperation of the database keepers.

Sweeney mentioned the new requirements for API manufacturers and the specific provisions for the import of APIs from third countries, API audit and risk assessment of excipients. Among the workload for the authorities in the implementation of the new provisions, Sweeney mentioned: audits of all API manufacturers; assessment of third country API supervisory systems; and the expansion of the scope of the EU EudraGMP database.

Concerning the sale of medicines on the Internet, Sweeney said that Internet pharmacies should notify the competent national authority of the Member State in which they are established of their street address, website and products offered. The websites should display a new EU logo which would link to the national authority’s website containing a list of authorised Internet pharmacies and a warning on the risks of Internet purchases. The EMA is to establish a website with links to the Member States’ websites.

Lidia RETKOWSKA-MIKA, the Head of the Legal Unit at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland, representing the EU Council Presidency in the 2nd half of 2011, mentioned that there were also many new obligations for the Member States as a result of the new provisions on pharmacovigilance and falsified medicines. She pointed to the change in philosophy concerning the definition of an Adverse Drug Reaction (ADR) (off-label use and medication errors are now included) and expected more patient reporting as a result of awareness campaigns directed to patients. On the other hand she expected less work in the assessment of periodic safety update reports (PSURs) for well-established use and herbal products. More work-sharing would also be possible thanks to international collaboration at the level of Heads of Medicines Agencies (HMA). In this context Retkowska praised the benchmarking work already carried out in the two previous BEMA rounds and said that the third round would be a pharmacovigilance audit of which the results will be transmitted to the European Commission in September 2013.



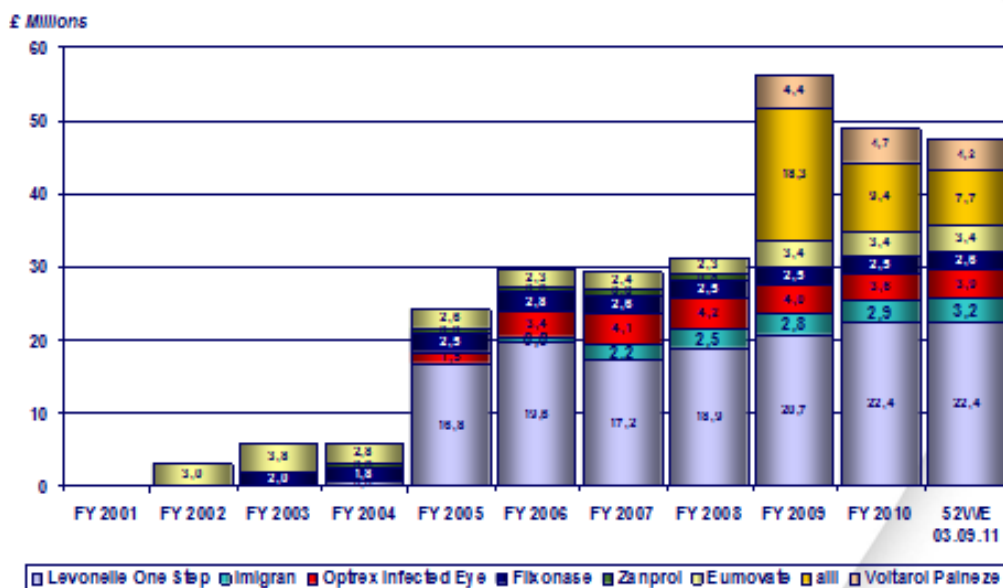
The centralised procedure for non-prescription medicines: Where are the road blocks?

Roger SCARLETT-SMITH, AESGP Vice-President and the President of GlaxoSmithKline Consumer Healthcare Europe, said the optional use of the centralised procedure was first and foremost a way of improving the availability of non-prescription medicines for people in Europe. Experience with the first centrally switched medicine (GSK’s weight management product alli®) had however shown that although the product was given a single licence across the EU, this had to be multiplied by 27 for implementation details. As other challenges, Scarlett-Smith mentioned that:

- the CHMP’s experience with OTCs was limited,
- there needed to be trust in industry and pharmacists,
- the incentives for industry were very limited as data exclusivity was limited to just one year
- communication possibilities remained too market-specific.

