



**OTC MEDICINES:  
THE ROLE OF GOOD CLASSIFICATION PRACTICES  
IN PROMOTING MEDICATION SAFETY  
AND ACCESSIBILITY IN EUROPE**

**REPORT**

**VENUE: HOTEL DUBROVNIK, ZAGREB (CROATIA)**

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## Expert Workshop Principal Conclusions and Recommendations

The Expert Workshop “Over-The-Counter (OTC) Medicines: The Role of Good Classification Practices in Promoting Medication Safety and Accessibility in Europe” brought together national and European health authorities, healthcare professionals, patients’ organisations, the pharmaceutical industry and pharmaceutical wholesalers to explain the mandate and work of the Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO), to collect feedback from different stakeholders on the main themes of the event, and progress towards harmonisation of good classification practices for OTC medicines, thus promoting safe and accessible medicines for patients in Europe.

The following is a summary of the main conclusions and recommendations grouped according to the workshop’s three themes.

### *Patients’ Awareness and Education with respect to Safe and Appropriate Use of Medicines, with Special Attention to OTC Medicines*

- Importance of patient-centred healthcare: by definition, healthcare should be focused on patients. To ensure that healthcare remains true to this central purpose, proactive collaboration among different stakeholders (e.g. national and European health authorities, pharmaceutical industry, and healthcare professionals) is strongly encouraged. In particular, a concerted effort should be made to deliver clear, easy-to-understand, reliable and neutral information on both prescription and non-prescription medicines. This will enable patients to take responsible decisions and use their treatments safely and effectively.

- CD-P-PH/PHO’s role: the CD-P-PH/PHO is advised to continue to take into account all aspects pertaining to health literacy when issuing recommendations for the classification of medicines. In particular, when recommending a switch from prescription to OTC status, special attention should be paid to the nature of the substance, local levels of health literacy and the actual needs of different countries. If necessary and with a view to fulfilling the above objective, consultative processes involving both patient and healthcare professional organisations in the work of the CD-P-PH/PHO could be launched.

### *Distance Trade of Medicinal Products and New Modes of Medicinal Product Distribution*

- Novelty of the phenomenon: distance trading and, more specifically, online pharmacies are still a rather new phenomenon in some of the Council of Europe (CoE) member states. As a consequence, in spite of the entry into force of European Union (EU) Directive 2011/62/EU (which, it should be noted, only applies in the European Economic Area (EEA)), the picture of online drug trading remains fragmented and a number of questions about regulatory and practical aspects of the delivery of pharmacy services at a distance are as yet unanswered (e.g. legal framework in the CoE member states, conditions of sale to member states in which the legislation is different, safe access to medicines, information about medicines, etc.).

- Internet-based healthcare delivery: safeguarding consumers and ensuring the quality of medicines that are sold via internet is both complex and difficult. While distance selling certainly has advantages for patients (e.g. round the clock access to medicines, large number of products available, privacy, convenience, etc.), it may also place them at risk (e.g. infiltration of the legitimate supply chain, inappropriate use of medicines, limited opportunity for advice, etc.). With a view to protecting public health and individual consumers, all stakeholders are encouraged to cooperate to ensure that patients are aware of the risks associated with distance selling of medicinal products, that the quality of healthcare products is guaranteed, and that patients have access to objective, accurate and transparent information. Finally, further studies are recommended to gather available evidence on the

phenomenon of distance trading of medicinal products, patients' knowledge of this new trend and their needs, and strategies to guarantee the quality, safety and efficacy of both medicinal products and the information pertaining to them.

- CD-P-PH/PHO's role: at this stage, the CD-P-PH/PHO is advised not to issue an additional recommendation on whether a medicinal product containing a given active substance should or should not be sold over the internet. However, when issuing a recommendation on the conditions for classification and supply of medicines, the CD-P-PH/PHO should take into consideration the fact that, in some CoE member states, certain medicinal products are available online.

In addition, given that the *Melclass* database could assist relevant stakeholders in verifying the terms and conditions under which a medicine is authorised for supply with or without a prescription in a given country in Europe, the Committee of Experts is invited to continue to maintain and regularly update the aforementioned database; if applicable, all stakeholders involved in medicine classification (e.g. health authorities, pharmaceutical industry, healthcare professionals, patients) could be invited to support the *Melclass* database by providing reliable and up-to-date information.

