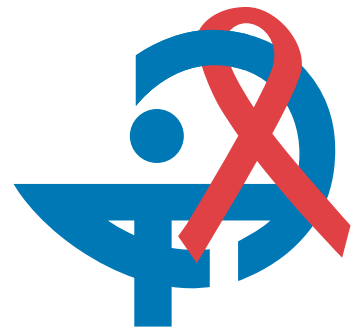


*R*ecommendations for pharmacy management and the dispensing of Anti-Retroviral Medicines in Resource-limited settings

FIP Working Group
on Pharmacists and HIV-AIDS



Recommendations for pharmacy
management and the dispensing
of Anti-Retroviral Medicines
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- Consejo General de Colegios Oficiales de Farmacéuticos, SPAIN.
- Pharmaceutical Association of Thailand, THAILAND.
- American Society of Health-System Pharmacists, USA.

List of Abbreviations

3TC	Lamivudine
ABC	Abacavir
ADAGIO	Aide à la Délivrance aux Ambulatoires et de Gestion Informatisée des Ordonnances
ADINPHORM	Aide au Développement INformatique appliqué à la Pharmacie HOspitalière et la Recherche Médicale
AIDS	Acquired Immune Deficiency Syndrome
AMC	Average Monthly Consumption
APV	Amprenavir
ARV	AntiRetroViral
ASHP	American Society of Health-system Pharmacists
AZT	Zidovudine
CBC	Complete Blood Count
CD4	Cluster of Differentiation 4
CD-ROM	Compact Disk-Read Only Memory
CESPHARM	Comité d'Education Sanitaire et Sociale de la Pharmacie Française
CHMP	Centrale Humanitaire Médico-Pharmaceutique
d4T	Stavudine
ddI	Didanosine
EDM	Department of Essential Drugs and Medicines (WHO)
EFV	Efavirenz
ELSA	Ensemble Luttons contre le Sida en Afrique
ESTHER	Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau
FAO	Food and Agriculture Organization of the United Nations
Fcfa	CFA franc
FIP	International Pharmaceutical Federation
FTC	Emtricitabine
HIV	Human immunodeficiency virus
ICRC	International Committee of Red Cross
IDA	International Dispensary Association
IDV	indinavir/ritonavir
IDV/r	indinavir/ritonavir
INN	International Non-proprietary Name
IT	Information Technology
LPV	Lopinavir
LPV/r	Lopinavir/ritonavir
MS	Minimum Stock
MSF	Médecins sans Frontières
MSH	Management Sciences for Health
NA	Not Applicable
NCBO	National Central Buying Office
NEML	National Essential Medicines List
NFV	Nelfinavir
NGO	Non Governmental Organization
NPA	National Procurement Agency
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NVP	Nevirapine
OI	Opportunistic Infections
ORS	Oral Rehydration Salts
PEPFAR	President's Emergency Plan for AIDS Relief
PI	Protease Inhibitor
QTO	Quantity To Order
ReMeD	Réseau Médicament et Développement
RS	Running Stock
RTV	Ritonavir
SOH	Stock On Hand
SQV	Saquinavir
SS	Safety Stock
TDF	Tenofovir (Disoproxil Fumarate)
UNAIDS	United Nations Joint Program on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USB	Universal Serial Bus
WHO	World Health Organization

Foreword

The world community recognizes HIV/AIDS as a global priority, and reversing the pandemic by 2015 is one of the Millennium Development Goals. More opportunities have appeared and it is thanks to a better awareness in resource-limited settings and substantial financial response from the Global Fund and private foundations to help fight AIDS, tuberculosis and malaria.

With the use of antiretrovirals, HIV/AIDS has become a chronic, rather than a terminal, disease. An international study published this year in the *Lancet* shows that patients taking antiretroviral drugs can now expect to live into their 60s and beyond (particularly for those starting their treatment when CD4 cells are not too low).

Scaling up treatment is a major challenge that needs appropriate development and actions from the pharmacists' community.

Dealing with HIV/AIDS treatment requires all areas of expertise of the pharmacist; successful treatment depends both on a continuous supply of antiretroviral drugs and good dispensing procedures.