Scarlett-Smith went on to defuse some myths about the self-care industry: First, a switch is not a licence to print money. Compared with the prescription industry, turnover is relatively modest. For a product such as Imigran®, annual turnover in the first year was €55 million v. more than €2 billion for the prescription version.

OTC Switches – Value Sales (RSV)



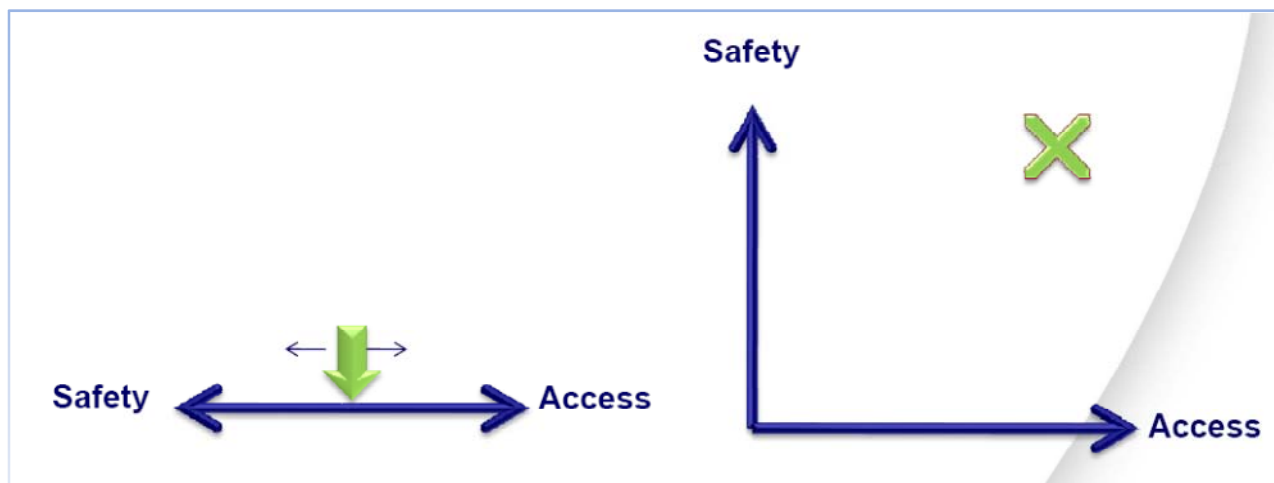
There are high regulatory costs involved in preparing for a switch, including comprehensive pharmacy education, advertising and marketing. After just one year competitors could take advantage of the switch innovator’s work.

Second, pharmacists will not hand over any product to any patient: a German study showed that

pharmacists solved more than 80% of problems correctly, and that pharmacists are well suited to detect drug related problems during their routine drug dispensing and patient counselling activities.

Third, self-medication does not stop patients from seeing doctors. A GSK European survey showed that of the 1721 overweight patients in eight markets, 86% saw a doctor in the last 12 months, 83% had a blood pressure check, 44% had a diabetes check and 58% were under a physician’s care for ongoing conditions.

And fourth, controlling access does not always provide maximum safety. This is illustrated in the figure in the next page:



In conclusion, said Scarlett-Smith, we need efficient and predictable regulation of the centralised switch:

- CHMP acceptance and experience with non-prescription medicines, keeping in mind that consumers across the EU have similar health aspirations
- Overcome the issue on the role of the pharmacists and collaborate with them
- Incentives for industry: longer data exclusivity
- Eligibility possible for every ingredient available without a prescription at national level
- Communication needs to be more harmonised across the EU.

Only when these conditions are met can centralised switches become a key catalyst for growth in self-care.

