

*AESGP Members' Meeting ♦ Warsaw ♦ 30-31 January 2002*  
*"Preparing for Enlargement by Revising the Rules:  
An Opportunity for Self-Medication"*

**"Preparing for Enlargement by Revising the Rules:  
An Opportunity for Self-Medication"**

Under this title, the AESGP Members' Meeting in Warsaw on 31 January 2002 provided the opportunity for the more than 150 speakers and participants to exchange ideas about the European Commission's proposals put forward at the end of November last year to revise the European Union's pharmaceutical legislation. The conference paid particular attention to the goal of matching the specificities of the new applicant countries with those of the current EU Member States, while not losing track of the aim to safeguard and improve the regulatory climate for self-medication products all over Europe.



From left: Polish Vice Health Minister Nauman, AESGP President Banchi and the European Commission's Weissenberg

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*AESGP's long-standing involvement Central & Eastern Europe*

In his introduction, AESGP President **Dr Alessandro Banchi** highlighted AESGP's long-standing involvement in debates in accession countries in Central & Eastern Europe about the structuring of the pharmaceutical system and the reform of these countries' legislation on medicines. This included:

- The provision of information on EU and worldwide legislation in general and on non-prescription medicines in particular.
- The establishment of close links and mutual understanding with representatives from authorities and local industry. Advice on the setting up of trade associations.
- The publication of a booklet entitled "Developing Self-Medication in Central and Eastern Europe" which was translated into Polish, Czech, Hungarian, Bulgarian, Russian and Ukrainian and had an overall print run of 50.000 copies.
- The invitation of speakers from Central & East European countries at AESGP Annual Meetings since 1990
- The first Annual Conference of our organisation in Budapest in 1997
- The provision of support to the first meeting of Drug Regulatory Authorities from Central and Eastern Europe in Sofia in 1997.
- Support in the organisation of the first conference of the Pan European Regulatory Forum in 2000.

**Accomplishments of the past years**

This means that in less than ten years, the following four elements were incorporated in the national legislation of applicant countries:

1. Medicinal products were divided into two major categories: prescription only and non-prescription medicines, usually in line with the criteria foreseen in the classification directive of the European Union.
2. For medicinal products available without prescription, the right and the need for communication – including public advertising – became generally recognised. Most countries established reasonable control systems allowing companies to invest in communication about the available medicines.
3. Appropriate rules were also established with regard to consumer understandable information through labels and leaflets, which is a key element in a policy on responsible self-medication. Most countries also established a policy on the permission of tradenames, which allowed manufacturers to keep the tradename once a medicine has been moved from prescription to non-prescription status and allowed the establishment of umbrella tradenames for different forms of non-prescription medicines.
4. Countries understood the importance of liberalising the prices for self-medication medicines in order to have a competitive market providing the best service to the public, in particular for those medicines which are not reimbursed by social security institutions.

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**AESGP's continued commitment to Central & Eastern Europe**

Dr Bianchi said that, as a logical continuation of the last ten years' activities, it is AESGP's role to make a constructive contribution to the ongoing political discussions, in particular to those on the marketing authorisation of medicinal products. This is in the centre of the European Commission's proposal for the revision of the pharmaceutical legislation, and is maybe at the same time the biggest challenge for the accession countries. AESGP believes that, generally speaking, the current debate is heading in the right direction. The European Commission has made an overall balanced and reasonable proposal for the revision of the pharmaceutical legislation, which should allow the system to develop in three forms:

- Widening the scope of the centralised procedure
- Improving the functioning of mutual recognition
- Guaranteeing efficient national authorisations.

This should go hand in hand, continued Dr Bianchi, with a commitment to ensure that assessment procedures are coherent and consistent and in line with good standards concerning transparency and performance. Evidently, all legally foreseen timelines for the granting of marketing authorisations should be respected.

Dr Bianchi also expressed appreciation for the recently adopted proposal for a directive on traditional herbal medicines, which he regarded as a missing piece of legislation to cover an area of medicines which exists in all countries. He considered that these new legislative provisions should also be particularly helpful for many accession countries.

The EU's directive on food supplements, which is likely to be finally adopted before the middle of this year, will clearly also have an impact on many accession countries which have so far not been used to such kind of product categorisation.

*Commission's current thinking on enlargement  
and the review*

**Challenge of accession**

In his keynote address, **Dr Paul Weissenberg**, Director for the Single market, management & legislation for consumer goods at the European Commission's Directorate-General Enterprise, spoke of the mutual challenge represented by the accession to the European Union of a large number of candidate countries in the next few years. The European Commission works on the hypothesis that 10 candidate countries will participate in the next elections for the European Parliament in 2004. According to Dr Weissenberg, accession of such a large number of candidates will have significant repercussions on the pharmaceutical sector. Therefore, the Commission has to prepare the future authorisation, surveillance procedures and organisational structures that will be part of an overall pharmaceutical policy to draft legislation that is still valid in 2010.

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**Objectives of the revision**

Dr Weissenberg told the audience that the main objectives of the revision of the EU's pharmaceutical policy were:

1. To meet the challenges of EU enlargement.
2. To guarantee a high level of health protection for European citizens and making safe innovative products available to patients as quickly as possible.
3. To guarantee a tighter surveillance of the market through strengthened pharmacovigilance procedures.
4. To complete the internal market for pharmaceuticals. For the moment, said Dr Weissenberg, the internal market for medicinal products is still fragmented.
5. To set up a framework which fosters the competitiveness of European industry. After all, Europe needs companies willing and able to put medicines on the market at affordable prices.