FIP has advocated and supported the involvement of pharmacists in HIV/AIDS as a priority since 1995 with the establishment of its working group on "Pharmacists and HIV/AIDS".

Since 1997, the pharmacist's role in the fight against HIV-AIDS has been recognised in a joint declaration by FIP and World Health Organization.

In September 2004, FIP set up a website (<http://www.fip.org/HIVAIDS>) for the International Network for Pharmacists on HIV/AIDS, in English and French. The website offers training modules specifically designed for pharmacists on preventing the transmission of HIV and caring for patients living with HIV.

In September 2005, the Working Group, "Pharmacists and HIV/AIDS", issued a report entitled "Survey of the Health Professionals Human Resources with Regard to the HIV/AIDS Pandemic on the African Continent".

With the present document, this group proposes a guidance that sets out principles and guidelines for procurement and dispensing of HIV/AIDS medicines. It provides examples of procedures and practical advice as well as offers many links for securing more information and advice.

Pharmacists are invited to explore and adapt this guidance to their specific environments.

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Immediate Past President of FIP

Introduction

Thanks to the WHO 3×5 Initiative (launched in 2003) and recent substantial financial support, such as that provided by the Global Fund for HIV/AIDS, Malaria and Tuberculosis, or the President’s Emergency Plan for AIDS Relief (PEPFAR), almost 3 million HIV-positive people living in low and middle income countries – 2,120,000 of whom live in Sub-Saharan Africa – now have access to antiretrovirals (ARVs) [1]. Nevertheless, this widened access to ARV drugs raises the question of the availability of human resources needed to ensure continuity and quality of patient care, treatment and follow-up.

Many weaknesses have been detected within the healthcare chain, mainly in the pharmaceutical link: weaknesses of national healthcare systems; failures in official pharmaceutical organizations; frequent stock shortage of medicines; insufficient pharmaceutical workforce; insufficient recognition for pharmacists and their loss of motivation due to inadequate compensation. And yet, this link is the source of medicine supply and is imperative in patient healthcare management. This deficiency, without doubt, directly affects the adherence of patients living with HIV and harms their quality of care.

Western Africa’s scarce literary resources on pharmacy management and difficult access to them are the primary roadblocks to training the pharmaceutical workforce in this region. This situation has had a negative impact on the correct dispensing of ARVs. Pharmaceutical teams are often under-trained in both pharmaceutical management and dispensing. In addition, team supervisors (i.e. pharmacists or directors of dispensing outlets) often lack the tools necessary to manage pharmaceutical activity.

WHO and allied stakeholders both locally and abroad have recently become aware of these gaps and have proposed solutions, including strengthening financial supports, improving and creating training opportunities, technical support, and experience sharing.

This document is aimed at providing grass-roots pharmacists and their teams with practical, basic and concrete guidelines for the correct management and dispensing of medicines for patients infected with HIV.

This document is intended for pharmacists in charge of dispensing HIV/AIDS treatments, whether they work in hospital pharmacies or other dispensing outlets such as those run by international humanitarian organizations (i.e.: MSF, ICRC) or by local community based associations. In the text, the word “organization” covers those structures.

This collection of fourteen technical sheets on good practice have been created in the framework of a PharmD Thesis based on data collected with five associative structures involved in HIV/AIDS care for patients infected with HIV both in Mali and Burkina Faso¹. These technical sheets were then adapted and updated by experts sought by the FIP “Pharmacists and HIV/AIDS” workgroup. A provisional version has been subjected for comment to all members in the first half of the year 2008. Their invaluable comments allowed to make sure of their relevance.

They describe pharmaceutical activities related to HIV care as they are carried out in French-speaking West Africa and present procedures related to the main functions and responsibilities of the pharmacist:

- the logistic and organizational management relative to the medicine, on one hand, the lay-out of the pharmacy premises, storage of medicines, selection of suppliers, organization of the orders, the inventory control and management, the waste management;
- and the process of dispensing and follow-up of the patients, on the other hand.

At the end of each sheet, bibliographical references (including their Internet address when available) are offered in order to provide access to further information on the topic.

These technical sheets are meant to be a practical resource to the pharmaceutical workforce in Africa. They may not, in any case, substitute for African national pharmaceutical guidelines, but rather complement them by providing concrete examples and details on several points which may not be developed in official documents.