Bert LEUFKENS, who chairs the Medicines Evaluation Board in the Netherlands and is a Member of the CHMP, set the scene for a detailed look at the functioning of the centralised procedure. He especially asked how science could be translated into daily practice to ensure a positive benefit / risk evaluation for medicinal products. He also speculated whether the current pharmacy system and pharmacist education were not working against switches. “We must certainly examine how the diversity in distribution systems can be translated back to our switch decisions”, said Leufkens.



Noël WATHION, the Head of the Unit “Patient Health Protection” at the European Medicines Agency, mentioned that many of the issues encountered with the optional use of the centralised procedure for non-prescription medicines were facilitated at the six-monthly AESGP-EMA Platforms, e.g. the use of invented names, the appointment of rapporteurs, risk management plans, scientific advice, etc. One of the outstanding issues discussed was the new guideline on pack design, on which many contributions were received and which is expected to be finalised at a workshop in March 2012.



When looking at the low number of eligibility requests and applications for non-prescription medicines in the centralised procedure, Wathion said the CHMP was aware there was a problem and was going to discuss this with the



European Commission, but he also thought there were more fundamental issues, for instance difficulties in the licensing systems even in relatively liberal countries such as Sweden and the UK and evaluators becoming more risk-averse under pressure from the media and political lobby groups. Specific action is envisaged in the EMA's "Vision to Reality" document to address this important issue, but Wathion wondered whether this would be enough. If in the end the conclusion was that the current legislation was not suitable, there would be a need to change it, said Wathion.

Wathion also wondered how the differences in healthcare systems could be addressed, and mentioned proposals to involve civil society more in risk management. "Eventually there should be a change in voting behaviour in the committees and how non-prescription medicines are viewed."

Citing the benefit-risk methodology project, he advised the self-care industry to become more proactive in ongoing benefit-risk research and to carry out studies before the regulators would ask for them. This is becoming even more urgent in light of the July 2012 deadline for the submission of data on all medicinal products under the EU's new pharmacovigilance legislation.

This was complemented by **Patrick LE COURTOIS**, the Head of the Unit "Human Medicines Development and Evaluation" at the European Medicines Agency, who said there were two main bottlenecks in the centralised procedure for non-prescription medicines: eligibility and the issuance of final opinions, with the most innovative products being the most challenging. He hinted at the need for a better benefit-risk assessment and questioned whether the CHMP was in the best position to determine the patient's interest given that the final decisions were mainly driven by national considerations. Also, much of the work at the Agency has a prescription setting in mind. If there is a strong political will to grant better access to non-prescription medicines, more should be done, said Le Courtois. He therefore called for a broader reflection on this subject.



Ian BANKS, of the European Patients' Forum (EPF) and the Men's Health Forum, insisted that self-care products should be widely available as men do not usually go to see their doctor in time to detect a serious health problem. On the other hand pharmacists were often able to detect a serious underlying health problem when asked about a minor ailment. Banks acknowledged that all medicinal products have inherent risks but that the risk of not treating patients was even greater. He mentioned the future role of patients in the reporting of adverse reactions under the new pharmacovigilance provisions although the yellow card system is not used very much in the UK.

Concerning the Internet sale of medicines, Banks said this could help people in areas that are far removed from a selling point. But for those living near a pharmacy, he suggested for the European Commission to carry out a study into why people continue buying certain lifestyle products online knowing very well that many of them are falsified and may harm their health. He concluded by asking whether "we can afford *not* to improve access to non-prescription medicines".





Jurate SVARCAITE of the Pharmaceutical Group of the European Union (PGEU) explained that pharmacy training was harmonised across the EU thanks to the Directive on professional qualifications and that a survey has shown that all pharmacists advise on self-care and non-prescription medicines. She even suggested that the directive should be modified to recognise this. Pharmacists know their patients well and can advise them on interactions between various types of medication. However, pharmacists have a PR problem and should make their added value in sorting out medication problems much clearer, in particular vis-à-vis medical doctors.



