21 November 2014, Zagreb, Croatia

OTC MEDICINES: THE ROLE OF GOOD CLASSIFICATION PRACTICES IN PROMOTING MEDICATION SAFETY AND ACCESSIBILITY IN EUROPE, 20-21 November, Zagreb, Croatia

Nearly 100 participants from 19 countries in Europe, representing national and European competent drug authorities, ministries of health, healthcare professionals, patients' organisations, the pharmaceutical industry and pharmaceutical wholesalers, participated in an expert workshop focusing on "over the counter" (OTC) medicines and the importance of good classification practices in promoting medication safety and accessibility in Europe, 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) in Zagreb, Croatia.

The classification into OTC or prescription-only medicines has implications on patient safety, accessibility of medicines to patients and responsible management of health care expenditure. The decision on the prescription status and related supply conditions is a core competency of national health authorities. The conditions of the supply of medicines vary considerably between member states, due to the fact that the provisions are differently interpreted and implemented and that important additional classification criteria are not harmonised as well as to different medical practices. Currently, for patients there are wide disparities in European countries and European harmonisation is on-going to address this.

The aim of the workshop was to explain the work of the Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO), which annually issues recommendations to health authorities of European Pharmacopoeia member states for the classification of medicines and establishes good classification practices, and to collect feed-back from the different stakeholders, including patient associations. The working programme of the CD-P-PH/PHO is coordinated by the EDQM and is based on Council of Europe Committee of Ministers Resolution ResAP(2007)1 on the classification of medicines as regards their supply.

The lively discussions focussed specifically on:

- patients' awareness, education and health literacy with respect to safe and appropriate use of over-the-counter medications;
- new modes of medicinal products' distribution, with special attention to distant trade of medicinal products;
- the possible regulation of supply modes of OTC medicines into "Pharmacy-only medicines" and "General sales medicines";
- the regulatory, scientific and societal dimensions of the above topics.

The workshop demonstrated the interest of all stakeholders in constructive approaches to progress towards harmonisation of good classification practices for OTC medicines, and ultimately promote safe and accessible medications for patients in Europe. Council of Europe Resolution ResAP(2007)1 and respective recommendations provide an excellent basis towards this goal.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally binding

[1]There are now thirty-eight members of the European Pharmacopoeia Commission: *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.* There are twenty-seven observers: *Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*

in European member states. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health protection.

The Council of Europe's activities related to classification of medicines as regard they supply have fallen within the remit of the EDQM since 2008. Pioneers in this field, the Council of Europe bodies have been concerned since 1961 with the classification of medicines into prescription and non-prescription medicines.

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.

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