**"Current situation regarding mutual recognition is unacceptable"**

Dr Weissenberg went into more detail on some of the proposed changes. Foremost for the self-medication industry, he said, were the proposed improvements to the mutual recognition procedure. "What happens now, i.e. that a Member State simply refuses to recognise an authorisation granted in another Member State, is not tenable in 10 years' time. In our proposal we are telling the Member States that if they want to block recognition, they will have to give us 'serious health objections' and not just 'health objections'. In a family of Member States such as the EU, such objections are simply not acceptable. We are proposing to set a deadline for such objections, after which the Member States will have a few weeks to settle their dispute. If they are unable to do so, the matter will be decided at the Community level."

These proposals combined with a gradual harmonisation of Summaries of Product Characteristics (SmPCs) will, according to Dr Weissenberg, contribute to making the mutual recognition process work more efficiently. In order to succeed, however, there should be greater cooperation between scientific experts before individual positions are taken, said Dr Weissenberg. Only serious risks for public health should be invoked to refuse mutual recognition. If Member States continue to disagree at the end of the procedure, the matter will be handled at Community level, and the ensuing Commission decision will be binding, not only upon the involved Member States but across the whole territory of the European Union.

Also of particular importance for the candidate countries were, according to the Commission, the proposals on the definition of what constitutes a generic medicinal product, the harmonised data protection period of 10 years and the clarification on the relations between a generic and a reference medicinal product.

**For candidate countries to align with the "acquis"...**

Many candidate countries, including Poland, still need to look carefully at the medicinal products already on the market. These products must be fully in line with EU requirements by the date of accession.

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**...there are several solutions:...**

Such alignment with the *acquis* does not automatically mean that the concerned marketing authorisation holder has to do new tests and trials on the product. Other solutions already existing in the EC pharmaceutical legislation or foreseen for the near future may be used. Once the Commission's proposal for a simplified registration of certain traditionally used herbal medicinal products is adopted, there will be three ways for allowing the marketing of a medicinal product.

- First, a normal marketing authorisation on the basis of new tests and trials.
- Second, the so-called "well-established use," where an application can rely on scientific information concerning safety and efficacy of a medicinal product. In this case, the product must be in use for at least a decade.
- Third, the new simplified registration, where tests and trials on the safety and efficacy can be replaced by reliable information on the traditional use of the product. Here, bibliographical data are to be submitted together with an expert report on the product's use for 30 years, 15 of which should be in the Community.

Now that the European Commission has put forward these proposals, continued Dr Weissenberg, the ball is in the camp of the European Parliament and the Council of Ministers.

**Transitional arrangement for candidate countries**

Some candidate countries including Poland have obtained a transitional period for aligning the existing marketing authorisations with the "*acquis*" requirements. This means that medicinal products authorised before accession may remain on the market of the acceding country for a limited time. Such products would however not be entitled to freely circulate within the Community. Irrespective of legal obligations, it might therefore be advisable for a company to align its products to the European standards in order to benefit from the extended market after accession.

***How Poland is preparing for accession***

**Current legal provisions...**

**Mr Aleksander Nauman**, Poland's Vice Minister of Health explained that existing legal provisions are laid down in the Act of 10 October 1991 regarding pharmaceuticals, medical devices, pharmacies, wholesale companies and pharmaceutical inspection.

**...in need of updating to comply with "*acquis*"**

Although these provisions were amended numerous times, they still did not comply with the requirements of the EU directives. Moreover, the Act had given rise to serious doubts over its constitutionality. Therefore, new legal provisions had to be elaborated. This was done in the Act of 6 September 2001 concerning pharmaceutical law, which was prepared by the Polish government and approved by Parliament. This Act, which will come into effect on 1 April 2002, completely adapts Polish law to the EU's legal provisions concerning medicinal products. It

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incorporates the provisions of the various directives concerning the manufacture, marketing authorisation, advertising and post-marketing surveillance of medicinal products and will prepare Poland fully for EU accession. As of 1 April 2002, medicinal products will thus be registered through the "Office of Medicinal Products, Medical Devices and Biocides Registration."

**Dossiers to be updated by end 2008**

Given that after the date of Poland's accession to the EU, no medicinal product whose registration is not consistent with the "acquis" can remain on the Polish market, Mr Nauman said that it was necessary to take measures during the transitional period, i.e. before 31 December 2008, to complete all the necessary documentation. "This requires human as well as organisational and financial commitment, but it primarily requires time. On the other hand, Polish manufacturers will benefit as compliance with the new Act will enable them to export their products to the EU as well as other countries."

**Data protection to be lengthened**

Regulations dating from 15 December 1993 introduced a 3-year data protection period for medicinal products. According to the new Act, this three-year data protection plan will remain valid until Poland's accession to the EU. After that date, a 6-10 year protection plan will be introduced according to the EU directives.

**Price regulation**

Price regulation is the second most important factor deciding about availability of medicinal. Under the new regulations, there will be equal treatment of local and foreign medicinal products in that they will be subject to equal criteria for legal price regulation.

