PERÚ | Ministerio de Salud

MANUAL OF GOOD PRACTICES DISPENSING

Ministry of Health

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Good Dispensing Practices Manual

General Directorate of Medicines, Supplies and Drugs. Directorate of Pharmacovigilance, Access and Use of Medicines. Functional Unit for Rational Use of Medicines

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The Ministry of Health thanks the professionals and institutions that collaborated in the review process of the Manual of Good Dispensing Practices.

MINISTERIO DE SALUD

No. 013 - 2009/MINSA

REPUBLICA DEL PERU

Resolución Ministerial

Lima, 15 de ENERO del 2009

Visto el Expediente N° 07-043125-001 que contiene el Memorando N° 1139-2008-DIGEMID-DG/MINSA de la Dirección General de Medicamentos, Insumos y Drogas del Ministerio de Salud y el Informe N° 005-2009-OGAJ/MINSA de la Oficina General de Asesoría Jurídica;

CONSIDERANDO:

Que, el artículo 64° de la Ley N° 26842, Ley General de Salud, dispone que las personas naturales o jurídicas que se dedican a la comercialización de productos farmacéuticos para desarrollar sus actividades deben ceñirse a las Buenas Prácticas de Almacenamiento y Dispensación que dicta la Autoridad de Salud a nivel nacional;

Que, la Décima Primera Disposición Complementaria, Transitoria y Final del Reglamento de Establecimientos Farmacéuticos aprobado por Decreto Supremo N° 021-2001-SA, dispone que por Resolución Ministerial de Salud, se aprobará el Manual de Buenas Prácticas de Dispensación;

Que, el artículo 53° del Reglamento de Organización y Funciones del Ministerio de Salud, aprobado por Decreto Supremo N° 023-2005-SA señala que la Dirección General de Medicamentos, Insumos y Drogas es el órgano técnico normativo del Ministerio de Salud en los aspectos relacionados a la dispensación y expendio de productos farmacéuticos;

M. Arce R.

Que, en tal sentido, la Dirección General de Medicamentos, Insumos y Drogas ha propuesto para su aprobación el Manual de Buenas Prácticas de Dispensación, cuyo objetivo es establecer los criterios, metodologías y requisitos para el cumplimiento de las Buenas Prácticas de Dispensación, con el fin de contribuir a mejorar la salud de la población a través de una correcta y efectiva dispensación en los establecimientos farmacéuticos a nivel nacional;

V.A. Grupa L.

Estando a lo propuesto por la Dirección General de Medicamentos, Insumos y Drogas mediante el documento del visto;

V. Drogas M.

Con el visado del Director General de la Dirección General de Medicamentos, Insumos y Drogas, de la Directora General de la Oficina General de Asesoría Jurídica y del Viceministro de Salud; y,

De conformidad con lo dispuesto en el literal l) del artículo 8° de la Ley N° 27657, Ley del Ministerio de Salud;

SE RESUELVE:

Artículo 1°.- Aprobar el "Manual de Buenas Prácticas de Dispensación" que en documento adjunto forma parte integrante de la presente Resolución Ministerial.

Artículo 2°.- Las Direcciones de Salud y las Direcciones Regionales de Salud a nivel nacional, son responsables de la difusión, implementación, supervisión y aplicación del citado Manual, dentro del ámbito de sus respectivas jurisdicciones.

Artículo 3°.- Disponer que la Oficina General de Comunicaciones publique la presente Resolución Ministerial en la dirección electrónica http://www.minsa.gob.pe/portal/06transparencia/normas.asp del Portal de Internet del Ministerio de Salud.

Regístrese, comuníquese y publíquese

OSCAR RAUL UGARTE UBILLÚZ
Ministro de Salud

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MANUAL OF GOOD DISPENSATION PRACTICES
INTRODUCTION

INTRODUCTION

In Peru, several studies report the irrationality in the use of medications as well as the existence of negative results of medication, produced by various causes, which can cause therapeutic objectives not to be achieved or effects to occur. not wanted.

