LIÈGE université
Médecine

Good Pharmaceutical Practices in Belgian primary care pharmacies
Part I

Prof. Patrick Herné

University of Liège

Belgium

Guide for BPPO

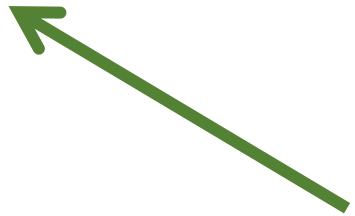
- A « guide for Good Pharmaceutical Practices in primary care pharmacies » is official in Belgium since 2009
- Why ? Because pharmacists must provide high **quality** services, for the benefit of their patients
- The guide was developped by health authorities, faculties of pharmacy, trade association of pharmacists
- Its respect is mandatory for all pharmacies open to the public (more or less 5000 in the country)
- Major scopes
  - Working environment
  - Dispensed products and advices
- Contains only general instructions: consequently, must be completed in each pharmacy with a « quality manual » adapted to its particularities.

What is « quality » ?

- Quality = degree of concordance between a product (drug) or a service (dispensing) and the expectations of the authorities or of the customer.
- Quality = risk, deficiencies and mistakes **prevention**
- Quality must be
  - Built
  - Accepted and integrated by each member of the pharmaceutical team
  - Evaluated on a regular time-basis (self-monitoring)
  - Adjusted when necessary

Self-monitoring

- What we must do
- What we want to do
- What we think we are doing
- ? ? ? What we really do



Self-monitoring

Fitting of the pharmacy

- Separated zones for
  - Receipt of goods
    - Are the received products the ones which were ordered ? Are there missing products ?
    - Check of the legality of the received products (see hereafter)
    - Absence of defects (damaged containers) and quality control
    - Expiration date
      - Pro-active methods to detect out-of-date products in the pharmacy.

- Storage and cold storage
  - Separation of drugs, food supplements and cosmetics
  - Separation of drugs and medical devices
  - Separation of poisons and non-poisons
  - Separation of drugs for internal or external use
- Dispensing
  - Separate counters to ensure medical confidentiality
- Compounding
  - Area separated from the other activities of the pharmacy, ideally by a partitioning wall, to avoid microbial or particular contamination from of to the dispensing zone.
- Counselling : confidentiality room
- Expired, defective or brought back products

Staff of the pharmacy

- Number and location of pharmacies are regulated
- The owner of a pharmacy is not necessarily a pharmacist
- Self employed pharmacists and pharmaceutical societies
- Only pharmacists and qualified assistants
- One pharmacist is the « incumbent » of the pharmacy, the others are « deputy-pharmacists »
- No particular experience required to be « incumbent pharmacist »
- At most 3 assistants per pharmacist
- The incumbent of the pharmacy (who is not necessarely his owner) takes the legal responsability for all the pharmaceutical acts
- The other pharmacists are responsible fot their own acts
- The assistants don’t have any legal responsability, and have thus to work under the effective supervision of a pharmacist.

Hygiene rules

- Staff:
  - wearing of apron with identification badge
  - Sustained hand washing and desinfection (especially when compounding)
- Premises of the pharmacy
  - No direct patient access to *drugs* or equipments
  - Avoiding microbial contamination:
    - Exterior doors and windows must be kept closed
    - Take care of disorder, parasites, insects…
    - Take care of sinks and garbages

Equipment and supply

- Furniture: convenient and easily cleaned
- Drugs and other pharmaceutical products:
    - Drugs: only drugs registered in Belgium – no foreign drugs
    - Food supplements: only notified food supplements
        - 3 classes: nutrients, plants products, others
    - Cosmetics: only notified cosmetics
    - Medical devices: only products with CE label
    - Raw products for compounding: only authorized products or products with certificate of analysis, whatever the product (chemical or natural)

Equipment and supply (cont.)

- Fridge
  - Internal temperature between 2 and 8°C at any place
  - Daily control required and documented
  - When a drug (or other product) has to be stored in the fridge, there is a clear information in this way on the container
  - “cold chain”: see “quality control in drug distribution”

Equipment and supply (cont.)

- Equipment for compounding
  - Weighing scales
    - Clean
    - Balanced
    - Accuracy controlled weekly by the phamacist
    - Conformity controlled every 4 years by metrology authorities
  - The whole equipment has to be validated and controled on a regular basis; the controls must be documented

Equipment and supply (cont.)