Throughout the development of this work, it became evident that there was a clear need to underline the value of the role of pharmacists in the care of patients living with HIV, from the technical and logistic functions through to clinical care.

Training pharmacists will contribute to ensuring Quality Assurance of the chain, essential to offering better healthcare management to patients living with HIV. For this purpose, several resources are available on the website of the FIP Working Group on Pharmacists and HIV/AIDS (<http://www.fip.org/hiv aids>).

1. LANGLOIS J. Pharm. D Thesis « Optimisation de la prise en charge communautaire des patients infectés par le VIH au Mali et au Burkina Faso: propositions pour une assurance qualité du circuit thérapeutique », publicly defended on 11 October 2006 at the School of Pharmacy of the University of Paris V – René Descartes.

1

Lay-Out of the Pharmacy Premises

Objectives

The Lay-out of the pharmacy premise should allow:

- Storage that protects the quality of medicinal products and material.
- Rational management of stocks.
- Pleasant atmosphere for the team working in the pharmacy and the patients frequenting it.

a. Choice of Premises

Space within the premises:

The pharmacy must have 2 well-separated areas corresponding to the flow of movement of the medicinal products:

- a reception area for packages and storage of “reserve stock”: accessible to vehicles (a delivery truck should be able to unload the packages in front of the door), the door must be large enough to allow large boxes to be brought through;
- an area where “current stock” will be placed and where medicinal products will be dispensed to patients: accessible to patients coming out of their medical consultation and in front of which there is a quiet and shaded waiting area with seats for patients.

There are two possible solutions:

- Either a large premises: a large single pharmacy with a separated area (wall or other type of partition) to receive and stock reserves.
This is the most practical solution but it requires a large space that can be divided into two areas.
- Or 2 separated rooms (non adjacent): a dispensing area where current stock is placed and patients are served, and another room for storage. This solution is a good alternative, especially for pharmacies with a large volume of reserves to be stored. It means that a room that is unsuitable for receiving patients can be used for storage. It is then necessary to organize the flow of movement between the storeroom and the dispensing area.

Rooms size:

It should be assessed in relation to storage needs depending on the following criteria:

- amount of medicinal products and material to be stored and dispensed in the pharmacy ;
- periodicity (frequency) of restocking (for the storeroom): the less frequent the orders, the larger the stocks and therefore the larger the storage space required;
- number of patients in the active file (taking anticipated increases into account);
- the number of people working in the pharmacy and the number of patients that the pharmacy receives at the same time (for the dispensing area).

Various characteristics to be taken into account when choosing the premises

- **Electrical Installations:** Sockets, electrical wiring and lighting must comply with safety standards. There should be enough sockets and lights to enable material, including telephone and computer material, to be installed.

- **Ventilation:** It should be possible to install a ventilator, and possibly (if the financial means allow it) an air-conditioner, which will have the advantage of regulating heat and humidity if correctly used (temperature should permanently remain between 20 and 25°C).
- **Material for good thermal insulation:** Walls built using insulating materials, an insulated sloping roof to prevent water stagnation, a false ceiling for good insulation, shutters to protect the windows from heat.
- **Floor:** Cement is the best material as it is easy to clean and does not get damaged as a result of moving heavy material. A sloping floor allows water to run off when it is being washed and in the event of flooding.
- **Safety of doors and windows:** secured door (solid door, solid lock, 2 locks if possible), windows protected from breaking and entering, insects (shutters and/or bars and/or a wire screen), secured external air-conditioner (wire screen to be placed behind the air-conditioner).
- **Fire Extinguishers:** Fire-fighting equipment (fire extinguishers) should always be available and in good working order. It is advisable to ensure that pharmacy staff has been trained to use the fire extinguishers (controls and training to be carried out initially and renewed every 2 to 3 months).
In order to find out the number and type of fire extinguishers imposed by safety standards, refer to national regulations. If there is no fire extinguisher available use sand to extinguish the fire (a sand pit should always be accessible and nearby).

b. Internal Lay-Out

The pharmacy should contain three completely separate areas:

- One area dedicated to the reception of parcels and storage.
- One area where the stock for everyday use is stored and where medicines are dispensed to the patients.
- One area dedicated to therapeutic education consultations.