From vision to reality: The implementation of the EMA Roadmap to 2015

Emer COOKE, the International Liaison Officer at the European Medicines Agency, provided the Agency's progress in the implementation of its *Roadmap to 2015*. The document From Vision to Reality details activities designed to improve performance in the three strategic areas identified in the Road Map and which support the Agency's current legislative tasks: addressing public health needs; facilitating access to medicines; and optimising the safe and rational use of medicines. She gave the following examples of implementing actions already started, all of which impact the non-prescription medicines sector:



- Implementing the new pharmacovigilance legislation (CHMP work programme 2011-2013)
- Strengthening the Eudravigilance system
- Improving the process for managing Risk Management Plans.

Support for self-care in the mutual recognition / decentralised procedures

Helen DARRACOTT, the Director of Legal and Regulatory Affairs at the Proprietary Association of Great Britain (PAGB), chaired a session in which speakers from the Co-Ordination Group for Mutual Recognition and Decentralised Procedures (Human) – CMDh looked at ways to improve the two procedures for which the group has competence, i.e. the mutual recognition and the decentralised procedures, for non-prescription medicines.

Colette MCCREEDY, who is 'Specialist in Self Medication' at the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), mentioned that a specific Task Force was set up in early 2011 by the Working Party on the Future of CMDh, a group mandated by CMD, to make the procedures more attractive for non-prescription medicines given that the procedures were under-utilised by the self-medication sector. The majority of OTC products indeed remain authorised on a national basis, and product ranges are expanded by national line extensions. One of the main elements of the Task Force's work was the establishment of a Best Practice Guide for the Authorisation of Non-Prescription Medicines which is currently out for consultation and which will complement the CMDh Best Practice Guide which applies to both prescription and non-prescription medicines. A longer-term objective was to explore the legal issues around a harmonised SmPC resulting in "sub-sets" of product information, leading to the issue of a new marketing authorisation with its own SmPC and versions of package leaflets suitable for OTC markets. Other issues addressed by the Task Force are Article 30 SmPC harmonisation and other approval routes for the authorisation of products containing recognised non-prescription actives, including the automatic rec-



ognition of marketing authorisations for well-known non-prescription substances along the lines of the Herbal Monograph model.

As challenges, McCreedy mentioned that:

- Legal classification remains a national issue: different healthcare systems in different Member States can have an effect on decisions on legal status
- Arrangements for the distribution of non-prescription medicines differ between Member States (inside or outside the pharmacy).
- Procedures for determining legal classification differ between Member States (product based v. substance based).



Pictured at the AESGP Conference in Canary Wharf, London on 19 October 2011 (from l):

Colette MCCREEDY, Medicines and Healthcare products Regulatory Agency (MHRA); **Truus JANSE-DE HOOG**, Chair, Co-Ordination Group for Mutual Recognition and Decentralised Procedures (Human) CMD(h); **Peter BACHMANN**, BfArM, Germany; **Helen DARRACOTT**, Director of Legal and Regulatory Affairs, Proprietary Association of Great Britain (PAGB); **Christa WIRTHUMER-HOCHE**, AGES, Austria; **Christine EISING**, Global Regulatory Affairs, Category Head New Growth Opportunities, Novartis Consumer Health; and **Werner KNOESS**, Chair, EMA Herbal Medicinal Products Committee (HMPC)

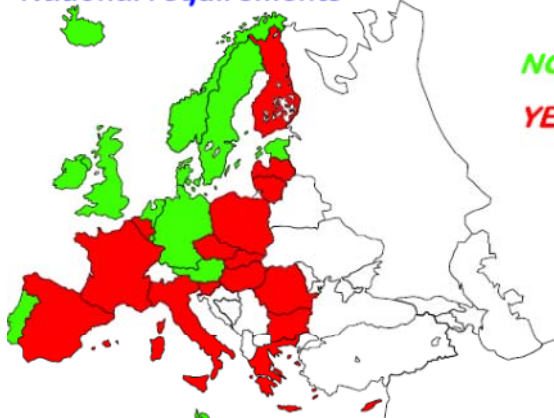
Truus JANSE-DE HOOG, who chairs the Co-Ordination Group for Mutual Recognition and Decentralised Procedures (Human) CMDh, encouraged the self-care sector to make better use of the mutual recognition and the decentralised procedures by enumerating the advantages. She showed the latest statistics on the number of procedures.

