

Responsible medication processes (“pharmaceutical care”) and good pharmaceutical practices for improved patients quality of life and better healthcare

INTRODUCTION

This summary provides

- an evaluation of the impact of the activities carried out by the **Committee of Experts on quality and safety standards in pharmaceutical practices and pharmaceutical care (CD-P-PH/PC)**¹ during its terms of reference (2011-2013) expiring on 31 December 2013.

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (Partial Agreement), Steering committee.

FIELD OF ACTIVITIES

Public authorities and the pharmaceutical manufacturing and distribution sector devote many resources to the quality, safety and efficacy of medicines. As important as product quality for the best possible medication outcome in an individual patient is the safe and appropriate use of medicines. Pharmaceutical care is a quality philosophy with specific working methods (see definition Hepler and Strand²) which puts patients in the centre of the medication process (through **patient involvement** in the therapeutic plan, **interdisciplinary cooperation (doctors, pharmacists, nurses, other health professionals), on-going review, adaptation and documentation of a therapeutic plan**). Specific, pragmatic pharmaceutical care indicators that measure correctly the quality of the medication process are indispensable for **policy-makers** for best patient outcomes, a more responsible and cost-effective healthcare system. The Committee of Experts CD-P-PH/PC **develops outcome- and patient-oriented indicators for measuring the quality of pharmaceutical care in Europe**.

As medicines prepared by industry do not always satisfy the individual health needs of patients, the preparation of medicines in pharmacies is important. Medicinal products manufactured by the pharmaceutical industry are not always available to cover these. Patients rightfully expect medicinal products that are of appropriate quality, safety and therapeutic value irrespective of whether they are prepared in a licensed pharmacy or by a pharmaceutical manufacturer. The Committee of Experts CD-P-PH/PC drafted the text of Council of Europe Committee of Ministers Resolution CM/ResAP (2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients, adopted in January 2011, to remedy the following: the preparation of medicinal products in pharmacies is not harmonised throughout Europe and falls under the national competencies of States. In the wider context of the above resolution, the Committee of Experts deals with good practices for reconstitution of medicines and automated dose-dispensing. Due to the large and growing number of patients in Europe who receive medication via automated dose-dispensing and because of varying regulations, guidelines and policies (or lack thereof) in different countries, the CD-P -PH/PC started to set-up appropriate standards for automated dose dispensing. These guidelines will focus on the domains associated with a risk for the patient and on high added value for the patient. They will aim to harmonize specific standards and approaches in Europe.

Demand in Europe is growing for foreign traditional medicines, including Traditional Chinese Medicine (TCM). The Committee of Experts CD-P-PH/PC noted the following regulatory gaps:

- lack of neutral and balanced information addressing also risks to health about this medicine system,
- lack of standardised curricula for health professionals and different requirements within Europe,
- absence of specific reporting systems for undesirable effects caused by the TCM system including unlicensed products,

¹ <http://www.edqm.eu/en/quality-and-safety-standards-1244.html>

² Hepler, D.D. & Strand, L.M, Opportunities and Responsibilities in Pharmaceutical Care, Am.J.Pharm.Educ.,53, 7S-15S(1989).

- the use of various common taxonomic names for the same ingredients or TCM herb/product and different uses of the same ingredients within TCM by different TCM schools posing challenges for pharmacists preparing pharmacy-preparations if the herbs were not yet included in the monographs of the Ph. Eur ;
- due to the specific therapeutic concept, widely divergent with western conventional medicine, not all products used in TCM are subject to the requirement for marketing authorisation although used in practice for therapeutic purposes or offered for such purposes;
- concern for the aspects determining quality and safety of medicines and their safe as both together.

In its response, the Committee of Experts reflected about approaches to ensure safely practising Traditional Chinese **Medicine** in Europe. A pilot study was carried out in patients and consumers to validate model information about TCM practices to assist patients and consumers in their choices of healthcare and in communicating with healthcare providers. Furthermore, a concept for an education /training curriculum for therapists and pharmacists in Europe was studied.

The EDQM supports the Committee of Experts CD-P-PH/PC in the frame of the Partial Agreement of the European Pharmacopoeia.

