

15 July 2013

Implementation of Norms Established by the Council of Europe for Quality Assurance and Safety of Medicines Prepared by Compounding Pharmacies Can Prevent Serious Incidents with such Medicines in Europe

There is no doubt that the preparation of medicines in pharmacies is indispensable in accommodating the individual needs and medical conditions of patients in Europe and beyond, in particular if an appropriate medicine does not exist or is not available on the market. The preparation of medicinal products in pharmacies, notably standards for quality assurance and safety, are not harmonised throughout Europe and fall under the national competencies of individual European countries.

Following the conclusions of a survey (2008) carried out by the Committee of Experts on Quality and Safety Standards for Pharmaceutical Practices and Pharmaceutical Care (Council of Europe) supported by the EDQM, a wide gap has been identified between respondent countries in terms of quality assurance and standards for pharmacy-made medicinal products, as well as a gap in quality assurance between preparation in pharmacies and medicines prepared by the pharmaceutical industry.

The Committee of Experts has proposed standards for harmonising quality and safety standards for pharmacy preparation of medicinal products in Europe in the form of a draft resolution.

The Committee of Ministers has adopted Resolution CM/Res AP(2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients and has recommended that member states adapt their legislation in line with the provisions of the above resolution.

Notably, the resolution is a major breakthrough in protecting patient safety and in preventing quality and safety gaps between medicinal products prepared in pharmacies and in industrial settings, through outlining key elements of quality assurance in preparation processes. An innovative approach, such as a decision-making aid for determining the required level of quality standards, is included in the resolution.

The resolution is at the disposal of authorities and pharmacists in order to prevent incidents with medicines prepared in compounding pharmacies – let's use it!

For interested readers:

- Expert workshop proceedings on [“Promoting Standards for the Quality and Safety Assurance of Pharmacy-Prepared Medicinal Products for the Needs of Patients”](#) held on 24 September 2009 at the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, in Strasbourg.
- [Survey report published in Pharmeuropa \(October 2010\)](#)
- [Council of Europe Committee of Ministers Resolution \(CM/Res AP \(2011\)1\) on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients](#)