Mr Nauman concluded by expressing the hope that the new legal regulations in the pharmaceutical area would strengthen the position of Polish manufacturers on the EU markets and that they would allow a fast registration of new products in Poland, leading to their greater availability for patients.

***Achievements and next steps in the enlargement process***

**Mr Jaroslaw Pietras**, the Polish Vice-Minister at the Office for European Integration, explained that Poland's wish to become an EU member is very deep-rooted and took form back in 1989. Mr Pietras then gave an exhaustive overview of the state of advancement of the different chapters in the accession negotiations with the EU. In fact, 20 out of the 31 chapters have already been closed, and of the 11 others two are non-negotiable.

Mr Pietras compared the situation in the area of justice and home affairs, and in particular the protection of the outside EU borders, with that of pharmaceuticals. In both areas, he said, there needs to be a process of confidence building at the end of which all parties should be convinced

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that the institutions of the applicant were capable of carrying out the necessary checks and balances.

Mr Pietras ended by expressing the hope that the accession negotiations with his country could be finalised by the end of 2002, allowing Poland as a first-wave candidate to participate in the elections for the European Parliament in June 2004.

## **HOW TO IMPROVE THE EUROPEAN REGISTRATION SYSTEM**

### *The point of view of the European Parliament*

In her introduction as moderator of the regulator panel, **Mrs Dagmar Roth-Behrendt**, Member of the European Parliament and long-standing member of the EP's Environment Committee, explained that she had always been very interested in health and food matters. She had followed the creation of the EU's marketing authorisation system with great interest and called the centralised procedure a great success and was pleased that the EMEA worked so well.

Mrs Roth-Behrendt referred to the revision of the EU's pharmaceutical legislation as the opportunity to modify the system "to prepare for enlargement to 25 or 27 Member States." Points up for improvement were, for instance:

- The *centralised procedure*, which the Commission is proposing to make compulsory for all new chemical entities. Here different opinions are being expressed.
- *Data exclusivity*, where the Commission is proposing a system of 10 years plus one year if a medicinal product covered by the normal data protection period has developed a new therapeutic indication with an important benefit for the patients. According to Mrs Roth-Behrendt, several models are possible, for instance 10 years plus three years.

#### **"We should have protection of switch data"**

Mrs Roth-Behrendt pleaded with insistence in favour of a data exclusivity period in case significant scientific research is carried out by companies in preparation of a switch from prescription to non-prescription status. "We should have this," she said, "and it would be worthwhile thinking about such a system of data protection."

#### **Topical issues for the self-medication industry**

Among the most topical issues for the self-medication industry, Mrs Roth-Behrendt cited the current discussions on:

- What is a medicinal product and how the distinction between foodstuffs and medicinal products should be made. She said that she had asked both the food and the self-medication industry to resolve this among themselves.

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- The proposed Directive on food supplements which is currently in second reading before the European Parliament
- The proposal on fortified food which has been announced by the Commission.
- The proposal on health claims, where the Parliament would need to look carefully at who would control these claims.

**Parliament in favour of proposal on traditional products**

The Parliament, said Mrs Roth-Behrendt, had since the debates in the early 1990s always supported the position of herbal medicines and had therefore pushed for a proper regulation of these products at the European level. In these attempts, revealed Mrs Roth-Behrendt, Parliament had initially been faced with a lot of opposition. That is why Parliament was so pleased with Commission's recent proposal, supported by the EMEA, to create a separate Committee for Herbal Medicinal Products at the same level as the CPMP and to introduce a simplified marketing authorisation procedure for traditional herbal medicines.

*The point of view of the national authorities*

The panel members from the national authorities were then asked to present their view on the role of the national competent authorities in an enlarged European Union, and with a revised marketing authorisation system.

**Associate Professor Heribert Pittner**, MD, of the Federal Ministry of Social Security and Generations in Austria and the only CPMP members to sit on the EMEA's Working Party for Herbal Medicinal Products explained that in the context of the forthcoming new EU legislation he saw the following important tasks for the national agencies:

- To deal with applications for purely national authorisations
- To nominate experts to the EMEA Committees and Working Parties
- To be the primary body for post-marketing surveillance and pharmacovigilance and to inform other Member States
- To implement urgent safety restrictions.

On the other hand, Prof. Pittner admitted that national agencies needed to accept more readily what was decided at the international level, for instance in the mutual recognition procedure. This is particularly important as it is becoming clear that full harmonisation of SmPCs is not feasible for all medicinal products.

For herbal medicines, national agencies should be ready to accept the so-called "core data" and show more mutual confidence.

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In summary, said Prof. Pittner, it was clear that not all national agencies would in future have sufficient experts to carry out all tasks. It was therefore important for them to recognise that certain activities are better carried out at the international level.

**Dr Fernando García Alonso**, who was appointed shortly after the meeting as the new Director of the Spanish Medicines Agency and who is also a member of the CPMP and Chair of the CPMP Pharmacovigilance Working Party, provided insight into the opinion of the Spanish Presidency on the revision proposals. These views differed in some details from the texts the Commission had put forward.

Thus the Spanish Medicines Agency wanted to remain involved in the evaluation of new chemical entities and supported the idea that for instance only the first product in a new category would have to go through the centralised procedure.