- Computers: essential for
  - Stock management
  - Registering of individual drug deliveries
  - Management of the patient files
  - Communication with social security authorities
  - Its access must be secure (medical confidentiality and patient privacy)

How to teach this part of BPPO?

- In a « didactic pharmacy » equipped with
  - Dispensing counter
  - Shelfs and drawers for the storage of drugs and medical devices
  - Fridge
  - Compounding area
- Focusing on the different working zones
- Control of fridge and weighing scales
- How to recognize an authorized medicinal product, food supplement or medical device ?
- Self-evaluation of the pharmacy

Didactic pharmacy: general view

Didactic pharmacy: Dispensing zone

Didactic pharmacy: teaching

Compounding

- In Belgium, compounding remains a significant part of the pharmacist's activities
- Two kind of compounding drugs
  - Magistral formulae: prescribed by doctors for individual patients
  - Officinal formulae: from an official handbook : Formulaire thérapeutique magistral
- Only made with authorized raw material (bulk)
- Compounding protocol as frequently as possible
- Weighing forms every time
- When possible, self-control of the preparation
- Legal requirements for labelling

How to teach this part of BPPO ?

- In the « didactic pharmacy »
- 4 separate groups of +/- 15 students
- Each group is in charge of making a magistral preparation, from beginning to end
  - Control of raw material
  - Analysis and formulation of the preparation
  - Control of the concerned compounding equipment
  - Practical realization
  - Control of the final preparation
  - Labelling

Example of weighing form

NOM DE LA PRÉPARATION : SIROP DE DEXTROMÉTHORPHAN 1 MG/ML DU DR.DUPONT

Composition qualitative et quantitative :
R. Bromhydrate de dextrométhorphan 200 mg
Acide citrique 300 mg
Sirop conservé q.s. ad 200 ml

Taille du lot : 1 flacon de 200 ml

Date de préparation :

Identité du préparateur

CONSTITUANTS	*Quantité à peser*	*Quantité pesée*	*N° d'ordre du constituant (registre des matières premières)*
Tare du flacon			
Dextrométhorphan HBr	***200mg***		
Acide citrique	***300 mg***		
Sirop conservé q.s. ad	***200 ml*** = ***g + tare*** =		

Didactic pharmacy: Compounding zone

Pharmaceutical care

= what the pharmacist has to do before, while and after dispensing a drug or health product to a patient

Relevant for the prescriptions, but also for requests without prescription (OTC drugs or healthcare products)

1. Before:
    1. Control of the legality of the prescription or request
    2. Validation of the prescription or request: are the asked or prescribed drugs appropriate (age, personality, condition of the patient, doses, interactions between drugs, lifestyle…) ?
    3. Are they compatible with the other treatments of the patient ?

Pharmaceutical care (cont.)

1. While:
    1. Dispensing the drugs always with a pharmaceutical advice (how to take it the most conveniently)
    2. Trying to check to good understanding and compliance of the patient
    3. Complete the pharmaceutical record
2. After: at the following meeting with the patient: check once more his good understanding and his compliance; rectify or refer to the physician in case of problems

How to teach this part of BPPO ?

- Two Workshop sessions in the « didactic pharmacy »

1. session

  - 4 separate groups of +/- 15 students
  - Each group handles a different situation
  - Each situation (sketch) is played by 2 actors (pharmacist and patient) on 3 different ways
    - Pharmacist giving patient minimal explanations and advices
    - Pharmacist giving « scholar » explanations and advices, without taking into account the personality or specificity of the patient
    - Pharmacist talking with patient, collecting appropriate informations, discussing comprehension and compliance and advising knowingly

- After each playlet, debriefing with the students
- Aim of the session: raise awareness about non compliance, importance of discussion with patients and knowledge of his personal circumstances, and give adequate and comprehensible advices.

- 2. session
  - 4 separate groups of students
  - Each group handles 3 different situations
  - All the situations are « border line » and implies pharmacist has to take his responsibility
    - Examples: a prescription of a narcotic drug which could have been falsified; a known patient who need a prescription drug to go abroad, but doesn’t have it; how react with a patient abusing or mesusing a drug; how handle a non « evidence based medicine » prescription…

- the beginning of the sketch, the situation is played by two actors (pharmacist and patient), who break off abruptly. After a time for reflection and consultation between students, one of them replaces the pharmacist-actor and ends the playlet as he pleases.
- Aim of the session: let students know that pharmaceutical interventions in pharmacy are not always simple or codified, and have to manage with reality.