Storage of Medicines

- **In the dispensing area:** store all medicines on shelves and in storage cupboards. ARV medicines should be stored in secured cupboards.
- **In the storeroom:** store cardboard boxes on shelves and in storage cupboards. Cupboards should be well-ventilated, especially if the room is not air conditioned. If this is not possible, they can be stored by piling them on pallets (never directly on the floor because of risks of flooding and animals/insects/rodents).

Shelving

- Should be solid and stable.
- Metal shelves are more suitable than wooden ones in tropical countries as they do not attract termites. Wooden (preferably treated) or aluminium cupboards can be used in areas near the ocean.
- Place the shelving in such a way as to avoid exposing products to direct sunlight.
- Leave a space between the walls and the shelves in order to improve ventilation.
- Lay the shelving perpendicularly to the walls with over 90 cm (approx. 34 inches) between each shelf (to allow movement between two shelves). This lay-out wastes less space than placing shelving along the walls.
- Quick-assembly shelving is recommended. This system allows you to modify the space between shelves if needed, in order to optimize the space used.

Storage Cupboards (secured by a lock or a padlock)

- Recommended for storing products that are dust and light-sensitive or for very safe storage (this is the case for ARV drugs due to their cost and high demand).

The Refrigerator

- For products that need to be stored between +2°C and +8°C (the upper part of refrigerators with a freezer is often the coolest).
- It is useful to place the thermometer in the fridge and to keep track of the temperature daily. The average monthly temperature should be around +4°C. The difference between two days should not exceed +2°C or -2°C. The temperature must not ever fall below 0°C.
- Do not overload the fridge with medicines, it prevents cool air from circulating properly.
- In the event of a power cut, do not open the refrigerator, in order to keep it cold for as long as possible.

Practical advice: Keep some bottles filled with water at all times in the refrigerator; they will enable you to ensure that the temperature in the refrigerator is above 0°C (otherwise the water in the bottles freezes, indicating that the temperature is too low, which is dangerous for the stability of the medicines) and they also keep the refrigerator cold in the event of a power cut.

Dispensing Area

- A counter, table or desk should be installed for dispensing medicines.
- This counter should be accessible from the shelves of current stock (for staff) and also from the entrance door (for patients): when patients enter they should be able to spontaneously head towards it. It should be clean and clear; patients should be able to sit down beside it while waiting for the staff to dispense their prescriptions.
- Confidentiality is particularly important as regards patients living with HIV. It is therefore important to remember this when laying out the dispensing area. To avoid obstruction at the counter, the queue could lead outside, in front of the dispensing area door (seats and shade are imperative).
- A storage unit (shelf, cupboard) near the counter should be provided for storing material necessary for dispensing medicines (dispensing register, a small pouch containing prescriptions dispensed, educational materials, etc.).

Staff Work Area

- A desk must be provided in the staff's work area. If possible, this desk should be away from the dispensing counter, so that someone can work at the desk while another person looks after dispensing at the counter.
- The desk should be large enough to place a computer, with enough extra room to work on documents beside it.
- It should be well lit, preferably by natural light and a desk lamp.
- There should be a storage cupboard beside this desk for storing working documents in progress (within reach), archives (at the very top or very bottom) and documentation. This cupboard should be securable as it contains confidential information.

Other Arrangements

- There should be as many chairs in the dispensing outlet as people working there. That way, there is a chair for each patient waiting for his/her products at the counter.
- A stepladder is necessary if the shelves are too high for staff to reach them (this is the case for both the dispensing area and the storeroom).

- A thermometer should be placed in the pharmacy (away from direct sun) in order to record the temperature daily (this may be checked at the same time as the refrigerator).
- A large, robust waste-paper basket should be placed in an accessible area for non-organic waste (cardboard and plastic boxes and papers). Another bin with a lid, for organic waste (foodstuffs) should also be available.

Bibliographical references for further information on this subject

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- “Guide to good storage practices for pharmaceuticals” (annex 9 of the WHO report “WHO Expert Committee on Specifications for Pharmaceutical Preparations”) WHO Technical Report Series, No. 908, 2003.
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Latest access on 15 January 2008.