Concerning the mutual recognition procedure, the Presidency agreed with the Commission that serious improvements were needed in the system and in the technical capabilities.

Dr García Alonso concluded that the big challenge was to strengthen the pharmacovigilance system, both in legislation and in practical arrangements. The Commission's proposal to give up the five-yearly renewals would inevitably lead to loss of income for the national agencies and would therefore impose problems in financing some national agencies.

**Associate Professor L'udevit Martinec**, Director of the State Institute for Drug Control in the Slovak Republic agreed with Dr García Alonso that post-marketing surveillance was one of the most important tasks of the national agencies. Moreover, the upgrading of existing dossiers is among the current priorities of agencies in Central and East European candidate countries. In Slovakia, this is an urgent problem, not only for the local industry holding 20% of the market but also for imported products. It is moreover the subject of the March 2002 Cadreac meeting.

The Cadreac countries are already familiar with most aspects of the EU marketing authorisation procedures, which they will have to implement fully from day one upon accession. The Cadreac countries have an agreement to recognise Assessment Reports from the centralised procedure, leading to average approval times from 3-6 months. The Czech and Slovak Republics moreover started a pilot project in 2001 with the mutual recognition procedure. Prof. Martinec fully endorsed the well-established use procedure and expressed support for the proposal on traditional herbal medicines.

**Dr Waldemar Zielinski**, Manager of the Registration Bureau at the Polish Drug Institute, said that his country, with the new Medicines Law that will come into force in April 2002, will have implemented the complete "acquis" in the pharmaceutical area. However, legislation does not always solve all problems. In Dr Zielinski's view, the absence of so-called "soft law" or guidelines implementing these legal provisions was a still somewhat of a problem.

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The main tasks of the Registration Bureau, which will be renamed "Office of Medicinal Products, Medical Devices and Biocides Registration," will be:

- To carry out the marketing authorisation procedures for human and veterinary medicinal products
- To keep the State Register of Medicinal products authorised for usage in Poland
- To develop and update evaluation reports
- To assure the clinical to be conducted according to Good Clinical Practice and to keep the Central Register of Clinical Tests
- To organise the pharmacovigilance and post-marketing surveillance
- To accredit the appropriate clinical research laboratories responsible for other than clinical research concerning public health
- To control and certify Good Laboratory Practice
- To publish a monthly bulletin with all administrative decisions in the field of medicines
- To publish at least once a year a Legal List of authorised for marketing Medicinal Products, with separate lists for human and veterinary use; these lists include the name of medicinal products, its form as well as information on its composition, warnings, pack size, etc.
- To develop and publish the Polish Pharmacopoeia

### ***Update on the CPMP Herbal Medicinal Products Working Party***

The Chair of the CPMP Herbal Medicinal Products Working Party (HMPWP), **Dr Konstantin Keller**, provided an update on the working party's new mandate approved by the EMEA Management Board on 18 December 2001. The working party is now composed of:

- A Chairperson and a Vice-Chairperson elected from amongst the delegates (2 per Member State, who may be accompanied by experts);
- Representatives from EEA-EFTA-States (1 per State, 2001: Norway), European Parliament (2), European Commission;
- Observers from CADREAC (2001: Hungary, Latvia, Poland) and the European Pharmacopoeia
- CVMP and CPMP members may participate.

#### **Mandate**

The HMPWP's mandate is to:

- Facilitate mutual recognition of marketing authorisations in the field of herbal medicinal products minimising CPMP arbitration;
- Create a forum for exchange of experience in the field of herbal medicinal products among member states;
- Provide guidance for competent authorities for the assessment of herbal medicinal products;
- Provide guidance for applicants to marketing authorisations for herbal medicinal products.

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**Outcome of activities**

1. Scientific guidelines on quality, safety and efficacy are adopted by CPMP (CVMP / Quality). Publication takes place on the EMEA website in the folder of the relevant CPMP Working Party (QWP, SWP, EWP) making reference to the work done by the HMPWP. Examples are Guidelines on Quality and Specifications.
2. Scientific guidelines on quality, safety and efficacy not adopted by CPMP (CVMP /quality)
3. Any other herbal specific document. Publication on the EMEA website under a separate window. Note added for clarification:  
"The views presented in this document are those of the HMPWP, which has been created as a forum for exchange of experience in the field of herbal medicinal products. This document is released for the purpose of transparency and has no legal force with respect to CD 2001/83/EC"
4. Texts related to legislative matter or to the NTA. Draft documents circulated first to the EC before being subject to consultation with interested parties. Final documents will be forwarded to the EC.

**Actions following the new mandate**

The term of office of the present HMPWP has ended. A letter has been sent by the EMEA Director to Member States, European Parliament and Observers asking them to nominate / reconfirm their delegates, etc. The first meeting of the new HMPWP is scheduled for 11-12 March 2002, when the election of the Chair and Vice-Chair will take place.