Finally, the CD-P-PH/PHO is encouraged to recirculate the survey administered in 2011, focusing on new trends in the modes of supply of medicines and their impact on good classification practices, in order to obtain a state-of-the-art overview of the situation.

#### *Possible Regulations of Supply Modes of OTC Medicines into "Pharmacy Only Medicines" and "General Sales Medicines"*

- "Pharmacy Only Medicines" and "General Sales Medicines": "Pharmacy Only Medicines" can only be sold in pharmacies, under the supervision of a pharmacist, whereas "General Sales Medicines" can be sold from retail outlets other than registered pharmacies, such as supermarkets and petrol stations, without the supervision of a qualified healthcare professional. Liberalisation of OTC medicine sales outside pharmacies is currently under discussion in a number of countries in Europe. It is the national authorities that are competent to decide whether or not to allow the sale of medicines outside pharmacies and several criteria are usually taken into account (e.g. health system, cultural background, nature of the substance, health literacy, and economic considerations). Nevertheless, when deciding to allow the sale of certain medicines outside pharmacies, health authorities are invited to also take into account protection, promotion and maintenance of the safety and quality of medicines for patients.

- CD-P-PH/PHO's role: it must be borne in mind that the Committee of Experts' recommendations on the classification of substances are not mandatory and that it is out of the CD-P-PH/PHO's scope to recommend one approach over another.

At this stage, the CD-P-PH/PHO is advised not to issue recommendations which further subdivide OTC status into "Pharmacy Only Medicine" and "General Sales Medicine". However, given that the sale of OTC medicines outside pharmacies could become more and more widespread in Europe, the CD-P-PH/PHO is encouraged to monitor the above trend as well as its potential impact on medicinal product safety and accessibility.

The Committee of Experts PHO is also invited to include in the *Melclass* database the distinction between "Pharmacy Only Medicine" and "General Sales Medicine" in countries where sale of OTC medicines is permitted outside pharmacies.

Lastly, the Committee of Experts is invited to consider not restricting access to its database and encouraging the use of *Melclass* by the general public as well.

## Introductory Note

This report provides a short summary of the workshop co-organised by the Council of Europe's European Directorate for the Quality of Medicines and HealthCare (EDQM) and the Croatian Agency for Medicinal Products and Medical Devices (HALMED) on 20-21 November 2014.

The workshop was held in Zagreb (Croatia) and was attended by a wide range of participants, including representatives of national and European competent drug authorities, ministries of health, patients' organisations, the pharmaceutical industry, pharmaceutical wholesalers and healthcare professionals.

The workshop was designed to enable participants to expand their knowledge and familiarise themselves with the work of the Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO), which issues recommendations to health authorities of European Pharmacopoeia Members<sup>1</sup> for the classification of medicines on an annual basis and establishes good classification practices.

## Workshop Background

The availability of medicines with or without a medical prescription has implications for patient safety, accessibility of medicines to patients and responsible management of health care expenditure.

The decision on prescription status and related supply conditions is a core competency of national health authorities. The conditions for the supply of medicines vary considerably in the Council of Europe member states, due to the fact that the provisions are interpreted and implemented differently at national level and that important additional classification criteria are not harmonised.

The Committee of Experts CD-P-PH/PHO is co-ordinated by the EDQM (Council of Europe) and its working programme is based on Committee of Ministers Resolution ResAP(2007)1 on the classification of medicines as regards their supply<sup>2</sup>.

In its work, the CD-P-PH/PHO focuses on the promotion of public health and uses scientific approaches and methods, taking into account national assessments of direct and indirect risks which may occur under normal treatment conditions and under medical surveillance and as a result of foreseeable misuse or abuse of medicines.

Every year, the CD-P-PH/PHO issues recommendations to health authorities of CoE member states (EU and non-EU member states) regarding the classification of medicines, and establishes good classification practices<sup>3</sup>.

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<sup>1</sup> *European Pharmacopoeia Members*: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, "The Former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom, and the European Union

*European Pharmacopoeia Observers*: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Israel, Kazakhstan, Madagascar, Malaysia, Moldova, Morocco, Republic of Guinea, the Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, the United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

<sup>2</sup> <http://go.edqm.eu/ResAP20071>

<sup>3</sup> <http://go.edqm.eu/PHO>

The recommendations are also intended for use by the pharmaceutical industry and legal commercial operators of the mail order trade.