EVALUATION (2011_2013)

20 MEMBERS : AUSTRIA, BELGIUM, BOSNIA AND HERZEGOVINA, CROATIA, CZECH REPUBLIC, ESTONIA, FINLAND, HUNGARY, IRELAND, ITALY, LATVIA, LUXEMBOURG, NETHERLANDS, NORWAY, POLAND, PORTUGAL, SERBIA, SPAIN, SWITZERLAND, UNITED KINGDOM. (Participant: GEORGIA).

Specific tasks (Terms of Reference, item 4)	Achievements	Impact
a) improve community, ambulatory care, primary care, hospital, home health care, and hospice, through specific programmes and policies, putting first the needs of patients and society in general, valuing the social and ethical context of healthcare (“Pharmaceutical care philosophy & working methods”);	Drafting of the text: Council of Europe Committee of Ministers Resolution CM/ResAP (2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients , adopted in January 2011.	This resolution is a major breakthrough to protect patient safety and to prevent quality and safety gaps between medicinal products prepared in pharmacies and at industrial scale through outlining assurance principles for structures and processes. An innovative approach is proposed by the Resolution: a risk assessment model as decision aid for the level of standards which could be used.
b) develop and carry out a programme of activities aiming promoting knowledge, skills, attitudes and values in practices and care involving pharmaceuticals , in particular quality assessment in pharmaceutical practices and care through indicators,	Coordination of a scientific network of 20 scientists & authorities in 13 member states, EU and non-EU members. A specific training was held in October 2013 for national pilot study scientists collaborating with the network. Pharmaceutical Care indicators developed: A set of indicators was developed for <ul style="list-style-type: none"> • self-assessment of pharmacists (individual self-learning tool and/or regional survey tool (indicator) for the impact of training/policy measures) • patient involvement (chronic treatment and poly-pharmacy) (2 indicators) • data linkage in anticoagulant and 	The scientist from the Ukraine, Kharkov University, supported the programme of the National Congress “20 years of Clinical Pharmacy in Ukraine”, Kharkov, 21-22 March 2013, aimed to inspire relevant policy-making. Quality indicators Pharmaceutical Care: Pragmatic indicators have been identified based on scientific findings. For the first time , experts from authorities and academia (CD-P-PH/PC- EDQM (Council of Europe) cooperate in a pragmatic, flexible pilot scheme to develop, test and validate a basic set of pharmaceutical care quality indicators.

<p>guidance on the quality and safety of pharmacy-preparations (reconstitution), and dose dispensing systems;</p>	<p>antibiotic therapy (2 indicators)</p> <ul style="list-style-type: none"> • interprofessional communication (3 indicators) • cooperation between pharmacists and doctors as regards adherence to clinical practice guidelines (set of indicators). <p>The CD-P-PH/PC presented the studies in the EDQM report (2012) “Pharmaceutical Care. Policies and Practices for a safer, more responsible and cost-effective health system”³ which was used as background report at the Dutch Ministers Summit on “The responsible use of medicines, setting policies for better and cost-effective healthcare”, 3 October 2012.</p> <p>The EDQM presented the pharmaceutical care indicators project at the Symposium for Senior Policy-makers, 30 August 2013, Dublin.</p> <p>An advanced draft guidance document “Reconstitution of medicines” has been prepared.</p>	<p>The Dutch Ministers Summit on “The responsible use of medicines, setting policies for better and cost-effective healthcare”, 3 October 2012, considered the EDQM report in its conclusions considered the report as “stimulating thinking and policy actions”.</p> <p>The senior officials received the information on the EDQM pharmaceutical care indicators project with interest.</p>
<p>b) advice to governments as regards safely practising Traditional Chinese Medicines (TCM)</p>	<p>Rapporteurs’ papers:</p> <ul style="list-style-type: none"> • Scientific criteria for identifying and presenting neutral, balanced information on TCM to the public • Basic model information on TCM for patients and consumers • Elements for a model curriculum for pharmacists & TCM therapists 	<p>The Committee of Experts CD-P-PH/PC drew the attention to of the CD-P-PH to regulatory gaps as regards safe practicing TCM in Europe and submitted the rapporteurs’ papers to the steering body.</p>
<p>c) assist in monitoring the adequate implementation of the results of the relevant activities at national levels; and d) promote the further development of pharmaceutical professionals, expertise, roles and co-operation of all partners within the medication and care chain, in particular the pharmacist, the doctor and the nurse, and care-</p>	<p>In the frame of a structured promotion plan, two web-based seminars targeted to competent authorities (June 2012) and pharmacist associations (November 2012) were carried out to promote the practical use of the resolution.</p>	<p>On the basis of a structured approach, the awareness of policy-makers in the authorities of the focus and value of Resolution Res AP(2007)1 has been increased and political will for implementation strengthened. At the same time, users in hospital and community pharmacies were actively supported as regards the use of the provisions through providing</p>