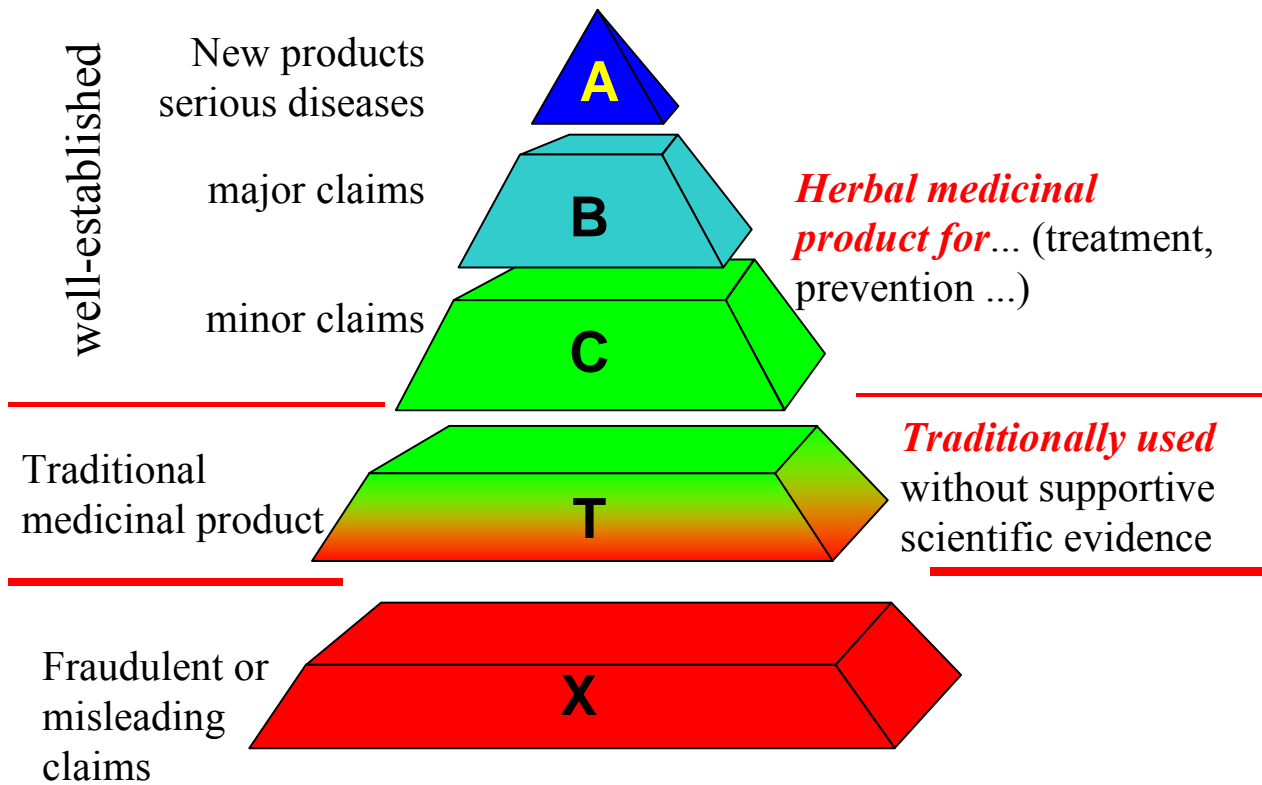
The timetable for activities has been set out in the Work Programme 2002-2003, as follows:

1. Quality-related Guidelines, e.g. "Compilation of general quality questions answered by the HMPWP"
2. Safety Guidelines, e.g. "Note for Guidance on non-clinical testing of herbal drug preparations ..."
3. Pharmacovigilance related issues, e.g. Kava-Kava, Hypericum, etc.
4. Efficacy guidelines, e.g. ESCOP monographs, core data (core SmPCs) for herbal drugs
5. EU Regulatory Activities, e.g.
  - use of ICH common technical document (CTD) for herbal medicinal products;
  - technical advice in preparation of the proposed Directive for traditional herbal medicinal products;
  - concept paper on definition of terms defining the level of evidence required for a certain claim;
  - points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications.

Concerning the last point, Dr Keller showed the following grading of recommendations:

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### Grading of Recommendations



#### Perspectives

Dr Keller concluded by giving the following perspectives on the work of the HMPWP:

- Phase of consolidation
- European legislation / Update of procedures responsibilities of scientific bodies / centres of excellence
- Implementation of expertise
- Implementation of scientific standards
- Exchange of information and transparency of criteria
- Constant update of standards in the light of experiences gathered by competent authorities and applicants.

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## **THE IMPACT OF THE REVISION ON SELF-MEDICATION**

Under the chair of **Prof. Frans Gosselinckx**, Counsellor at the Federal Ministry of Social Affairs, Public Health and Environment in Belgium, the audience was informed about the impact of the revision on classification and switching, as well as on the latest developments in the food area.

### *Classification and advertising of human medicines: the future of OTC products*

#### **The current Community code**

##### ***Classification***

**Mr Nils Behrndt** of the Pharmaceutical Unit, DG Enterprise at the European Commission explained the background to the classification rules in existing EC law. The major provisions are contained in Title VI (Art. 70-75) of Directive 2001/83 (the Community code) laying down two sets of categories for classification:

- obligatory: classification as POM/OTC
- optional: certain subcategories

A product is a prescription-only medicine if the product is "likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision"

For the moment, legal status is not part of the SmPC (Art. 11 of Directive 2001/83), and mutual recognition does not extend to legal status. This means that the legal status of the same product may differ in the Member States.