The classification criteria set out in the CoE Resolution ResAP(2007)1 and its previous versions have been taken over by EU Directives 92/26/CEE and 2001/83/EC (art 70-75). Directive 2001/83/EC refers to the Council of Europe in its whereas 32: “It is therefore appropriate, as an initial step, to harmonise the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe”.

The working programme of the CD-P-PH/PHO is carried out with the awareness that:

- the current European Union directives foresee only two obligatory classification categories (prescription and non-prescription);
- important additional classifications applied by the Council of Europe resolutions in this field are not considered as mandatory;
- no other peremptory lists on the conditions of use for medicines classified as prescription or non-prescription are currently available;
- the classification status of medicines authorised in the EEA via the national and mutual recognition procedures remains a national competency of the member states. This was confirmed in EU Directive 2004/27/EC.

The CD-P-PH/PHO supervises the *Melclass* database, hosted by the EDQM<sup>4</sup>, which stores national information about the classification and supply conditions of medicines as well as the annually revised appendices to Resolution ResAP(2007)1. The information is publicly available. Other institutions, such as the European Medicines Agency (EMA), the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI), and World Health Organization (WHO) Centre for Drug Statistics Methodology, provide information about the classification and supply status of medicines authorised in the European Union via the centralised, decentralised and mutual recognition procedures for marketing authorisation. Recommendations about 2400 medicines are published in the *Melclass* database.

Providing a platform for dialogue and consensus-building on the conditions for the supply of medicines in Europe as facilitated by Council of Europe Committee of Ministers Resolution ResAP(2007)1, the CD-P-PH/PHO promotes patient safety and, where appropriate, access to medicines without a prescription across Europe, thereby fostering public health and encouraging responsible management of healthcare resources.

## **Workshop Aims**

The workshop was focussed on:

- Understanding and learning about levels of patient awareness, education and health literacy with respect to the safe and appropriate use of OTC medications;
- Learning about new modes of medicinal product distribution, with special attention to distance trading of medicines;

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<sup>4</sup> <http://www.edqm.eu/melclass>

- Examining the possible subdivision of OTC medicine supply modes into “Pharmacy-Only medicines” and “General Sales List medicines (GSL)”;
- Providing a platform for discussion of the regulatory, scientific and societal dimensions of the above topics;
- Identifying key elements of good medicine classification practices related to the above topics, taking into account the regulatory, scientific and societal dimensions;
- Confirming and promoting the CD-P-PH/PHO’s results as well as strengthening the CD-P-PH/PHO’s role and function in the European context, with a view to enhancing the safety and accessibility of medicines in Europe.

## **Workshop Working Methods**

Keynote speakers, representing different stakeholder groups (health authorities; pharmaceutical industry; pharmaceutical wholesalers; healthcare professionals and patient representatives), presented the existing situation at European and national level and shared their views on the workshop topics.

Keynote presentations were followed by parallel breakout sessions intended to identify key elements of good medicine classification practices and develop specific contributions to the CD-P-PH/PHO’s work programme and activities related to the workshop topics. The main outcomes of the breakout sessions were summarised in the plenary session.

Key outputs from the workshop were summed up on the closing day.

## **Workshop Programme, Press Release and Presentations**

The workshop programme, press release and presentations are available on the EDQM’s website, under Publications, Products and Services; Publications; Proceedings of International Conferences; 20-21 November 2014, Zagreb, Croatia (link: <http://go.edqm.eu/proceedings>).

## Summary of Breakout Sessions

### 1. Patients' Awareness and Education with respect to Safe and Appropriate Use of Medicines, with Special Attention to OTC Medicines

#### Breakout Session "Regulatory Dimension"

Moderators: Ms Frias (EMA) and Ms Macolic-Sarinic (HALMED)

The following points were highlighted during this breakout session:

##### *Patient engagement*

Patient engagement is valuable both nationally and where centrally authorised products are concerned.

At national level it is important to have the local patient perspective. National decisions should be tailored to the local situation and reflect patients' needs and circumstances. Issues such as health literacy, local language and healthcare systems are relevant to classification decisions and should be taken into account during the decision-making process.

Where centrally-authorised products are concerned, the EMA mainly consults patients about medicines for serious diseases or when an innovative reclassification/switch is proposed. In the OTC sector, their opinion is most frequently sought on herbal medicines.