Janse-de Hoog mentioned that the Heads of EU Medicines Agencies (HMA)'s focus was on improving the transparency of availability and use of slots for the DCP in an efficient way and on reducing the number of cancellations of agreed submissions and the time needed to validate applications. To facilitate this, the CMDh had published on its website a common request form for the RMS in the DCP and information on national timeslot bookings with direct links to national agencies' websites.



Peter BACHMANN of the Federal Institute for Medicines and Medical Devices (BfArM) in Germany provided the details of the work undertaken by the CMDh to carry out the tasks outlined by Janse-de Hoog, in particular on the guidance document already published or under preparation. He

National requirements



Federal Institute
and BfArM

NO
YES

also showed the extent of the various national requirements in connection with the two procedures which are not in the current EU legislation. It was remarkable to see, said Bachmann, that the six Member States *without* additional requirements served as the Reference Member State in 80% of the decentralised procedures started in 2010.

Bachmann showed that the number of CMDh referrals had considerably decreased in the last few years and represented around 1% of cases, out of which only 0.3% was in the end referred to the CHMP.

Christa WIRTHUMER-HOCHE of the Austrian Agency AGES explained the CMDh's plans for worksharing activities in the area of the Active Substance Master File (ASMF). The ASMF may be used for multiple marketing authorisation applications and/or variations in one or more Member States which may or may not be connected through a European procedure. The ASMF has been used for a number of non-prescription ingredients, e.g., Pantoprazole, Clotrimazole, Xylometazoline and Nicotine. The Working Group on the ASMF will investigate the feasibility, practical and legal aspects of and proposals for:

- one central assessment for ASMF going through the centralised and decentralised procedures
- a centralised database for all Assessment Reports of ASMFs
- an EU numbering system for Active Substance Master Files.

Moreover, there is new and updated ASMF guidance which will be discussed at a meeting with interested parties in November 2011.

Christine EISING, Global Regulatory Affairs, Category Head New Growth Opportunities at Novartis Consumer Health presented the self-care industry's view that all CMDh efforts to improve the procedures for non-prescription medicines were very much appreciated. With regard to slot booking, said Eising, it was still difficult to find out how many slots were open EU-wide in the absence of a 'central' booking platform. In AESGP's opinion, pre-submission meetings to be held at least six months prior to submission should replace slot booking. Here the applicant could submit a briefing document including specific questions for an optimal preparation of such a meeting.

Although validation times had generally improved, some Member States still insisted on specific documents. Applications should be validated in 14 days without any further national requirements.

Eising further formulated AESGP's wishes in respect of so-called 'Stumbling Blocks'; the too long national phase following the MRP/DCP (in particular it is proposed to disconnect marketing authorisation approval from the review / approval of artwork to speed up the process); the evaluation of applications (she asked for an 'OTC/non-prescription champion' in each Agency and sufficient training of the evaluators); and the role of the Reference Member State as the facilitator.

Although legal status is officially not part of the MRP/DCP and falls outside the Summary of Product Characteristics, it is an integral part of the discussion due to the impact on the harmonised product information. Therefore AESGP proposed a "mixed legal status" where a product could have



prescription status in some Member States and non-prescription status in others, thereby paving the way for further switches. Through two different product information ‘Sub-sets’, there would be an SmPC and a PIL for each legal status agreed at the end of MRPs/DCPs. Although the European Commission has expressed reservations AESGP would like to pursue the idea further.

Werner KNOESS, who was elected to the position of Chair at the EMA’s Committee on Herbal Medicinal Products (HMPC) in October 2010, mentioned that up to now around 90 Community herbal monographs and around 10 List entries had been adopted, sometimes with divergent opinions being documented. Nine herbal products had successfully completed the mutual recognition procedure leading to 55 national authorisations. The first decentralised procedure was finalised in 2009. Knoess mentioned that herbal companies were currently exploring the potential of the mutual recognition and decentralised procedures based on monographs, with an increasing number of procedures being started and announced.