##### ***Switching***

Concerning the switch from prescription to OTC, there are no explicit provisions other than that the legal status should be checked upon renewal of the marketing authorisation or in case new facts come to light (Art. 74).

A "Guideline on changing the classification for the supply of a medicinal product for human use" was adopted by Pharmaceutical Committee in 1998 and sets out a *common understanding* without any binding legal force:

- explains classification criteria: relevance of information
- describes necessary data (not covered by data protection)

Most consequences of a switch follow from *national* law (e.g. dispensing, price or reimbursement), while certain consequences follow directly from *EC law*, e.g. in the area of advertising.

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### ***Advertising***

Here the major provisions are contained in Title VIII (Art. 86 - 100) of the Community code. It states that advertising includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products (Art. 86§1). There is a strict ban of advertising to general public of prescription-only medicines (Art. 88§1). Further bans may be enacted by the Member States, e.g. in case of reimbursement (Art. 88§3). Certain information activities were not covered (Art. 86§2), e.g. correspondence needed to answer a specific question about a product. In case of a switch, advertising is therefore in principle allowed but depends nevertheless on national legislation

### **Changes proposed in the revision exercise**

#### ***Classification***

The provisions of Title VI on classification will in principle not undergo any major changes. Re-examination of legal status is only foreseen in case of new facts (Art. 74) since the proposal is to make the marketing authorisation valid infinitely.

Proposed changes to Art. 11 on the SmPC stipulate that the legal status will now become part of the SmPC (new point 10 of Art. 11). This means that legal status will be part of the mutual recognition procedure and that the legal status will be harmonised in the Community at the end of a mutual recognition procedure.

#### ***Switching***

There is nothing explicitly stipulated. However, it is proposed to grant one year additional data protection where a new therapeutic indication with significant clinical benefit in comparison to existing indications is authorised (Art. 10§1).

#### ***Advertising***

The only proposed change impacting OTC medicines is that advertising to the general public of certain therapeutic indications such as tuberculosis or cancer – which was so far strictly banned irrespective of legal status (Art. 88§2) – will be lifted (new Art. 88§3). The Commission has also made proposals concerning enhanced information on prescription-only medicines (proposed Art. 88§2).

### **Conclusions**

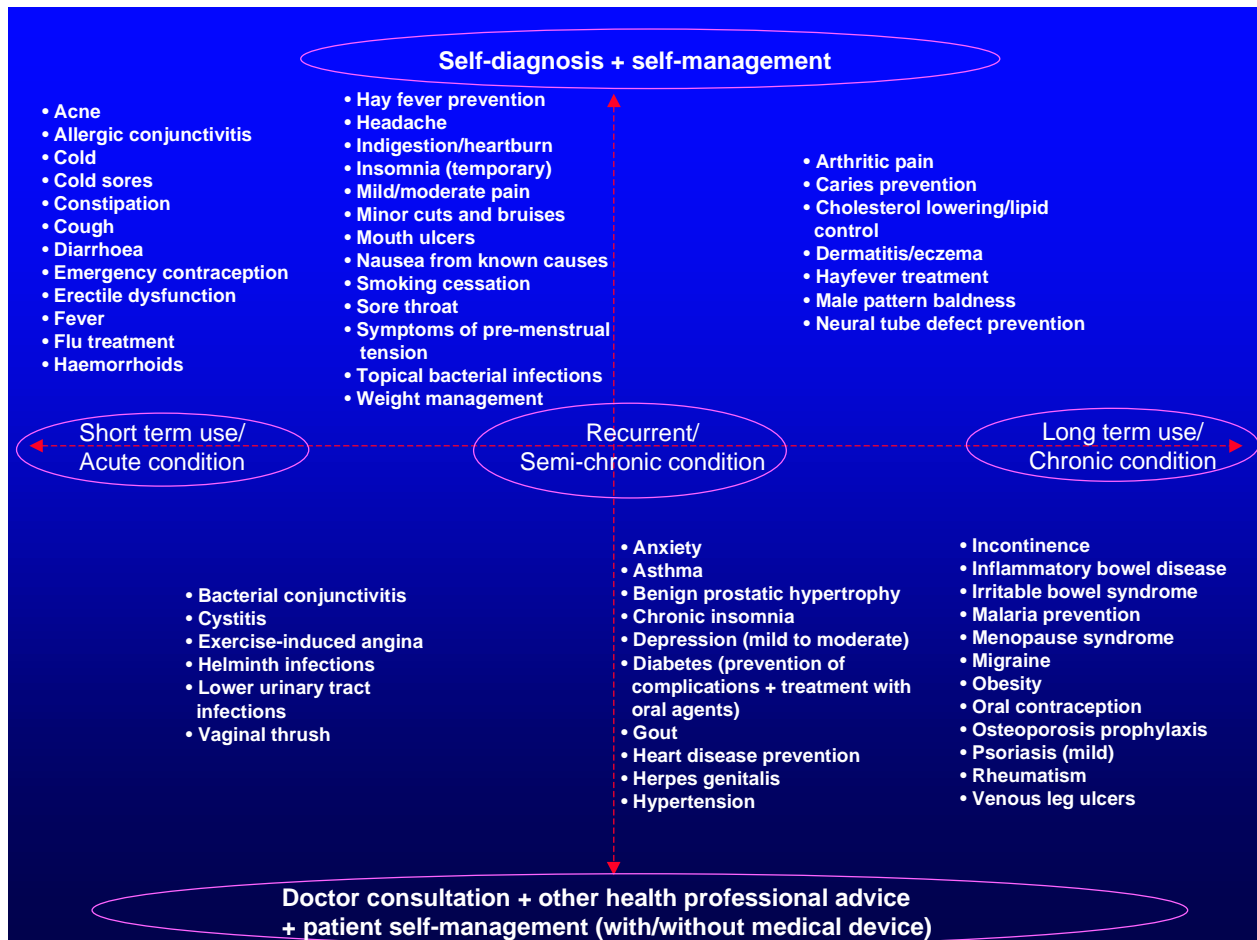
Responsibility on the situation of OTC products is shared between EU and Member State competencies. In the current frame there are harmonised criteria for classification, but no harmonised status. The consequences of a switch depend to a large extent on national legislation, in particular with regard to price, reimbursement and advertising.