##### *Successful reclassification*

Attention is drawn to the report of the EU Working Group on Promoting Good Governance of Non-prescription Drugs in Europe<sup>5</sup>, where the circumstances that enhance the likelihood of a successful reclassification/switch are described. In particular, the above report points out that the agreement of all stakeholders is important. The prescriber must support the switch, it must be practical for the pharmacist to implement if the medicine is proposed for OTC sale and supply, and the patient must be capable of understanding what constitutes safe and appropriate use of the medicine in the pharmacy-only or general sales list setting.

##### *Role of the CD-P-PH/PHO and EMA*

The role of the Committee of Experts CD-P-PH/PHO is to provide information that will assist patients/consumers, industry, and regulators with classification decisions. The decisions represent good practice but are not mandatory unless or until they are incorporated into national law.

The EMA classifies medicines authorised through the centralised procedure as prescription or OTC, but the decision as to whether the medicine should be available from pharmacies only or on general sale is up to the member state and should reflect the national situation.

#### Breakout Session "Industrial Dimension"

Moderators: Mr Dziekan (WSMI) and Mr Morris (HPRA)

The following points were highlighted during this breakout session:

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<sup>5</sup> <http://goo.gl/aTDtmG>

### *Role of healthcare professionals*

Healthcare professionals can help patients decrease the risks related to medicines and get the maximum benefits from their treatments. In particular, both physicians and pharmacists can provide leadership and support for safe and appropriate drug use. However, this is only possible if patients inform their healthcare providers about the medicines they are using. Inter-professional communication about patients' medicines is also to be encouraged.

Patient engagement is to be supported and this in turn requires political will. National self-care policies are necessary, an example being national self-care week in the United Kingdom. This must be underpinned by more accurate information for patients and national policies on health literacy. Many patients today suffer from chronic or non-communicable diseases and this is challenging in terms of communication to patients and the promotion of health literacy. This includes patients taking OTC medicines such as pain killers and cold remedies.

### *Information sources*

Information on OTC products should be clear, reliable, independent and available to all.

In general, the patient information leaflet (PIL) is necessary for the safe use of medicines, but does not tell patients all they need to know about how to take their medicine, its potential side effects and the precautions for use required. Direct counselling and support from healthcare professionals is highly recommended.

Advertisement may also influence patients' decisions on the selection of OTC products. Medicine advertisements should be closely monitored in order to ensure that they are truthful and are not misleading or unfair. In this respect, it is recommended that advertisements reflect the information that is contained in the PIL which, in turn, should be unbiased, evidence-based, and presented in a clear, understandable and easily-readable way.

### *Role of the CD-P-PH/PHO*

The CD-P-PH/PHO should continue to coordinate the updates of the *Melclass* database, presenting the classification status of medicines in the Council of Europe member states. However, the CD-P-PH/PHO should also consider adding more informative details for patients into the *Melclass* database and promote its use by the general public.

### **Breakout Session “Social Dimension”**

Moderators: Ms Kreso (Croatian Alliance for Rare Diseases), Mr Hanzevacki (Health Center Zagreb-west), and Ms Hadjihamza (Government of the Republic of Macedonia Ministry of Health)

The following points were highlighted during this breakout session:

### *Role of healthcare professionals*

Both physicians and pharmacists play an important role in raising patient awareness of safe and appropriate use of OTC medications. On the one hand, physicians should stay abreast of the trends in OTC medicines usage patterns as well as the risks associated with incorrect use of OTC drugs, instruct their patients on the safe and appropriate disposal of all types of medicines, and routinely incorporate discussions on OTC drugs into medical appointments. On the other hand, pharmacists should provide clear information on OTC treatments and usage, assist patients in the selection of appropriate drug therapies, provide guidance on the circumstances under which a physician should be consulted before



patients start self-medicating, and promote the safe, appropriate, effective and responsible use of all medications.

Each of these efforts will help patients get the maximum benefit out of their OTC treatments while minimizing the risks of misuse.

### *Information sources*

Information on OTC medicines is provided to patients through different channels (e.g. healthcare professionals, PILs, pharmaceutical industry). In general, there is a clear need for better access to objective and unambiguous sources of information instructing patients on the efficacy, safety and cost of OTC treatments.