Knoess also showed figures for the number of traditional use registrations, which had increased considerably from only one in 2005 to 202 in 2010. Here also Knoess saw possibilities for a MRP/DPR or even a centralised procedure in the future.

In conclusion, said Knoess, “the HMPC has in the seven years of its existence gathered a lot of scientific and regulatory expertise on herbal non-prescription medicines”.

The way forward

In the final session, **Dagmar ROTH-BEHRENDT**, Vice-President of the European Parliament,



sketched the “big picture”, i.e. ensuring that there are enough medicines for patients to treat all conditions and to make safe medicines available in a fast manner for a growing self-care market. In the past she used to encourage the non-prescription sector to use the centralised procedure “now that you have it”, but companies do not seem convinced. Therefore Roth-Behrendt was not sure that her advice was still valid and that the CHMP was still the right body to evaluate non-prescription medicines. “Either send the CHMP members to an education course or take the centralised procedure to another Committee”.

She insisted that the self-care industry needed the smartest possible legislation with the least possible administrative burdens. In this context the issue of pack design should soon be resolved without investing unnecessary human resources.

Careful attention should also be paid to whether there is a need to bring minor issues for discussion in a central platform. “It seems that referrals have recently been initiated very widely – even in situations where the need was doubtful. This needs to be carefully monitored so that the EMA is not unnecessarily overloaded,” insisted Roth-Behrendt.

Concerning the proposed modifications to the EU’s pharmacovigilance legislation, we need to keep an eye on whether this is properly done. “Just adding a few but still significant changes to a completely different legislative proposal (i.e. that on information to patients on prescription medicines) is certainly not a “clean” approach,” concluded Roth-Behrendt.



Andreas POTT, the Acting Executive Director of the European Medicines Agency, stressed that the Agency had been given many new tasks which it should carry out with no significant staff increases. Therefore the Agency favours procedures and processes that are fast, lean, easy and non-bureaucratic, said Pott. One of the Agency's problems is that it deals with many moving targets (public health, quality, safety and efficacy) and 27 Member States with different culture and traditions. It is moreover clear that communication with the public and with health professionals should be improved.



Pott was confident that the issue of pack design for non-prescription medicines would soon be resolved, possibly at an upcoming platform between the Agency and AESGP.

AESGP Director General **Hubertus CRANZ** concluded that the recent experience with the centralised procedure for non-prescription medicines had not been encouraging. However, AESGP was pleased to see the commitment on the part of the Committee for Medicinal Products for Human Use and the European Medicines Agency to make the system work.

“AESGP is delighted by the advice to become pro-active in the debate on an adequate benefit-risk equation,” said Cranz. He referred in this context to the imminent publication of a new model for the benefit-risk evaluation of non-prescription medicines based on scientific research commissioned by the World Self-Medication Industry.

AESGP's main concerns with regard to the new pharmacovigilance provisions are more with the interpretation being given to them than with the legislative text itself, continued Cranz. “However, several really important issues are at stake such as for example the interpretation of Article 57(2) of the Regulation. In this context everybody needs to be reminded that the industry operates in tight economic terms.”

Cranz mentioned that AESGP was involved in the various working areas of the so-called Tajani initiative on Corporate Social Responsibility, which includes a specific working group on Good governance for non-prescription medicines. This working group is expected to produce good recommendations, e.g. for the uptake of medicines moved to non-prescription status.

Finally, he thanked the speakers for their open remarks and invited all to the AESGP Workshop in Copenhagen on 21-22 February 2012 at which the proposal for a new benefit-risk model for non-prescription medicines would be discussed with a large number of Heads of EU Medicines Agencies.



**AESGP Workshop with the EU
Heads of Medicines Agencies
A new approach for the benefit-risk
assessment of non-prescription
medicines**

**Copenhagen, Denmark
21-22 February 2012**