In the proposed frame, there is an important step forward to harmonise classification, there is a new provision on data protection and some clarification and change to information/advertising. However, Member States retain important competencies in the areas of pricing, reimbursement and advertising.

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*How to move medicines from prescription to non-prescription status*

Mr Jeremy Mean of the Medicines Control Agency's Post-Licensing Division in the United Kingdom provided background information to the recently completed consultation in the United Kingdom to promote the move of medicines from prescription to non-prescription status. He said that this initiative was delivering what people expect in today's world and in keeping with patient's attitudes and expectations. It also tied in closely with the EU-wide research project sponsored by the European Commission on new indications for self-medication and related information needs. This project had led to the following chart, said Mr Mean, where the objective was to move the vertical axis to the right and the horizontal axis to the bottom.

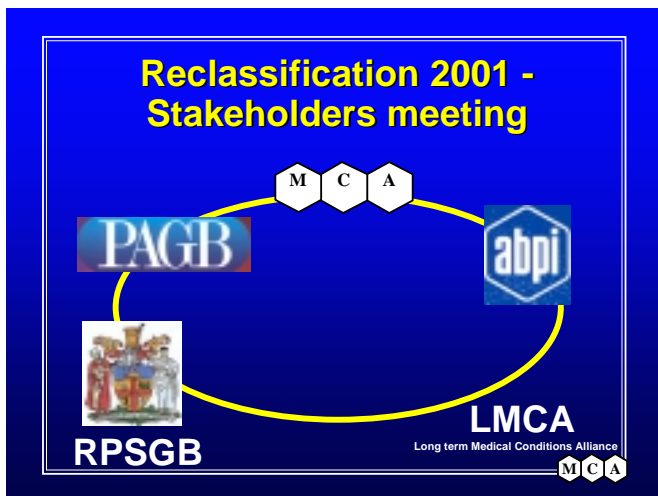


Significant developments in this respect were:

- Self-medication for prophylaxis
- Emerging understanding of 'lifestyle' health issues smoking, alcohol, obesity, impotence
- The 'expert' patient concept.

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The UK government had said in the NHS Plan that more OTC medicines should be available by 2002. It therefore sought stakeholder consensus to stimulate POM to P switching through a work plan centred on patients and focussing on 3 key work streams and commenced in March 2001. The area of therapeutic categories was examined under the guidance of the RPSGB; information and training was led by PAGB; and process and policy was supervised by the MCA.



For self-medication to move forward, said Mr Mean, strategic success factors include:

- Appropriate change in regulatory framework
- New industry approach - product life-cycle includes reclassification where appropriate
- Stakeholder consensus in new therapeutic areas
- High quality, accessible information and training

Certain changes to facilitate the move to self-medication were already proposed during the 2001 review, e.g.

- Improvement in patient information leaflets, where more flexibility is needed
- Application of one-year exclusivity for new indication bringing 'significant clinical benefit' to reclassification applications.

Mr Mean continued that the new industry approach is likely to mean that marketing authorisation holders will:

- Anticipate reclassification as part of product life-cycle link to periodic safety updates (if renewal lost)?
- Obtain data in OTC-type environments
- Work with stakeholders to achieve consensus on reclassification parameters in particular therapeutic areas.

The information and training needs examined established that reclassification was to be supported by:

- Core information accessible to all stakeholders
- User-tested patient information

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- Record keeping and shared access
  - Personalised programme for patient self-management where appropriate.
- Maybe a specialist pharmacy status would develop as a result.

Mr Mean concluded that the checklist to make a switch successful included:

- Stakeholder consensus
- Define education and training needs
- List of potential switch candidates
- Move to product based switching
- Dedicated expert committee for switching
- Market exclusivity for innovative switches
- Transparent switch procedure
- Switched products can be advertised to the public
- Switch products should not lose reimbursement
- Switch only following external application
- A positive approach by regulators.

*Health claims and food supplements*  
*The borderline between medicines and food*

**Mr Patrick Deboyser**, who is Head of Unit, Food law and biotechnology at the European Commission's Directorate-General Health and Consumer Protection, provided some background on the Commission's current initiatives in the area of food legislation. He said that there is growing acceptance worldwide that there is a (positive or negative) link between diet and lifestyle on the one hand and risk factors of several chronic diseases on the other. However, current EU legislation does not permit the use in food labelling of claims related to the prevention of disease or to the reduction of disease risk, regardless of whether such claims could be substantiated. At the same time, European consumers are increasingly interested in obtaining clear, consistent and reliable information on which to base their decisions about what they eat. However, nutrition claims and functional claims on food labels are not regulated at EU level.

