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Recommendations for the development of standards for good practice in pharmacy

VERBAND DER EUROPAÏSCHEN SOZIALEN APOTHEKEN
EUROPEAN UNION OF THE SOCIAL PHARMACIES
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QUALITY ASSURANCE WITHIN PHARMACIES VIA THE IMPLEMENTATION OF STANDARDS FOR GOOD PRACTICE

1. The **medicine chain**, from manufacturer to consumer, must provide sound guarantees relating to quality, efficiency and safety. Our review revolves around this basic principle.

   The **industrial** production of medicines has already been subject to good practice guidelines for many years. Spurred on by the EU, the pharmaceutical industry has developed ***principles and guidelines for good manufacturing practice*** that have permitted a European convergence in the various phases that result in the introduction of medicines onto the market[1].

   The sector for the **wholesale distribution** of medicines took an identical approach[2].

   Although the **dispensation of medicines to patients** is governed by strict precautionary measures in all European countries (access to the profession, authorisation to establish a business, mandatory execution of activities by the pharmacist or under his supervision and responsibility, compliance with the pharmacopoeia, etc.), most countries do not have **standard guidelines** for all pharmaceutical activities relating to the management of medicines and dispensation to patients.

2. Consequently, this is the context and objective of the existing recommendations with a view to drawing up **guidelines for good practice in pharmacies** within all European countries.

3. Pharmacists must develop and implement an **efficient system for pharmaceutical quality assurance**, which will require their active participation as well as that of all pharmacy employees. It therefore involves implementing quality management, focussing on the patient, and **accessibility, efficiency and safety**.

   To realise this objective, pharmaceutical activities must be identified, analysed and hierarchised, and **procedures to be followed for every activity** must be laid down.

   This approach naturally involves **extemporaneous dispensing** and resembles, in this respect, the formulation of guidelines for good practice in the pharmaceutical industry (hygiene, personnel training, work areas, documentation, verification, etc.).

   However, it also relates to the process of purchasing, storage, conservation, return, etc. of **industrially manufactured medicines**.

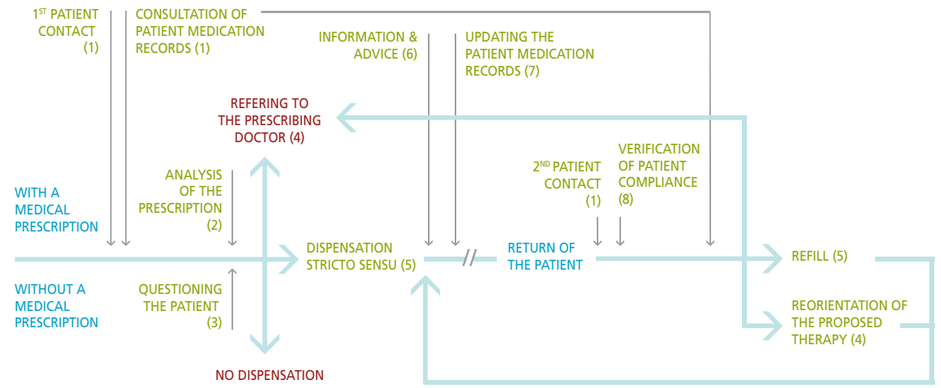
4. It primarily comprises the **process for the dispensation** of medicines, irrespective of their nature (industrially manufactured or prepared in pharmacies, prescription or non-prescription), including verification-related activities, advice and follow-up preceding, accompanying and succeeding dispensation.

   The ***Flowchart for the dispensation of medicine to patients*** contains a sample list of activities for each sequence that must be subject to good practice guidelines.

1 *Commission Directive 2003/94/EG of 8 October 2003, laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use – OJEC L 262 of 14.10.2003, page 22.*

2 *Guidelines (94/C 63/03) on Good Distribution Practice of Medicinal Products for Human Use – OJEC C 63 of 1.3.1994, page 4.*

THE DISPENSATION OF MEDICINE TO PATIENTS



(1) Patient contact, willingness to listen, dialogue, consultation of patient medication records, confidentiality, etc.