2 Storing Medicines

Objectives

Meticulous organization of stored, current drugs in the dispensing outlet makes it possible to:

- **find** medicines quickly on the shelves;
- easily assess the **number of boxes left**;
- **foresee running out** whenever there is a label in front of an empty space.

a. Organizing pharmaceutical products and equipment

In the dispensing outlet

- The current stock of medicines distributed to patients on a daily basis is kept in the dispensing outlet. All the medicines are stored here in adequate quantities ranging from several days' worth to several weeks worth. (i.e. a month's supply) depending on the box size of the product (i.e. for liquid formulations which come in larger boxes, we might keep less than a month's supply) and the available shelf-space. It is re-stocked regularly (i.e. monthly) with boxes from the reserve / warehouse.
- Storage shelves are organized based on dosage form (how the medicines and devices/equipment are administered [2]):
 - Orally.
 - By injection and intravenously.
 - Topical use (creams, ointments, drops, etc.) and disinfectants.
 - Small disposable supplies: bandages, syringes, sterile compresses.
 - Infant feeding supplies (powered milk, bottles).
- In each category (oral, injectable, intravenous, topical) medicines are arranged in alphabetical order of their International Non-proprietary Name (INN). For medical supplies and infant feeding supplies, it is best to organize items by function so as to find them quickly: injection supplies, bandages, sutures...
- Each medicine is assigned a specific area on shelves marked for that purpose marked by a solid label indicating: the name of the drug or its INN, formulation and dosage.
Ex: ampicillin, tablets, 250mg
- Drugs that have to be kept under lock and key are stored by form (route of administration), grouped by class (ARVs, narcotic drugs, etc.) and arranged in alphabetical order within each class.
- If ARVs need to be separated based on their funding sources, then set aside a specific place in the ARV section for each funding program (National Program, financial partner X or Y).
- By the same token, for drugs that require refrigeration, organize them using a system of labels, classification by category (vaccines, hormones, ARVs, reagents) and alphabetical order.
- Drugs and cardboard drug boxes must never be stored on the ground or on the lowest level of a shelf. They should be stored sufficiently high to prevent any damage caused by water or animals at floor level.

In the reserve storage room

- Drugs should be kept in cardboard boxes. These boxes should be stocked on shelves, in closets or on pallets (do not place the cardboard boxes on the ground).
- Drugs should be organized exactly the same way as in the dispensing area (in other words, by how they are administered and in alphabetical order of their INN).
- Clearly label each box with the following information: the drug's INN, its formulation, dosage, minimum and maximum expiration date and number of boxes that it contains, and, if necessary, the funding program that purchased them (sponsor).
- In the reserve warehouse, all the boxes containing the same product must be kept together.
- Scattering the packages makes it harder to use drugs in order of expiration date and harder to manage supply.

Preventing expiration during storage

- Apply the “first-to-expire, first-out” rule [3], when moving drugs from storage to the dispensing area shelves as well as when dispensing drugs to patients.
 - Keep products which expire soonest at the front of the shelves and keep those with a later expiration date behind them.
 - Caution! Products are not necessarily delivered according to the order of their expiration dates! Those delivered most recently are not necessarily those which will last the longest!
 - Highlight expiration dates very clearly on the boxes (either by copying them over with a marker on the front of the box or by underlining in color the date already printed on the label).
- Make the rest of the team aware of its responsibility to manage the stock according to the expiration dates.
- Inform prescribers of the difficulties caused by expiration dates.

b. Recommendations to prevent spoiling of pharmaceutical products

A damaged product should never be dispensed to a patient. Products whose freshness you question put patients at real risk. It is therefore advisable to prevent the spoiling of stored products in the pharmacy by trying to keep them in the kinds of conditions indicated on the product and controlling the storage environment: temperature, air circulation, moisture and exposure to light. When drugs are being shipped:

- Ensure that the cardboard boxes used are strong enough. Fill any empty spaces in the box with polystyrene chips or newspaper.
- Be cautious so as to avoid any risk of theft.
- Temperatures can reach 50 to 60°C inside vehicles, containers or at departure sites (tarmac, docks). If this is the case, conservation and expiration dates can no longer be guaranteed. It is therefore important be able to detect at each stage from shipping to patient reception (reception of the product delivered, placement in storage, dispensation), the physical characteristics of its deterioration.