### *Health literacy*

Broadly speaking, patients' health literacy seems to be rather limited; therefore, there is a need to address the gap between the health information currently available and consumers' ability to understand and use this information to make safe and appropriate decisions.

The following strategies were proposed to address this issue:

- Health authorities should make health information more widely available and easily usable;
- Health professionals should be educated to become better communicators;
- Health literacy skills should be increased among both children and adults, and health literacy should be integrated into children's education programs;
- Health literacy incentives should involve all stakeholders from all relevant sectors and cooperation among these stakeholders should be strongly encouraged.

### *Role of the CD-P-PH/PHO*

Health literacy should remain one of the core criteria for medicine classification and should be carefully considered when issuing a medication classification status recommendation.

The CD-P-PH/PHO should continue to promote high quality, safe, and accessible medications. In order to do so, regular consultations and active engagement with patient organisations should be considered.

Lastly, more broadly speaking, the EDQM is encouraged to continue its efforts to improve the rational use of medicines, prevent inappropriate drug use, optimise treatment outcomes, and contribute to efficient and effective use of resources. In this context, reference was made to the mission and work of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)<sup>6</sup>. In particular, attention was drawn to the CD-P-PH/PC's active contribution to advancing patient-centred care and enhancing healthcare professionals' communication and cooperation for the benefit of patients and enhanced responsible use of medications.

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<sup>6</sup> <http://go.edqm.eu/PC>

## **2. Distance Trade of Medicinal Products and New Modes of Medicinal Product Distribution**

### **Breakout Session “Legal Dimension”**

Moderators: Ms Escribano Romero (AEMPS) and Mr Pongratz (AGES)

The following points were highlighted during this breakout session:

#### *Legislation*

To date, legislation concerning distance trade of medicinal products is limited in Europe. Therefore, further development of policies, plans and legislation that regulate sale at a distance of medicines is needed. While the entry into force of EU Directive 2011/62/EU could be seen as a legal instrument that resolves some of the current concerns across different countries in Europe, it should be borne in mind that this directive only applies in EEA member states and, therefore, in only some of the Council of Europe member states. Furthermore, different legal provisions could be in force in the different European countries, which may not be fully in line with those of EU Directive 2011/62/EU.

#### *Impact of distance trade of medicinal products on classification practices*

It was recalled that in 2011 the CD-P-PH/PHO had circulated a questionnaire focusing on the implications of electronic prescribing and new modes of medicine supply (e.g. e-pharmacies and non-pharmacy-outlets) on classification practices in the CoE member states. The Committee of Experts CD-P-PH/PHO was encouraged to carry out this survey again in order to keep abreast of any relevant developments that may have occurred in the member states since 2011 and which could have an impact on classification decisions. The survey outcomes, in turn, could support the CD-P-PH/PHO in the classification process and contribute to ensuring public health protection, and the safe and effective use of medicinal products.

#### *Role of the CD-P-PH/PHO*

The *Melclass* database could serve as a reference tool to verify the classification status of medications in the different European countries. Therefore, the CD-P-PH/PHO is encouraged to actively work towards the completion of this database and ensure that the data are kept as state-of-the-art as possible.

### **Breakout Session “Regulatory Dimension”**

Moderators: Mr Chiavoni (AIFA) and Ms Badoi (ANM)

The following points were highlighted during this breakout session:

#### *Sale at a distance*

Distance selling of medicinal products is still a relatively new mode of distribution.

EU Directive 2011/62/EU introduces tougher rules to improve the protection of public health with new harmonised measures at European level, which ensure that medicines are safe and trade in medicines is rigorously controlled.

In spite of the entry into force of the above directive, initiatives and provisions are still needed, at national and international level, to build a clearer picture of distance selling practices, clearly assess the benefits and risks for patients, and ensure the quality of online healthcare.

### *Classification status*

As soon as EU Directive 2011/62/EU is fully transposed in the EEA member states' national law, differences between member states in terms of the classification of medicinal products and the conditions for their supply could increase the number of applications for switches from prescription to OTC status. Health authorities should carefully evaluate such applications in accordance with national guidelines and legislation, and ensure that any such changes do not adversely affect public health or compromise the safe and effective use of medicinal products.