(2) Accurate analysis and verification (authenticity, validity, identity of the prescribing doctor, identification of prescribed medicines, etc.), attention to any drug-related problems (DRP), whether or not there is any standardised contact with the prescribing doctor (principle of pharmaceutical opinion), etc.

(3) Questioning the patient: for whom is the advice intended? How long has the patient exhibited symptoms? Which actions were taken by the patient? Does the patient take other medicines? etc.

(4) Providing an explanation to the patient about the reasons, motivation, grounds, any communication with the prescribing doctor, etc.

(5) Procedures that ensure the correct medicine is dispensed in the correct dosage, is properly verified, etc.

(6) Information about the medicine, treatment modalities, precautionary measures and instructions for use. Specific advice during a first and second dispensation. Motivation for patient compliance with treatment, etc.

(7) Information about the patient's complaints, medicinal history, any particular actions taken by the pharmacist, etc.

(8) Verification of patient compliance, re-evaluating the DRP, following-up on actions taken by the pharmacist, etc.

5. Naturally, these recommendations correspond to the **continuity** of the activities undertaken by our Union since the General Meeting held in Tours in 2000, geared to the existing role of the pharmacist and the approach that the pharmacist must take to guarantee **quality assurance** during the dispensation of medicines to patients (refer to *Six Commitments for Quality Pharmaceutical Services, EUSP 2001*).

   The complete list of the various processes required for the pharmacist to exercise in a professionally correct manner also provides **reference points for suitable remuneration of the pharmacist**. (Refer to *Recommendations for an Appropriate System of Payments for Pharmaceutical Services - EUSP 2003*).

   Finally, these recommendations permit the use of **patient medication records** during the exercise of the profession to be described in a fully operational manner (refer to *Recommendations for Patient Medication Records - EUSP 2005*).

6. **A classification of intended activities** will be proposed, positioned around the two most relevant axes relating to the pursuance of the profession, already explained and elaborated on in previous publications.

   The pharmacist guarantees the **distribution of medicines**, and must, in that capacity, manage the purchase, correct storage and sale of medicines. This is the **material** dimension of the profession, which focuses on the management of products.

   Parallel to this, mainly during the dispensation of medicines, but not only at that moment, the pharmacist does not supply any material goods, but **immaterial** goods, such as pharmaceutical follow-up.

   In other words, we ask ourselves with regard to every activity whether it relates more to the **product** itself, the medicine in particular, or more to the **service** that the pharmacist has to provide to the patient.

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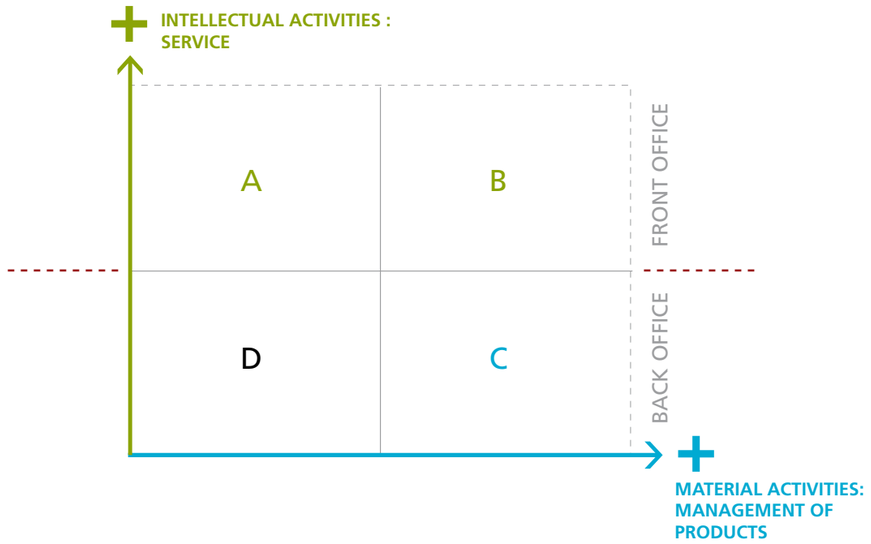
In this way we obtain four sections, each of which classifies a series of activities that are similar in nature:



These sections are defined as follows:

> Section A classifies **activities of an intellectual, immaterial nature,** such as the compilation of patient medication records, coordination of patient care, intercollegial consultation, consultation between doctors and pharmacists, etc.