Several reasons supported the need for a national medicines policy, one of them was that medicines represent a high percentage of health spending, becoming the second item of expenditure in institutions and the first item of family health spending; The use of medications by health professionals and patients to face health problems and the inappropriate use of these medications has important consequences on the health of patients as well as effects on public health1 .

In relation to what was mentioned above, other national studies such as those carried out within the framework of the Disease Initiative

Infectious Diseases in South America (SAIDI) revealed that 62.6% of patients interviewed in the Constitutional Province of Callao in 2007 fully complied with the treatment, which indicates that 37.4% do not comply, which could generate complications in their health status. of the patient and create resistance to antibiotics2 .

In this sense, it is necessary to prepare, approve and publish regulatory documents related to the
Pharmaceutical Care with the purpose of making tools available to Pharmaceutical Chemical professionals that facilitate the implementation and development of this service based fundamentally on dispensing as part of Care

1 Ministry of Health, National Medicines Policy; Need for a national medicines policy; National Medicines Committee, Lima 2004.

2 SAIDI; Study on the determining factors of the use of antibiotics in consumers in Peru. South American Infectious Diseases Initiative (SAIDI) Project funded by USAID, April 2007.

Pharmacist.

This Manual of Good Dispensing Practices is a set of standards, established with the objective of ensuring proper use of medicines, establishing criteria, methodologies and requirements for compliance with the Good Dispensing Practices for Pharmaceutical Products established in the Regulations of Pharmaceutical Establishments approved by Supreme Decree No. 021-2001-SA.

Through the implementation and development of Good Dispensing Practices (BPD), the aim is to contribute to improving the health of the population through the correct and effective dispensing of medications in pharmaceutical establishments nationwide.

MANUAL OF GOOD DISPENSATION PRACTICES

I. PURPOSE

Contribute to improving the health of the population through correct and effective dispensing of medications in pharmaceutical dispensing establishments nationwide, providing a quality and warmth service, ensuring the well-being of patients, and respect for their rights as citizens. .

Good Medication Dispensing Practices (GDP) is a set of standards established to ensure proper use of these products. Correct dispensing practices ensure that the correct medication is delivered to the appropriate patient, in the prescribed dose and quantity, with clear information on its use and storage, and in a container that maintains the quality of the medication.

II. GOALS

1. GENERAL OBJECTIVES

Establish the criteria, methodologies and requirements for compliance with Good Medication Dispensing Practices.

2. SPECIFIC OBJECTIVES

2.1. Contribute to compliance with medical prescriptions.

2.2. Guide patients to the proper use of medicines.

23. Contribute to the pharmacotherapeutic monitoring of patients according to specific criteria.

2.4. Identify and contribute to the solution of problems related to the use of medications.

2.5. Promote coordination and communication between health professionals.

III. SCOPE OF APPLICATION

The Manual of Good Dispensing Practices will be applicable in all public and private pharmaceutical dispensing establishments nationwide.

IV. BASE LEGAL

1. Law No. 26842. General Health Law.
2. Law No. 27657. Law of the Ministry of Health.
3. Law No. 28173. Pharmaceutical Chemist Labor Law From Peru.
4. Supreme Decree No. 010-1997-SA and its amendments. Regulations for the Registration, Control and Health Surveillance of Pharmaceutical and Related Products.
5. Supreme Decree No. 021-2001-SA. Regulation of Pharmaceutical Establishments.
6. Supreme Decree No. 023-2001-SA. Regulation of Psychotropic Narcotics and other substances subject to Health Control.
7. Supreme Decree No. 023-2005-SA. Regulations of Organization and Functions of the Ministry of Health are approved.
8. Supreme Decree No. 008-2006-SA. Regulations of the Pharmaceutical Chemist Labor Law are approved.
9. Supreme Resolution No. 014-2002-SA. Sectoral Policy Guidelines for the Period 2002 –2012.
10. Ministerial Resolution No. 585-99-SA/DM. Approves Manual of Good Storage Practices for Pharmaceutical and Related Products.
11. Ministerial Resolution No. 519-2006-MINSA. Approves the Technical Document for Health Quality Management System.