### *Counterfeit medicines*

Illegal sale of medicinal products via internet poses significant risks to public health. To date, patient's awareness and knowledge of counterfeit medicines still appears to be limited. In order to safeguard and improve the quality of online healthcare, initiatives should be set up to provide legal certainty to business and citizens, heighten awareness of the risks related to counterfeit medicinal products supplied via internet, and guarantee the quality, efficacy and safety of medicinal products sold at a distance.

### **Breakout Session “Social Dimension”**

Moderators: Ms Groves (IAPO), Mr Gritschneider (EAMSP) and Ms Meissner-Wantuch (Polish Ministry of Health)

The following points were highlighted during this breakout session:

#### *Patient awareness and needs*

Online pharmacies can be beneficial to patients (e.g. privacy, easy access to information, easy purchase of medications), but can also have numerous disadvantages (e.g. lack of patient-healthcare professional interaction, misdiagnosis, inappropriate use of medicines). In spite of the growth of this new mode of medication distribution, no clear and consistent information seems to be available to patients concerning the sale at a distance of medicinal products and its related risks. In particular, it seems that patients are not fully aware that products sold by online pharmacies may not have the same composition and quality as those supplied by community pharmacies and that the information they are given about these treatments may not be correct or appropriate.

In view of the above concerns, more research is recommended in order to better understand patients' needs with regard to sale at a distance of medicinal products as well as their awareness of its attendant risks, and to ensure that safe and high-quality medications are provided together with clear and comprehensible instructions on the careful and appropriate use of the purchased products.

Finally, to enhance the benefits and minimize the risks of online pharmacies, harmonised laws regulating the phenomenon, not only at the European level but also internationally, are strongly recommended.

#### *Role of the CD-P-PH/PHO*

The *Melclass* database contains non-binding recommendations for the legal classification of medicines. Nevertheless, the above database could be used at e-pharmacy level to verify the legal status of a medication in CoE member states.

In addition, when issuing recommendations on the classification of medicines, the CD-P-PH/PHO should take into consideration the fact that certain products could be sold over the internet and make sure that, if this is the case, its advice safeguards the appropriate and good use of medicines.

### **3. Possible Regulations of Supply Modes of OTC Medicines into Pharmacy Only Medicines and General Sales Medicines**

#### **Breakout Session “Regulatory Dimension”**

Moderators: Ms Williams (MHRA) and Ms Hadjihamza (Government of the Republic of Macedonia Ministry of Health)

The following points were highlighted during this breakout session:

##### *GSL sales*

Where member states have a GSL category of medicines, it would be useful to have national information about the medicines which fall into this category, such as the definition and criteria for GSL classification, a list of GSL products, the decision-making process by which GSL classification is approved and the framework in which GSL medicines are available on the market.

Easier access to this information would be of interest to other regulatory agencies and stakeholders (e.g. healthcare professionals and patients).

##### *Health literacy*

Information about GSL medicines available in a member state should be readily available to members of the public to promote easier access to medicines.

In general, people using non-prescription medicines might have different levels of knowledge and understanding of self-medication. Therefore, PILs should provide high quality, consistent and easily-accessible information in order to help patients make the appropriate choices. In addition, the information provided should truly meet patients’ needs and, especially in case of GSL medicines, should convey key details for the safe and effective use of the product, as well.

##### *Role of the CD-P-PH/PHO*

Information about the supply of GSL medicines could be collected from relevant member states by the CD-P-PH/PHO and included on the *Melclass* database area of the website, for example in the form of a hyperlink to the member state’s website, if feasible.

More generally, the EDQM website publishes useful information about the activities of the CD-P-PH/PHO and the *Melclass* database; consideration could be given to including a feedback form for comments on substances and/or corrections to the database. This could facilitate the exchange of information between the CD-P-PH/PHO and other stakeholders around the *Melclass* database, and help make the dataset as complete and useful as possible.

#### **Breakout Session “Industrial Dimension”**

Moderators: Mr Cranz (AESGP), Ms Derecque-Pois (GIRP) and Mr Chiavoni (AIFA)

The following points were highlighted during this breakout session:

#### *GSL sales*

Concerns were raised about the safety of the distribution of OTC medicines without the assistance of a pharmacist (i.e. GSL medications). In particular, attention was drawn to the following risks: sale of illegal and/or counterfeit medicines; spread of poor-quality medicines before adequate detection and intervention; failure to guarantee appropriate drug safety monitoring (pharmacovigilance); difficulties in ensuring prompt batch withdrawals; no face-to-face patient counselling.