> Section C classifies activities directly related to the production, purchasing, storage, conservation, etc. of products. In other words, the **material management of products** in the pharmacy;

> Section B classifies the activities of the pharmacist situated at the **crossroads of the dimensions of " service provider " and " product dispenser "**. This concerns the process of dispensing the medicine in its various phases and in accordance with the nature of the medicine or conditions of dispensation;

> Section D classifies activities **not directly related to the product or the services provided to the patient**, but which are **necessary criteria** for the high-quality performance of the activities of the three other sections: the appropriate fitting-out of buildings and work areas, the IT system, personnel management, etc.

7. We use this classification in the ***Recommendations***, which are outlined below.

Note that sections A and B mainly classify the activities of the " front office ", which is in direct contact with patients, while sections C and D comprise the activities of the " back office ", which has no contact with patients, in the knowledge that all of the pharmacist's activities are naturally geared to the provision of services to patients.

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RECOMMENDATIONS

1. The EUSP recommends the development and implementation of the principles and guidelines for good practice within pharmacies in various European countries.
2. These must be developed in cooperation with the profession and must be subject to a gradual obligation for everyone within the framework of the pursuance of the profession.
3. These principles and guidelines must comprise all activities carried out within a pharmacy, in particular the safe dispensation of medicines, as well as all processes that accompany and support this primary duty.

Consequently, the activity fields that must become the subject of principles and guidelines for good practice are as follows:

A SERVICE-RELATED ACTIVITIES

A1 Provision of basic information about the pharmacy during patient's first visit

In principle, the patient receives the necessary information during his or her first visit about the services provided by the pharmacy and the relevant procedures relating to these services: opening hours, medicine dispensation, pharmaceutical follow-up, etc.

A2 Compilation of patient medication record for pharmaceutical follow-up

The patient medication record contains structured information about the patient (for which he or she has given approval) and his or her medicinal treatment, as well as actions taken by the pharmacist in the context of medicine dispensation and treatment follow-up (refer to *Recommendations for Patient Medication Records – EUSP 2005*).

A3 Coordination of patient care – intercollegial consultation and consultation between doctors and pharmacists

A coordinated approach between various healthcare providers is necessary for the efficient treatment of the patient. The pharmacist supports this approach, in particular with the doctor. Intercollegial consultation and consultation between the doctor and pharmacist can also facilitate the implementation of healthcare standards and the performance of pharmaceutical services in general.

A4 Promotion of public health and illness prevention

The pharmacist helps promote public health and illness prevention by providing objective information and participating in campaigns organised by the government, amongst others.

A5 Pharmacovigilance

In accordance with the guidelines on the collection, verification and presentation of suspected adverse reactions and cases of misuse and serious abuse, pharmacists – like other healthcare providers – will forward any information that comes to their attention to the national pharmacovigilance system.

B DISPENSATION RELATED ACTIVITIES

This concerns the dispensation of medicines and pharmaceutical care, the main process in the pharmacy. It is of course crucial that the correct medicines are dispensed to the correct patient. The pharmacist is also responsible together with the prescribing doctor and the patient for ensuring that medicinal treatment proceeds properly and that the expected therapeutic results are obtained.

Please refer to the *Flowchart for the dispensation of medicine to patients* on page 3.

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B1 Prescription medicines

> The steps required for ensuring optimal dispensation occurs are:

- Patient contact
- consultation of patient medication records
- analysis of prescription
- questioning of patient
- referral to the prescribing doctor, if necessary
- information and advice
- update of patient medication records

> Plan for pharmaceutical surveillance

The formulation of a plan for the pharmaceutical surveillance of the patient can occur at the request of the patient or doctor, or be proposed by the pharmacist.