12. Ministerial Resolution No. 304-2002-SA/DM. Scale of Fines for Violation of the Regulation of Pharmaceutical Establishments.

13. Ministerial Resolution No. 1753-2002-SA/DM. Directive of the Integrated System for the Supply of Medications and Medical-Surgical Supplies-SISMED and its amendments are approved by Ministerial Resolution No. 367-2005/
ONCE.

14. Ministerial Resolution No. 616-2003 SA/DM. They approve the Model Regulation of Organization and Functions of Hospitals.

15. Ministerial Resolution No. 769-2004/MINSA. Technical Standard No. 021-MINSA/DGSP/V.01: "Categories of Health Sector Establishments" is approved.

16. Ministerial Resolution No. 597-2006/MINSA. Approves NT No. 022-MINSA/DGSP-V.02 Technical Health Standard
for Clinical History Management.

17. Ministerial Resolution No. 1240-2004/MINSA. “The National Medicines Policy” is approved.

18. Ministerial Resolution 677-2005/MINSA. They approve the constitution of the “National Network of Health Establishments that have a Unitary Dose Medication Dispensing System in the scope of the Health Sector.”

19. Ministerial Resolution No. 826-2005/MINSA “Standards for the Preparation of Regulatory Documents of the Ministry of Health”.

V. GENERAL PROVISIONS

1. OPERATIONAL DEFINITIONS

to. Concentration.- Amount of active ingredient contained in a certain weight or volume of

medicine. The concentration of the drug substance or active ingredient is generally expressed in the following ways: weight/

weight, weight/volume, unit dose/volume. It is not synonymous with the dose of a medication.

b. Contraindication.- Indication that the administration of a specific medication should be avoided in certain conditions or clinical situations.

c. International Common Name (INN).- Common name for medicines recommended by the World Health Organization, in order to achieve international identification.

d. Dosage / Posology.- Describes the dose of a medication, the intervals between administrations and the duration of treatment.

and. Dose.- Total amount of a medication administered at once or total fractional amount administered over a given period.

f. Efficacy.- Ability of a medication to produce the proposed effects determined by scientific methods. The effectiveness of the drug is generally determined from phase II clinical trials, by comparing treatments that use the problem drug versus a control group (that receives no treatment or receives a placebo).

g. Stability.- Ability of an active ingredient or a product to maintain its original properties within the specifications relating to its identity, concentration or potency, quality, purity and physical appearance.

h. Pharmaceutical Dispensing Establishments.- Pharmacy, pharmacy or pharmacy services of the

health establishments of the public and private subsectors, in which medications and other pharmaceutical products are dispensed; and/or master and official formulas are prepared. These establishments are under the responsibility of a leading Pharmaceutical Chemist.

Yo. Expiration or expiration date.- It is the information indicated on the labeling of the immediate and immediate packaging of the product, which indicates the month and calendar year beyond which the product cannot be expected to retain its stability and effectiveness. This information is expressed with cardinal numbers, prefixing the term “EXPIRES” or “EXPIRES”.

j. Form of Presentation.- It is the way in which the product is offered for marketing in relation to the type of packaging and content in volume, weight and/or number of units.

k. Pharmaceutical Form.- Form or physical state in which a product is presented for administration or use in humans and animals, such as tablet, capsule, dragee, syrup, cream, injectable solution, among others.

l. Master Formula.- Pharmaceutical product intended for an individualized patient prepared by the governing Pharmaceutical Chemist or under his direction, in express compliance with a detailed prescription of the medicinal substances that it includes, according to the technical and scientific standards of the pharmaceutical art, dispensed in the pharmacy, pharmacy or pharmacy service and, with proper information to the user.