What kinds of problems can be caused by the deterioration of pharmaceutical products?

The major consequence of product deterioration is a decrease in the product's efficacy but there are also other serious potential consequences. Spoiling is often associated with a change in the look of the products that the pharmacist should be able to see.

Chart n°1: Signs of spoiling of 'vulnerable' drugs and health consequences for patients [8]

Vulnerable drugs	Signs of spoiling	Consequences and risks for patients	
Some antibiotics Some ARVs Products with very low therapeutic margin	Various physical changes in the product (color, smell, taste)	Decrease in drug effectiveness	Outbreak of resistant bacterial or viral strains (HIV is very sensitive to under-dosage of ARVs)
Tetracycline	Yellow powder becomes brownish and viscous	Increased drug toxicity	Increased renal toxicity: renal tubular lesions
Suppositories, capsules, creams, ointments	Various physical changes (color, smell, taste, texture)	Heterogeneous dissemination of the drug's active ingredient	Uneven absorption: over- or under-dose depending on areas of contact
Oral Rehydration Salts (ORS)	Compact, brownish, not dissolvable	Unusable form	Not for human consumption

How to identify spoiling [5]?

Chart n°2: Signs of drug spoiling depending on their pharmaceutical formulation [4].

Pharmaceutical Formulations	Examples	Signs of spoiling	Consequence: appropriate disposal of drugs
All products		Broken or torn package. Incomplete, illegible or missing labels.	
Liquids	<i>Liquid paracetamol.</i>	Color change. Cloudy appearance. Sediment (at the bottom of the bottle). Broken seal on bottles, ampoules, or cracked vials. Moisture inside the package.	
Latex products	<i>Examination gloves</i>	Dried out, crumbly or cracked.	
Latex products with lubrication	<i>Lubricated condoms.</i>	Sticky, stained or moist wrapper (leaking lubricant). Change in color or odor of lubricant.	
Tablets, pills, capsules, powders	<i>Aspirin. Amoxicillin, ampicillin, Penicillin V. Retinol.</i>	Color change. Crumbled pills or crushed capsules. Missing pills (from the blister pack). Sticky (especially capsules and gel covered tabs). Unusual odor.	
Injectable solutions	<i>Reconstituted antibiotics. Oxytocin.</i>	The liquid is not a stable and homogenous solution after it is reconstituted.	
Sterile products	<i>Sterile gloves. Sterile compresses.</i>	Torn, dented or stained package. Missing, twisted or broken pieces. Moisture inside the package.	
Tubes (creams, ointments)	<i>Tetracycline (ophthalmic ointment).</i>	Sticky tube. Leaking of contents or perforations of tube.	

How to prevent deterioration [6]?

Heat

- Protect the storage area from sunlight (shutters/window and door blinds, drop ceiling).
- Install a fan and/or air conditioner. If air conditioning is installed the thermostat needs to be set to maintain the temperature between 20 and 25°C. Do not keep it too cold (< 20°C) nor vary the temperature since large temperature differences lead to medicine spoiling.
- Use a thermometer to control extremes in temperature in the room and in the refrigerator (especially in the reserve storage room so that products are not spoiled by heat).

Cold

- follow the storage recommendations on the label:
In the freezer: -15°C to 0°C
In the refrigerator: + 2°C to + 8°C
In the cold: + 8°C to + 15°C
Room temperature: + 15°C to + 30°C (< 25°C is the most appropriate)
- Products that need to be kept at room temperature cannot be kept in the refrigerator because moisture and large differences in temperature will lead to spoiling.
- Use of the refrigerator: please see the section in sheet n°1 which covers this topic.
- If fans or air conditioners have been installed in the room make sure that there is airflow around the refrigerator.

Light

- Drugs should not be exposed to direct sunlight (Northern exposure if possible, shades, blinds or curtains on windows, trees in front of windows.)
- Especially protect all medicines in liquid form (syrups and injectables are unstable to heat) by keeping them in their opaque packages sheltered from the light).
- Careful: tinted glass does not completely protect from exposure to light!

