Good Pharmaceutical Practices in Belgian primary care pharmacies
Part I

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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 developed 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
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      • Pro-active methods to detect out-of-date products in the pharmacy.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 necessarily his owner) takes the legal responsibility for all the pharmaceutical acts
- The other pharmacists are responsible for their own acts
- The assistants don’t have any legal responsibility, 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 pharmacist
    • Conformity controlled every 4 years by metrology authorities

• The whole equipment has to be validated and controlled 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
  • Shelves 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
**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**

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

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<th>CONSTITUANTS</th>
<th>Quantité à peser</th>
<th>Quantité pesée</th>
<th>N° d’ordre du constituant (registre des matières premières)</th>
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<tr>
<td><strong>Tare du flacon</strong></td>
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<tr>
<td><strong>Dextrométhorphan HBr</strong></td>
<td>200mg</td>
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<tr>
<td><strong>Acide citrique</strong></td>
<td>300 mg</td>
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<tr>
<td><strong>Sirop conservé q.s. ad</strong></td>
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\text{Sirop conservé q.s. ad} = g + \text{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.