m. Official Formula.- Pharmaceutical product prepared and guaranteed by the governing Pharmaceutical Chemist or under his direction, in accordance with the official pharmacopoeia, and dispensed in the pharmacy, pharmacy or service.

pharmacy and intended for direct delivery to the patients served by the establishment.

n. Indications.- Refers to the pathological states for which a medication is applied.

either. Drug interaction.- Any interaction between one or more medications, between a medication and a food, or between a medication and a laboratory test. In general, the first two categories of interactions are important because of the effect they produce on the pharmacological activity of the medication: they increase or decrease the desirable effects or the adverse effects.

p. Medication.- Act of administering or applying medication to a patient by a certain route of administration, for example, orally. The term medication is sometimes used as treatment.

It is a mistake to use the terms medication and medication as synonyms.

q. Essential medicines.- According to the World Health Organization (WHO), essential medicines are those medicines that meet the health needs of the majority of the population, therefore they should be available in adequate quantities, in appropriate dosage forms and a price affordable to the community.

The concept of essential medicine implies a high health value and should not be confused with the concept of generic medicine. An essential medicine can be marketed as a generic medicine or as a brand name medicine.

r. Generic medication.- It is the pharmaceutical product whose name corresponds to the “Common Name

International" of the active ingredient, recommended by the World Health Organization (WHO) and is not identified by a brand name.

s. Brand name medicine or Pharmaceutical Specialty.- It is that pharmaceutical product that is marketed under a name determined by the manufacturer, different from the International Common Name.

t. Caution.- Information included in the medication labeling, aimed at healthcare personnel and the patient, on the care that must be taken to avoid undesirable consequences that could result from its use.

or. Active ingredient.- It is the raw material, substance or mixture of substances endowed with a specific pharmacological effect.

v. Adverse Drug Reaction.- Harmful and unintentional reaction that occurs at the usual doses used in humans for the prophylaxis, diagnosis or treatment of diseases or to modify physiological functions.

w. Health Registration.- Procedure through which the competent Health Authority, after evaluation, authorizes the manufacture, import or marketing of a pharmaceutical or related product. The registry also establishes the intrinsic characteristics of the product, its specific use, indications and contraindications for its use.

x. Rational Use of Medications.- Rational use of medications requires that patients receive medications appropriate to their clinical needs, at a dosage that meets their individual requirements for an adequate period of time and at the lowest cost to them.

and his community. (The Conference of Experts on the Rational Use of Medicines convened by the World Health Organization -WHO in Nairobi in 1985).

2. MEDICINE DISPENSATION

Medication dispensing is the professional pharmacist act of providing one or more medications to a patient usually in response to the presentation of a prescription prepared by a licensed professional. In this act, the Pharmaceutical Chemist professional informs and guides the patient about the proper use of the medication, adverse reactions, drug interactions and the storage conditions of the product.

It is Good Dispensing Practice to promote, at all times, the rational use of medications.

The Pharmaceutical Chemist professional must promote access to medicines through adequate management of their supply.

It is also responsible for the correct preparation of the master and official formulas.

The Pharmaceutical Chemist professional cooperates with actions aimed at contributing to the guarantee of the quality, safety and effectiveness of medicines that are marketed in the country, and participates in the identification and complaints related to counterfeit or adulterated products and products with quality or quality problems. effectiveness.

Good Dispensing Practices must be complied with comprehensively and in accordance with legal regulations related to pharmaceutical activity in general.

SAW. SPECIFIC PROVISIONS

1. OF THE DISPENSATION PROCESS

The medication dispensing process includes all the activities carried out by the Pharmaceutical Chemist professional from receiving the prescription to delivering prescription or non-prescription medications to the patient. Correct dispensing must be a procedure that guarantees the detection and correction of errors in all its phases.