> Monitoring and evaluation of the use of medicines

The pharmacist focuses on drug-related problems (DRP) in particular: the accuracy of the instructions, interactions, absence of contra-indications, compliance with treatment, etc. However, should drug-related problems arise, the pharmacist must act in consultation with the prescribing doctor and the patient in order to optimise medicinal therapy.

B2 Non-prescription medicines

> The steps for proper dispensation are identical to those for dispensation with a prescription (except for the analysis of the prescription of course);

> The supervision and questioning of the patient occurs on the basis of standards. Specific attention is devoted to questioning the patient. If necessary, the patient will be referred to other health-care workers.

C ACTIVITIES RELATING TO THE MANAGEMENT OF PRODUCTS

C1 Extemporaneous dispensing

With regard to medicines that are not industrially available and that are prepared in the pharmacy, the pharmacist is responsible for both the quality of production and the quality of dispensation. The standards are based on good manufacturing practice, adapted to the preparation of medicines in small quantities: hygiene requirements, preparation according to a procedure, final inspections and checks carried out during preparation, preparation stability, etc. If necessary, preparations that require specific experience or equipment are delegated to colleagues who fulfil these criteria.

C2 Industrial preparation

A crucial process within the pharmacy concerns the quality of dispensed pharmaceutical specialities and logistical aspects relating to the reception and conservation of pharmaceutical products. Although the quality of industrially manufactured medicines is determined primarily before products enter the pharmacy, their availability and the conservation of their quality must be assured: a stringent method for determining the range and guaranteeing supplies, selection of suppliers, checking received products, optimal classification of products, management of validity dates, respecting conservation requirements (temperature, humidity, luminosity), etc. As the final link in the medicine chain to the patient, the pharmacist also fulfils his role in systems for the withdrawal of products.

D REQUIRED CRITERIA FOR ENSURING THE PROFESSION IS PURSUED IN A HIGH-QUALITY MANNER

D1 Pharmacy personnel

Pharmaceutical care is often provided by other members of staff. Consequently, the pharmacist will do everything possible to ensure the quality of their performance: following a strict recruitment and selection procedure, taking care of new personnel, job description, motivation, evaluation, training and additional education programmes, respect for rules relating to working conditions and occupational safety, etc.

D2 Infrastructure

A well-adapted and properly maintained structure is an important element for quality assurance. This requirement not only relates to the building and furnishings and fittings, but also to the materials and instruments, information sources, etc.

IT equipment that supports the pharmacy's information and management system forms a key element of the infrastructure.

D3 Management and organisation

Like all health workers, the pharmacist is obliged to make choices relating to the organisation and the management of his pharmacy, while always focussing on the patient. In particular, the pharmacist ensures the best accessibility to services (opening hours, availability of personnel, information about the local out-of-hours service, etc.).

D4 Documentation

A documentation system comprising the activities of the pharmacy is created and updated by the pharmacist. The documentation system covers the various phases of the activities and allows operations and executed checks to be compiled again a posteriori.

D5 Evaluation and verification of the quality of provided services

Frequent evaluation based on the expectations of all concerned parties is a key element of the quality assurance system. Spontaneous complaints from customers, anomalies in the provision of services and all kinds of incidents serve as the point of departure for corrective measures and a continuous process for quality improvement. Indicators are defined and followed-up in order to evaluate the activities of the pharmacy in an objective manner.

D6 Research and development

The pharmacist ensures a structured approach in relation to the development of provided services. Before offering a service, he checks whether the necessary competencies and infrastructure are available.

D7 Services provided by third parties

When the quality of internal processes is sufficiently under control, attention will of course be devoted to services provided by third parties that help ensure the pharmacy functions efficiently.

The detailed principles of the good practice in each of the aforementioned fields of activity can be found under the PUBLICATIONS section of the website of the European Union of the Social Pharmacies: http://www.eurosocialpharma.org.

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