In light of this situation, continued Mr Deboyser, people are sometimes criticising the EU's current food and pharmaceutical legislation, as a barrier to the development of a new generation of food products, the so-called "functional foods" or "nutraceuticals," which are alleged to provide clear nutritional benefits or possess well-established physiological functions. According to the food industry, this undermines Europe's research into an important cluster of innovation and deprives consumers of important advances in nutritional and medical science.

Mr Deboyser wondered whether this criticism was justified. He explained that the current EU food legislation provides a regulatory framework for the placing on the market of food for special medical purposes and novel foods and novel food ingredients. Moreover, legislation is being developed to provide a framework for food supplements and food fortification.

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### **Food claims**

In the area of food claims, Mr Deboyser explained that the Commission is of the opinion that Directive 2000/13 on the labelling, presentation and advertising of foodstuffs should be amended to distinguish "disease prevention" claims from "disease risk reduction" claims. After this, the Commission aims to allow "disease risk reduction" claims. However, this is not for the immediate future (see the Commission's *White Paper on Food Safety*). Mr Deboyser said that the priority is to enable consumers to make up their own minds about the health value of a food, in the context of their total diet. Although it can be useful to highlight an aspect of a food's nutritional value, to be meaningful for consumers nutrition claims should be consistent for all products. They should preferably be defined in terms of quantitative thresholds, and substantiated on the packaging by reference to the composition and content of the food. Functional claims referring to the well-established and generally accepted role of a nutrient in growth, development and normal physiological functions of the body should only be allowed where they can be justified and substantiated.

### **Commission's work programme**

Apart of the area of food claims, Mr Deboyser summarised the rest of the Commission's work programme, as follows:

#### Accomplished:

- Lay down the General Principles of Food Law
- Set up a European Food Safety Authority
- Streamline "food safety" procedures

#### Ongoing:

- Legislate on "food supplements"
- Improve food labelling
- Reform genetically modified food approval and labelling

#### In the pipeline:

- Legislate on "food fortification"
- Reform "novel food" approval and labelling

#### For the future:

- Reform "nutrition labelling"
- Evaluate / modernise "food labelling."

### **Borderline medicines / food**

Mr Deboyser explained that up to very recently, there was no definition of "food" in Community law. This definition should be independent of that of "medicinal product," he said, and the latter should not be used to resolve the boundary between the two.

With the final adoption of *Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety* two days before the meeting, there is now a definition of "food". This definition refers to the definition of "medicinal product" which is and will remain instrumental in defining the boundary between "food" and "medicinal products". Mr Deboyser further mentioned that the definition of

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"medicinal product" is currently being looked at in the framework of the revision of the EU's pharmaceutical legislation.

### *Conclusions*

In his closing address, AESGP Director General **Dr Hubertus Cranz** pointed out that the issues related to non-prescription medicines in the enlargement countries and the EU countries were not fundamentally different. What all parties were looking for were:

- Efficient national marketing authorisation procedures
- A well functioning mutual recognition system
- Extension of the centralised procedure to innovative non-prescription medicines.

Much work remained to be done in the area of marketing authorisation, though, said Dr Cranz. Areas needing particular attention included improvement of the mutual recognition procedure and proper implementation in the Member States of the Directive on well-established use adopted in 1999. This instrument is an important aid in the update of old dossiers. Dr Cranz also expressed AESGP's appreciation for the proposed directive on traditional herbal medicinal products, which he called a useful new initiative that would provide manufacturers with the missing tool to bring their products to market all over Europe. However, some clarifications were still needed on this proposal.

The main issues for the self-medication industry were summarised as follows:

- To provide consumer understandable labelling;
- To allow public advertising for all non-prescription medicines in all media;
- To leave manufacturers free to set their prices at least for non-reimbursed medicines
- To promote a switching policy that would encourage manufacturers to initiate more switches. Dr Cranz stressed that the AESGP project for the European Commission had as objective to create a wider understanding and support for indications of non-prescription medicines covering long-term diseases based if necessary on an initial diagnosis by a medical doctor and to define related information needs. The recent initiatives in the United Kingdom seem to be very much in line with this project.
- To deepen the understanding for the importance of tradenames as a crucial determinant of success in the self-medication sector.

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*AESGP celebrates founding of the  
Polish Association of the Self-Medication Industry (PASMI)*



Pictured at the reception on 30 January 2002 are (from left to right):  
Mr Jaček Węgrzyk, Mr Michael Kloss, Dr Alessandro Banchi, Dr Paul Weissenberg, Mr Olivier Quillet and  
Mr Trevor Atkinson

The reception preceding this year's AESGP Members' Meeting was the occasion for participants in the meeting and officials to celebrate the founding of the Polish Association of the Self-Medication Industry (PASMI).

Dr Paul Weissenberg, Director, Single market, management & legislation for consumer goods, Directorate-General Enterprise, European Commission, joined AESGP President Dr Alessandro Banchi in congratulating the Polish self-medication industry with this accomplishment and wished the founding members of the new association the best of luck in their endeavours.