In the dispensing process, there are five main activities:

1. Reception and Validation of the prescription.
2. Analysis and Interpretation of the prescription.
3. Preparation and Selection of products for delivery.
4. Records.
5. Delivery of products and information by the dispenser.

1.1 Reception and Validation of the prescription

The prescription as a result of a process, concludes in a diagnostic orientation and therapeutic decision that is reflected in a prescription.
This must be presented for its respective dispensation to the Pharmaceutical Chemical professional in a legally registered establishment.

The dispensing of prescription medications or other pharmaceutical products must be limited to prescriptions that are presented in clear and legible handwriting in order to avoid misunderstandings.

The content of the recipes must be subject to the provisions of current legislation3,4

Upon receipt, the Chemical professional
Pharmacist must confirm:

a) Name, address and registration number of the professional who issues it and name of the health establishment when it comes to standardized prescriptions.

b) Patient identification: Names and surnames of the patient.

c) Name of the pharmaceutical product being prescribed in its international common name (INN).

d) Concentration and pharmaceutical form.

e) Dosage, indicating the number of units per dose per day, as well as the duration of treatment.

f) Place and dates of issue and expiration of the prescription.

g) Seal and signature of the prescriber who issues it.

Depending on the validation carried out, the Pharmaceutical Chemist will decide whether or not to dispense the medication and/or the relevance of a consultation with the prescriber.

In the case of prescriptions for psychotropic medications and narcotics, these will be adjusted to the particular conditions that determine the

3 Supreme Decree No. 021-2001-SA. Regulation of Pharmaceutical Establishments, Cap. IV.

4 Ministerial Resolution No. 1753-2002/MINSA. Integrated System for the Supply of Medications and Medical-surgical Supplies Directive ; 7.8 annex 10.

specific legal regulations in this regard5 .

If the prescription is not followed, the patient will be informed of the problem detected, taking care not to question the actions of other healthcare professionals.

Once the validity period of the prescription set by the prescriber has expired, no product sold under a medical prescription may be dispensed against its presentation.

1.2 Analysis and Interpretation of the prescription

The analysis and interpretation of the prescription includes reading the prescription, correct interpretation of the abbreviations used by the prescribers, confirmation of the adjustment of the doses based on the particular state and situation of each patient, correct execution of the dose calculation and the quantity of the medication to be delivered, identification of drug interactions and therapeutic duplication. If there are doubts about the prescription, these must be resolved through consultation with the prescriber.

In accordance with the provisions of Article 33 of the General Health Law, the Pharmaceutical Chemist professional is authorized to offer the user alternative medications that are chemically and pharmacologically equivalent to the one prescribed in the prescription, in the same pharmaceutical form and dose.

Furthermore, they must refrain from inducing the user to acquire some of these alternatives.

5 Supreme Decree No. 023-2001. Regulation of narcotic drugs, psychotropic drugs and other substances subject to health control, Art. 30 and 36

1.3 Preparation and Selection of products for delivery

The preparation of products for delivery to the patient represents one of the main aspects of the dispensing process and begins once the prescription has been understood without doubt.

The identification of products on the shelves is done by carefully reading the product label. In the case of medications, it must be ensured that the name, concentration, pharmaceutical form and presentation correspond to what is prescribed.

Before delivery, it must be checked that the product(s) have the appropriate appearance, verifying that the primary and secondary packaging is in good condition. The labeling of both containers must correspond to the same product and comply with the specifications established in current legal standards (6).

To count tablets and capsules in bulk, special materials must be used (gloves, manual counters, among others) to prevent the dispenser's hands from being in direct contact with the medication.

The products must be packaged in safe packaging for conservation and transportation, respecting the cold chain when appropriate.

Products that are dispensed in units smaller than the content of the primary container must be packaged in containers in which at least the following information will be recorded:

a) Name and address of the establishment.

b) Name of the product.

c) Concentration of the active ingredient.

d) Route of administration.

e) Expiration date.

f) Lot number.