Industry representatives reiterated their willingness to continue their collaboration with national competent authorities in order to ensure the safe and proper use of medications and public health protection.

Finally, it was underlined that the classification of medicines as regards their supply is a core competency of national health authorities; therefore, the final decision about the classification of OTC products into pharmacy-only or GSL medicines is taken by individual member states.

#### *Health literacy*

It was pointed out that, in some European countries, patients have higher levels of health literacy and, consequently, are able to make more informed decisions about the use of GSL medications.

To provide a general overview about the potential misuse of GSL medications, it was suggested that pharmacovigilance data collected in countries with and without GSL medicines should be compared.

To conclude, the Italian approach was mentioned as an example of a possible balance between patient empowerment and delivery of health information: in Italy, OTC medicines can be sold from non-pharmacy outlets but only if a pharmacist is present.

#### *Role of the CD-P-PH/PHO*

Given the different health literacy levels and needs in the Council of Europe member states, it is advisable that individual countries take their own final decision about the supply of OTC medicines as pharmacy-only and GSL products (based on an in-depth assessment of the national situation).

Finally, the Committee of Experts CD-P-PH/PHO is encouraged to continue to support national competent authorities in the medicines classification process, with the aim of harmonising the conditions for the supply of medicines in the Council of Europe member states.

### **Breakout Session “Social Dimension”**

Moderators: Mr Chave (PGEU) and Ms Van der Biest (FAMHP)

The following points were highlighted during this breakout session:

#### *GSL sale*

Not all countries seem to be ready for GSL sales. This readiness is mainly dependent on patient education and the country's healthcare background.

For instance, in the United Kingdom, consumers have long been familiar with GSL medicines and many feel comfortable with taking decisions about their health and the medicines they need. In Ireland, GSL medications have also been available for a relatively long time and consumers are used to this type of product.

Conversely, in many other countries, habits are different and the level of health literacy does not seem to support supply of GSL medicines. In particular, patients seem to be less aware of the benefits and risks of OTC medications and which could make it difficult for them to select the appropriate treatment.

In addition, in most European countries, OTC medicines are readily available because a wide network of pharmacies is in place. However, in countries where OTC accessibility is limited, the availability of GSL products could have advantages for patients. Nevertheless, it is important to point out that in some European countries the issue of drug availability is not restricted to OTC products, but also affects prescription-only medications. Therefore, more comprehensive measures should be established to help address shortages of both over-the-counter and prescription medications.

### *Health literacy*

Health literacy plays a crucial role when it comes to GSL medicines. Given that health literacy was the main theme of the 1<sup>st</sup> session of the workshop, it was not discussed in detail in this breakout session. However, attention was drawn to the fact that health professionals, consumers, the pharmaceutical industry, and health authorities need to work in partnership if we are to achieve safe and appropriate medication use and, finally, enhanced health outcomes.

### *Role of the CD-P-PH/PHO*

Given that not all countries in Europe seem to be ready for GSL medicines, it was suggested that the CD-P-PH/PHO should not expand its recommendations to further subdivide the OTC category into pharmacy-only and GSL medicines. Nevertheless, the restricted part of the *Melclass* database<sup>7</sup> could include data on pharmacy-only and GSL status in countries where the above supply conditions are in place. In addition, the possibility of making the *Melclass* database fully accessible to all users could also be considered.

Lastly, attention was drawn to the fact that the CD-P-PH/PHO issues recommendations if a given active substance used in a medicine for a specific therapeutic purpose is authorized in at least 3 countries. When issuing a recommendation, scientific, regulatory and social aspects of the supply conditions of medicines are taken into account whereas purely economic aspects are not considered. Recommendations are dialogue- and consensus-based. In the case of OTC medicines, the CD-P-PH/PHO currently provides recommendations about OTC supply under limited circumstances (e.g. restricted pack size, age limit, short-term treatment, etc.), which could be taken on board by authorities in countries where GSL distribution is authorised.