³ <http://www.edqm.eu/en/quality-and-safety-standards-1244.html>: Pharmaceutical care. Policies and Practices for a Safer, More Responsible and Cost-effective Health System (2012)

givers;	<p>A specific survey was carried out in 2013 to follow up the impact of the resolution 2 years after adoption.</p> <p>Information was published on the Committee of experts website on the value of implementing the resolution to prevent harm to patients by pharmacy-preparations (such as the 2012 fatal incidents with pharmacy-prepared cortisone injections)</p>	<p>them a discussion platform.</p> <p>A survey tool is available to follow-up progress with quality assurance for pharmacy-made products before and after the adoption of Resolution ResAP(2007)1.</p>
e) maintain and develop links with national, European and international institutions, organisations and professional bodies active in the sphere of practice and care involving pharmaceuticals;	<p>Delegations and experts are regularly represented as speakers at science oriented associations such as the European Hospital Pharmacists association (EAHP), the International Pharmacists Federation (FIP), and the EuroPharm Forum.</p> <p>EuroPharmForum gave input to the working party "Indicators" and EAHP to the working party "Reconstitution".</p>	
f) assess the impact of the results of its work programme in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.		See Overall Evaluation (2011-2013)

OVERALL EVALUATION (2011-2013)

Indicators of the Quality of Pharmaceutical Care

The Committee of Experts has developed a generally applicable and more specific set of indicators of the quality of pharmaceutical care in Europe which should be validated and implemented in different countries, health care systems, medical tradition. In 2012, the EDQM report (2012) "Pharmaceutical Care. Policies and Practices for a safer, more responsible and cost-effective health system" was submitted to a Ministers Summit on the benefits of the responsible use of medicines (the Netherlands, 3 October 2012). The report proposed a specific health policy agenda focusing on the responsible use of medicines for best medication outcomes in patients and sustainable healthcare, particular through the implementation of pharmaceutical care. Indicators provide information indispensable for policy-makers and professional regulators to steer this process.

- The awareness and support of **Ministers of Health from all regions of the world** present at a Dutch Ministers Summit (October 2012) for pharmaceutical care indicators as global applicable tools was obtained: **The summit report refers to the EDQM report as "...stimulating thinking and policy actions"**. The report proposed a specific health policy agenda focusing on the responsible use of medicines for best medication outcomes in patients and sustainable healthcare, particular through the implementation of pharmaceutical care. Indicators provide information indispensable for policy-makers and professional regulators to steer this process. International co-operation will make the establishment of quality indicators for pharmaceutical care, evaluation and follow-up for healthcare policies and best professional practices effective and sustainable.
- The presentation about the multinational indicator pilot studies of quality of pharmaceutical care (CD-P-PH/PC) received attention and interest at the August 2013 Symposium for Senior Policy-Makers and is expected to mobilise further political will.

- Specific common standards (indicators of the quality of pharmaceutical care in 6 areas relevant for patients' best medication outcome), understanding, interpretation and practical use of the pharmaceutical care (PC) concept were developed to ensure the same level of care to patients in Europe.
- Specific pilot study protocols for validating the above indicators of the quality of pharmaceutical care in 6 key areas are available.
- Pilot study scientists are aware of the specific methods to validate the indicators and know how to use them.

Council of Europe Committee of Ministers *Resolution CM/ResAP (2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients*

- This resolution is a major breakthrough to protect patient safety and to prevent quality and safety gaps between medicinal products prepared in pharmacies and at industrial scale through outlining assurance principles for structures and processes.
- An innovative approach is proposed by the resolution: a risk assessment model as decision aid for the level of standards.
- The Committee of Experts CD-P-PH/PC assists actively through individual delegates' external presentations and in the frame of a structured promotion plan the practical implementation of the resolution.
- Based on and inspired by the resolution, areas have been identified requiring practical guidance such as reconstitution of medicines and ensuring patient safety and added value as regards automated dose-dispensing.