quality and safety of pharmacy preparations in Europe

Henk Scheepers, Pharm D, Senior-Inspector
Public Health Supervisory Service
Health Care Inspectorate
The Netherlands

Nothing to disclose

quality and safety of pharmacy preparations in Europe

1. Council of Europe / EDQM
2. Project quality and safety of pharmacy preparations
3. Survey of questionnaire results
4. EDQM workshop
5. Further steps

Council of Europe / EDQM

- Council of Europe (1949)
- Headquarters: Strasbourg (France).
- Intergovernmental political organisation
- Distinct from European community
- 47 member states in Europe
- observers

Core values: protection of human rights, of pluralist democracy & the rule of law

Council of Europe / EDQM

Council of Europe bodies:
- Committee of Ministers
- Parliamentary Assembly
- Congress of Local & Regional Authorities
- European Court of Human rights

European Convention on Human Rights &
Fundamental Freedom
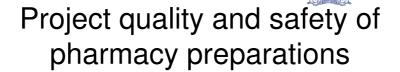
Council of Europe / EDQM mission

European Directorate for the Quality of Medicines & Health Care (EDQM)
• contribution to access to good quality medicines & healthcare:

Standard-setting, certification, inspection, laboratory cooperation

• Convention on the Elaboration of a European Pharmacopoeia Convention & Protocol.

Project quality and safety of pharmacy preparations

EDQM Committee of Experts on quality and safety standards in pharmaceutical practices and pharmaceutical care (CD-P-PH/PC)

Working party
- comprising the delegations form Austria, Norway, Switzerland, the Netherlands (chair) and a representative of the EAHP.

Project quality and safety of pharmacy preparations

Objectives

- to ensure safe and effective medicinal products for the patients independent of production site.

- improved and harmonised quality standards for pharmacy preparations
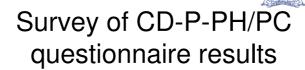
Survey of CC-P-PH/PC questionnaire results

- Wide variety in quality assurance and standards for pharmacy preparations.
- Gap in quality assurance between pharmacy preparations and manufacture at industry level
- Terminology used for pharmacy preparations shows a wide variety
- Quality and safety gap between preparations/reconstitutions of medicinal products in pharmacies and hospital wards

Survey of CD-P-PH/PC questionnaire results

- Requirements for preparation
  - Only general requirements in most countries
  - Additional requirements in some countries (e.g. sterile products)
  - Regulation for preparation in other healthcare establishments (e.g. hospital wards) in very few countries
  - Differences in definition (reconstitution / preparation)

Survey of CD-P-PH/PC questionnaire results

- Restrictions for pharmacy preparations
  - No restrictions
  - Restrictions
    - Limitation to patients served by the pharmacy.
    - Restrictions concerning the scale of the preparations.
    - Other.

Survey of CD-P-PH/PC questionnaire results

- Definitions for pharmacy preparations
  - Wide variation
  - Magistral and officinal – not clear enough to distinguish between the different forms of preparation.

Survey of CD-P-PH/PC questionnaire results

- Delivery to other pharmacies
  - Hospital pharmacies more often involved than community pharmacies
  - In some countries companies are involved in pharmacy preparations

Survey of CD-P-PH/PC questionnaire results

- Authorisation of pharmacies
  - 'normal' authorisation includes permission to prepare medicinal products
  - Licences
    - For presentation forms
    - Dependent on production scale
    - Enterprises not being pharmacies

Survey of CD-P-PH/PC questionnaire results

- Quality standards
  - Typical GMP chapters are covered but to a varying extent.
  - Missing in some countries: QC, recall.

Survey of CD-P-PH/PC questionnaire results

- Additional standards for preparations carrying a higher risk
  - In a minority of the respondent countries
  - Definition of a larger batch varies widely
  - Delivery to other pharmacies: wide variation in regulation

Survey of CD-P-PH/PC questionnaire results

- Clinical relevance / risk benefit ratio
    - Some countries: pharmacy preparation not allowed if therapeutic alternative is on the market
    - Obligation to deliver all medicines prescribed in some countries
    - Sound and documented proof for therapeutic rationale in some countries

Survey of CD-P-PH/PC questionnaire results

- testing of raw materials
    - Identity testing in more than half of the countries
    - Other tests required in less than half of the respondent countries
    - Authorisation system for suppliers / manufacturers is in place in some countries

Survey of CD-P-PH/PC questionnaire results

- Pharmacovigilance
    - Required for pharmacy preparations in about half of the countries
    - National registers for adverse events not always adequate for pharmacy preparations

Survey of CD-P-PH/PC questionnaire results

- Marketing authorisation
    - Not required in most countries
    - Required in some countries when maximum allowed quantities for pharmacy preparations are exceeded
    - Number of registrations varies form 0 to 100

Survey of CD-P-PH/PC questionnaire results

- Trade in pharmacy preparations
  - Regulation in most of the countries
    - Not allowed unless specific conditions are met
    - License required in some countries
    - Only allowed when no registered equivalent / alternative is marketed
    - Only allowed when chemical, pharmaceutical and microbiological data are available in the pharmacy

Survey of CD-P-PH/PC questionnaire results

- Centralisation / decentralisation trends
  - So-called 'chains' do not want to have production in all of their pharmacies.
  - In some countries legislation allows to a larger extent than before to buy pharmacy preparations.
  - Pharmacies have difficulties in complying with quality requirements for preparation.

EDQM Experts Workshop
September 2009

Topics:

1. Gap between medicinal products prepared in pharmacies and those manufactured in the industry?
2. Best practices for preparation in pharmacies; overview of available guidance
3. Therapeutic relevance; pharmacovigilance
4. Distribution to other pharmacies

EDQM Experts Workshop
September 2009

Topics:

5. Terminology for preparations made in pharmacies.
6. Criteria for product dossiers
7. Criteria for pharmacy preparations, if authorised therapeutic equivalents are on the market
8. Criteria for production quality
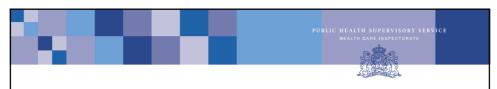
EDQM Experts Workshop
September 2009

Topics:

9. Criteria for licensing the preparation process of medicinal products in pharmacies
10. Criteria for the distribution of medicinal products prepared in pharmacies to other pharmacies
11. Aspects of reconstitution of medicinal products

Project pharmacy preparations

Risk based approach:

1. Type of preparation
2. Amount prepared annually
3. Pharmacological effect of the active substance
4. Preparation process
5. Supply

Project pharmacy preparations

risk assessment:

- Preparation process (level of quality system).
- Product dossier.
- Reconstitution of medicinal products.

Project pharmacy preparations

- Possible disadvantages and added value of the pharmacy preparation

- Pharmaceutical equivalents on the market

Project pharmacy preparations

- Distribution
- Patient information
- Etc.

Project pharmacy preparations

- Further steps

- Questions?