When preparing masterful or official preparations, the amount of the product for a complete treatment must be calculated and it is recommended to follow strict hygiene standards, especially hand washing, as well as the use of appropriate implements to avoid contamination. Its preparation must comply with the requirements and demands of current legal regulations6 .

In order to avoid errors, self-verification procedures must be implemented to guarantee the quality and accuracy of the care provided.

1.4. From the Records

Records of medication delivery to patients are essential in an efficiently managed pharmaceutical dispensing establishment. These records are useful for verifying stocks and are essential in solving problems related to medications delivered to patients.

Registrations must be carried out in accordance with current legal regulations7 .

The use of computer systems allows

6 Supreme Decree No. 021-2001-SA. Regulation of Pharmaceutical Establishments, Cap. 3.

7 Supreme Decree No. 023-2001. Regulation of narcotic drugs, psychotropic drugs and other substances subject to health control, Title Six.

keep all this information, which can be recovered for the preparation of the corresponding reports.

Once a recipe for master preparations has been dispensed, the seal of the establishment, the name of the person who prepared the preparation and the date of preparation will be placed on it. The recipe must be copied into the recipe book of the dispensing establishment, in correlative and chronological order.

When the Pharmaceutical Chemist professional dispenses an alternative medication to the one prescribed, he must write on the back of the prescription the name of the alternative dispensed, the name of the manufacturing laboratory, as well as the date on which the dispensation is made and his signature.

1.5. From the Delivery of the products and Information by the dispenser

Medications must be delivered to the patient or their representative with clear instructions, adding any information deemed appropriate.

The Pharmaceutical Chemist professional is responsible for providing information and guidance on the administration, use and dosage of the pharmaceutical product, its drug interactions, its adverse reactions and its storage conditions.

When it deems appropriate, provided that the necessary conditions are met and the legal regulations in this regard are met, it will propose the corresponding pharmacotherapeutic follow-up to the patient or their representative, based on previously established criteria.

Warnings related to possible undesirable effects must be made objectively.

and clarity, in order to prevent the patient from abandoning treatment.

The frequency, duration of treatment and route of administration of the medications must be emphasized, and information must also be provided on:

a) When to take the medication, in relation to food (e.g. before, after, with food) and in relation to other medications.

b) How to take or apply the medication (e.g. chew it, with lots of water, apply it locally).

c) How to store and protect medications for proper conservation.

It is necessary to ensure that the patient understands the instructions and whenever possible, the patient will be asked to repeat the instructions provided.

Patients must be treated with respect and it is essential to maintain confidentiality and privacy when dispensing certain types of medications or treating certain pathologies.

In order to provide adequate information to patients, there must be access to independent and up-to-date scientific information on medicines, information on first aid and toxicological emergencies, and official information on pharmaceutical alternatives to medicines.

2. THE ENVIRONMENT FOR THE DISPENSING SERVICE

The basis for correct medication dispensing practice is provided by a work environment

appropriate; The environments in which dispensing is carried out must be clean, safe and organized. Adequate organization is essential so that dispensing is carried out accurately and efficiently.

2.1 Physical environment

Within the pharmaceutical establishment, there must be a separate area for the act of dispensing, with sufficient space to properly carry out the tasks of preparation and delivery of medications, as well as information for their correct use.

The physical environment must be kept clean, free of dust and dirt. Although the care area must be accessible to patients, due care will be taken to ensure that it is located in a location protected from dust, dirt and pollution.

2.2Shelves and surfaces used during the job

The available space must be organized to create a safe and efficient work area, there must be sufficient space for staff to move during the dispensing process and the distance that a dispenser must travel during this process must be reduced to a minimum, with the aim of contribute to service efficiency.

Food and beverages must be kept out of the dispensing area.

The refrigerator will be used exclusively for medications that require low temperatures. There must be a schedule to check the cleaning and defrosting of the refrigerator.

