



**18 November 2011, Strasbourg, France**

## **GOOD PRACTICES FOR THE CLASSIFICATION OF MEDICINES AS REGARDS THEIR SUPPLY (STRASBOURG, 8-9 NOVEMBER 2011)**

Classifying whether medicines require a medical prescription or can be sold over the counter is the responsibility of the national health authorities in Europe. Across the continent, authorities use different standards for this classification. The Council of Europe has been involved in the classification of medicines since 1961 and has inspired relevant EU legislation in line with its core values of the promotion of human and social rights.

On 8-9 November 2011, the Committee of Experts on the classification of medicines as regards their supply organised its first workshop on “Good practices for the classification of medicines as regards as their supply which protect public health and promote the accessibility of medicines in Europe”. The meeting was attended by 38 representatives of the competent authorities of 17 member states of the Council of Europe, the European Medicines Agency, national sick funds, patient associations, pharmacists and medical professionals as well as the pharmaceutical industry. Topics discussed included the specifications, needs and expectations of national healthcare systems and other stakeholders involved in the classification of medicines, and what lessons can be learned from each other’s experiences.

As workshop outcomes, the participants identified key elements of good medicines’ classification practices, the need for improved awareness of the work of the Committee of Experts and better understanding and use of the results, and provided direction for the future work programme of the Committee of Experts.

The role and function of the Committee of Experts in the European context was promoted and strengthened. The Committee of Experts will continue to act and further improve its status as a source of expertise through:

- providing a platform for member states to work collectively towards harmonised standards for the classification of active substances for a given therapeutic use,
- providing reviews and advice on classification practice in selected therapeutic areas and in relation to new modes of medicines supply,
- comparing benefits to risks of changes of classification status,
- making available its expertise to national and European authorities, for example through consultation,
- improving the quality and comprehensiveness of the database on the classification of medicines by more data through targeted studies,
- seeking and taking account of stakeholders’ specific views.

The Committee of Experts on the classification of medicines as regards their supply, coordinated by the EDQM, is unique in Europe as it has the mandate to work towards harmonisation of classification standards through dialogue and consensus. It offers a rationale to authorities for the classification of active substances according to their therapeutic use rather than for individual medicinal products, and its recommendations are addressed to Council of Europe member states, whether or not they belong to the EU.

Currently, recommendations for about 2400 substances are published in the database on the classification of medicines hosted by the EDQM: [www.edqm.eu/melclass](http://www.edqm.eu/melclass).

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***A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.***