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<sup>7</sup> The *Melclass* restricted part is a password-protected area of the database. It contains details on the classification status of medicines in the member states. The password can be requested at this email address: [melclass@edqm.eu](mailto:melclass@edqm.eu)

## **Annexes**

### ***Speakers***

Mr Ivica BELINA, Coalition of Associations in Healthcare – Croatia

Mr John CHAVE, Secretary General, Pharmaceutical Group of the European Union (PGEU)

Mr Marcello CHIAVONI, Pharmacist, Counterfeit Prevention Unit, Italian Medicines Agency (AIFA) – Italy

Mr Hubertus CRANZ, Director General, Association of the European Self-Medication Industry (AESGP)

Ms Monika DEREQUE-POIS, Director General, European Association of Pharmaceutical Full-line Wholesalers (GIRP)

Mr Gerald DZIEKAN, Director General, World Self-Medication Industry (WSMI)

Ms Belen ESCRIBANO ROMERO, Head of Department - Pharmaceutical Inspection and Enforcement Department, Spanish Agency of Medicines and Medical Devices (AEMPS) – Spain

Ms Zaide FRIAS, Head of Regulatory Affairs and Best Evidence and Head of Human Medicines Research and Development Support (ad interim), European Medicines Agency (EMA)

Mr Klaus GRITSCHNEDER, Deputy Director and Secretary General, European Association of Mail Service Pharmacies (EAMSP)

Ms Joanna GROVES, Chief Executive Officer, International Alliance of Patients' Organizations (IAPO)

Mr Miroslav HANŽEVAČKI, Medical Doctor, Health Center Zagreb-West – Croatia

Ms Susanne KEITEL, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM)

Ms Tihana KRESO, Activity Coordinator, Croatian Alliance for Rare Diseases – Croatia

Ms Viola MACOLIC-SARINIC, Head of Agency, Agency for Medical Products and Medical Devices (HALMED) – Croatia

Mr Markus PONGRATZ, Expert Regulatory Affairs, Austrian Agency for Health and Food Safety (AGES) – Austria

Ms Amanda WILLIAMS, Expert Pharmaceutical Assessor Vigilance and Risk Management, Medicines and Healthcare products Regulatory Agency (MHRA) – United Kingdom

### ***Expert Workshop Organising Committee***

#### **Delegations of the CD-P-PH/PHO**

Ms Simona BADOI, Head of National Procedure Department, National Agency for Medicines and Medical Devices (ANM) – Romania

Mr Marcello CHIAVONI, Pharmacist, Counterfeit Prevention Unit, Italian Medicines Agency (AIFA)  
– Italy

Ms Merjem HADJIHAMZA, Head of Unit for Pharmacoinformatics, Agency for Medicines, Ministry  
of Health - The Former Yugoslav Republic of Macedonia (FYROM)

Ms Viola MACOLIC-SARINIC, Head of Agency, Agency for Medical Products and Medical Devices  
(HALMED) – Croatia (Chairperson of the CD-P-PH/PHO)

Ms Irena MEISSNER-WANTUCH, Medical Doctor, External Expert, Ministry of Health – Poland

Mr J. Michael MORRIS, Director Scientific Affairs, Health Products Regulatory Authority (HPRA) –  
Ireland

Mr Markus PONGRATZ, Expert Regulatory Affairs, Austrian Agency for Health and Food Safety  
(AGES) – Austria (Vice-Chairperson of the CD-P-PH/PHO)

Ms Eline VAN DER BIEST, File Manager, Federal Agency for Medicines and Health Products  
(FAMHP) – Belgium

Ms Amanda WILLIAMS, Expert Pharmaceutical Assessor Vigilance and Risk Management,  
Medicines and Healthcare products Regulatory Agency (MHRA) – United Kingdom

#### HALMED

Ms Viola MACOLIC-SARINIC, Head of Agency

Ms Maja BAŠIĆ, Public Relations Associate

Ms Anamarija ČUKMAN, Assistant to the Head of Agency

Mr Saša LONČARIĆ, Technical Worker

Mr Tomislav MANDARIĆ, Technical Worker

Ms Jasminka TADIN, Spokesperson

#### Secretariat

European Directorate for the Quality of Medicines & HealthCare (EDQM) (Council of Europe)

Biological Standardisation, Network of Official Medicines Control Laboratories (OMCL) and  
HealthCare Department (DBO)

Responsible for the organisation of the Expert Workshop:

Mr François-Xavier LERY, Head of Section for Pharmaceutical Care, Consumer Health Protection  
and Anti-Counterfeiting

Ms Silvia RAVERA, Scientific Officer

Mr Michael HALDANE, Assistant