Maintaining a clean environment requires a regular system of cleaning shelves and

Daily cleaning of floors and work surfaces.

Spilled liquids should be dried up immediately, especially if they are viscous, sweet, or attractive to insects.

2.3 Medicines, equipment and packaging materials

All medications in general must be stored in an organized manner on shelves, keeping their labels within easy reach and properly preserved.

Recommended storage conditions

Regarding temperature, light and humidity, they must be strictly adhered to in order to maintain the quality of the products. Cleaning the equipment and materials used in storage and dispensing is essential.

A stock rotation system must be established that minimizes product expiration.

3. STAFF

Personnel involved in dispensing and sale must be properly identified, maintain correct personal hygiene and wear clean and protective clothing.

3.1 Of the Pharmaceutical Chemist

The Pharmaceutical Chemical Professional of the pharmaceutical establishment must:

a) Participate and promote the selection of medicines necessary for the community applying rational use criteria.

b) Establish an effective and safe dispensing

of medications, verifying, among others, the health record and expiration date of the medications available in the pharmaceutical dispensing establishment.

c) Adopt a guiding and educating attitude for patients in everything related to medications.

d) Promote patient adherence to the prescribed treatment.

e) Select, train and supervise the auxiliary personnel for whose actions in this process, the Pharmaceutical Chemical professional is directly responsible.

f) Stay updated to adequately answer patients' questions and concerns, controlling self-diagnosis and self-medication.

g) Comply and enforce Good Storage Practices where applicable.

h) Comply with the corresponding legal and health regulations.

In the act of dispensing medications, professional ethical duties with the patient and due respect between health professionals must be kept in mind. One must act with the security provided by scientific support, without forgetting the limitations of the pharmaceutical profession.

3.2 Auxiliary Personnel

To comply with the Good Practices of
Dispensing Medications, it is advisable to have auxiliary personnel capable of carrying out dispensing tasks, who will be under supervision

of the Pharmaceutical Chemist. These auxiliary personnel must be incorporated into continuous training processes to carry out a correct sale of products.

Auxiliary personnel are prevented, under the responsibility of the leading Pharmaceutical Chemical professional and the owner of the dispensing establishment, from carrying out acts corresponding to dispensing or offering users alternatives to the prescribed medication.

The dispensing of medications is the exclusive responsibility of the Pharmaceutical Chemist professional.

4. DOCUMENTATION

The documentation of pharmaceutical services makes it possible to obtain statistical data that contributes to achieving improvements in health care in general and in the use of medicines in particular. In this sense, pharmaceutical establishments where medicines are dispensed must have the following books official, which must be numbered, duly updated and available to the inspectors.

to. Recipe book, when master and official formulas are prepared, which will be copied in correlative and chronological order.

b. Narcotic and psychotropic drug control book, where the dispensing of controlled substances or medications is recorded8 . Each of the pages of this book must be endorsed by the agency

8 Supreme Decree No. 023-2001. Regulation of narcotic drugs, psychotropic drugs and other substances subject to health control, Art. 44.VIII.

deconcentrated health department at the corresponding territorial level.

c. Book of occurrences, where changes in the work schedule and rotation of the pharmaceutical chemical professionals who work in the establishment will be recorded, as well as the absences of the manager and other observations related to the operation of the establishment that are deemed appropriate.

VII. RESPONSIBILITIES

1. The Ministry of Health through the General Directorate of Medicines, Supplies and Drugs is responsible for disseminating, directing, supervising, monitoring and evaluating compliance with this Manual in the various instances of the subs. public and private sectors.

2. Compliance with this Manual is the responsibility of the competent health authorities of the departments of the Ministry of Health, as well as public and private health establishments at the national level 3. Dispensing activities will be carried out under the responsibility of the Pharmaceutical Chemist. in pharmacies, pharmacies and pharmacy services of health establishments in the public and private sectors, where medications are dispensed; and/or master and official formulas are prepared.

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