Moisture

- Ensure proper ventilation in the building by opening windows regularly. Fans help circulate fresh air. Air conditioning also allows protection against moisture.
- All containers have to be kept shut with a top, especially medicines in dry form.
- Bulk medicines that have been separated into individual sachets should not be packed too far in advance (not more than one month ahead). Pills are better protected in their original containers than they are in transparent baggies that are not as well sealed.

Cleanliness

- Sweep and mop the storerooms daily.
- Wipe off shelves regularly to remove dust and dirt.
- Put trash in bins with covers.
- Empty the trashcans on a daily basis and dispose of all trash in such a way as to not attract pests.

Note: These routine cleaning chores should be scheduled and posted on a sign in the dispensing outlet so that each person knows for which chore they are responsible and when it needs to be done.

Note: The purchase of cleaning supplies should be included in the dispensing outlet's projected overhead budget.

Be cautious about the possibility of counterfeit drugs

The pharmacist and his team will have to be particularly aware of the risk of counterfeit drugs. He will refer, if necessary, to the national counterfeit risk prevention recommendations.

Several websites offer information and practical tools on this subject:

- FIP's website (International Pharmaceutical Federation); in English:
http://www.fip.org/www2/subsections/index.php?page=menu_counterfeitmedicines&menu_counterfeitmedicines=menu_counterfeitmedicines_policy
- LEEM's website (Union of French Drug Companies); in French:
http://www.leem.org/hm/themes/article.asp?id_sous_rubrique=91&id_article=479
- « Centrale Humanitaire Médico Pharmaceutique » website (CHMP); in French :
<http://www.chmp.org/html/publications.html>
- The website of the network ReMed (network medicines and development); in French:
http://www.remed.org/html/marche_illicite_de_medicaments.html
- WHO's website; in English:
http://www.who.int/medicines/counterfeit_conference/en/index.html

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3 Waste Management

Objectives

Rigorous waste management makes it possible to:

- protect pharmaceutical products;
- protect patients and health center staff;
- sorting and disposing waste in accordance to their specific category.

a. Advantages of a rigorous waste disposal system

An organized and rigorous waste disposal system protects both pharmacy users and the products stored within.

Protection of Pharmaceutical Products

A clean pharmacy:

- Avoids attracting animals and insects (rodents and insects love dirt) that could damage the medicines.
- Prevents premature deterioration of medicines as they are stored in a clean environment.

Protection of People (patients and health center staff)

- Prevents accidents (injury, intoxication, etc.) linked to improper handling of pharmaceutical waste.
- Avoids supplying parallel channels with medicines that are dangerous for consumers and short-cut the reliable operational supply systems.
- Prevents contamination of neighboring water reserves, used by the population living close to the pharmacy.
- Prevents production of polluting fumes due to incineration of toxic products.
- Protects the pharmacist who is responsible for respecting the environment and people through reasoned management of pharmacy waste. All staff members should know and respect the country's current legislation.

b. Types of Waste collected at the Pharmacy [7]

Chart 3: Classification of Waste to be collected and disposed of in a Community Pharmacy.

Non-Medical Waste	Health Care Waste
<ul style="list-style-type: none"> – ordinary household rubbish: food, papers, paper handkerchiefs, etc. – packaging: cardboard & plastic. 	<ul style="list-style-type: none"> – Pharmaceuticals (without their cardboard or plastic packaging): medicines, expired or damaged consumables. <i>These can be solid, liquid or aerosols and will thus be treated differently depending on their form.</i> – biological waste: secretions such as blood, biological liquids, human tissue, and all objects stained with blood or biological liquids. – sharps waste: glass bottles and ampoules, needles, blades, etc.

c. Waste to be Disposed of by the ordinary disposal system (public service)

- **All Non-Medical Waste (cf. above table)**

Comments: cardboard and plastic packaging should preferably be recycled.

- **Certain Health Care Waste**

- Solid pharmaceutical waste (tablets, powders, capsules, etc.) in small quantities, once the volume is less than 10% of the other waste products (non pharmaceutical).
- Glass packaging, must first be wrapped in solid paper or cardboard, in order to prevent injury to people bringing the waste to the municipal dump.
- Aerosols (sprays, inhalers, etc.): ensure that they are wrapped in a closed and insulated box if they contain toxic substances (indicated by a pictogram).

Comments

Comment 1: Regarding waste disposal through the official channel, the official documents should be filed and a copy should be kept in the pharmacy.

Comment 2: If there is no waste disposal system provided by the town, the above-mentioned waste products must be burned and the remains buried. Remember: aerosols should never be incinerated or burned as there is a high risk of explosion!

d. Specific sorting and Disposing of certain Waste

All waste products to be sorted and disposed of specifically are part of the **medical waste category** [8].

Chart 4: Recommendations for Sorting and Disposing of Health Care Waste

Type of Waste	Disposal Method
1. solid pharmaceutical products if their weight becomes greater than 10% of total waste	<ul style="list-style-type: none"> – ideally: high temperature incineration (recommended by the WHO) – otherwise: burning and burying.
2. liquid pharmaceutical products	<ul style="list-style-type: none"> – ideally: high temperature incineration – otherwise: dilute them and then discharge them to a sewer.
3. glass ampoules and bottles containing liquid products	<ul style="list-style-type: none"> – ideally: high temperature incineration after breaking the ampoules – otherwise: crush them, wrap them in solid paper or cardboard, and throw them in the dump.
4. disinfectants and antiseptics	<ul style="list-style-type: none"> – these must be diluted – then discharged to a sewer. Do not exceed 50 liters per day. – it is also possible to pour them into a fast-flowing river or stream but never into stagnant water!
5. anti-infectious medicines (especially antibiotics) and antineoplastics (toxic)	<ul style="list-style-type: none"> – ideally: high temperature incineration – otherwise: they can be brought to the dump but must be placed in a well-insulated box first (the objective being to neutralize the product).
6. sharps waste (needles, blades)	<ul style="list-style-type: none"> – to be placed in a safety box then: – ideally: high temperature incineration – otherwise: burning and burying.
7. biological waste	<ul style="list-style-type: none"> – to be placed in a special bin (with a solid, impermeable bin liner), then: – ideally: high temperature incineration – otherwise: burning and burying. It is possible to pour thin cement into the bottle where the needles have been collected and then to bury this "solid" bottle.
8. certain regulated substances (certain analgesics and psychotropic substances)	<ul style="list-style-type: none"> – eliminate them according to the country's legislation in force.

e. Practical Organization for Waste Disposal

- Provide a large bin for all waste that can be disposed of at the municipal dump. This waste will follow the normal channel provided by the country.
- **Sort specific waste as you go, according to the recommended means of disposal [9]:**
 - **keep all waste for incineration or burning in a box** placed to one side, stating that it contains potentially dangerous waste;
 - sharps waste must be sorted in such a way as to prevent injury to staff in charge of waste disposal. Special boxes exist to safely store this type of waste (safety boxes). Otherwise, it is possible to make a safe container with material at hand (*e.g. a plastic bottle lined with another cut bottle inside, and closed with a cap*);
 - **high temperature incineration** (closed incinerator, temperature > 1 000°C) is the best method as it destroys everything (including sharps and micro-organisms), reduces the volume of waste and does not pollute. This technique requires financial and human means (initial investment, staff training, fuel and maintenance of the incinerator);
 - the other alternative is **medium or low temperature burning + burying**: you must burn the material in a brick hearth or a simple burning pit (open burning) dug in a place that is far away from passers-by, far from sources of water and placed 1.5 m above the groundwater level. In this case, you must then bury the remaining material with 10 to 15 cm of dirt, as this type of burning does not totally destroy waste and does not kill micro-organisms. As the smoke from this type of burning is pollutant, the hearth or the pit should be placed in such a way so as to avoid smoke exposure to people.
- Waste to **be discharged to a sewer** should be done little by little (after checking that the sink is not blocked). It is better to store this waste for as short a period as possible. This type of waste must **be handled with care**: protection is essential (gloves, goggles and overalls) when diluting these products in water and discharging them to a sewer, as there are very real risks of inhalation and projection of toxic substances.

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4 Selection of Medicines

Objectives

The elaboration of a formulary for the pharmacy makes it possible to get:

- **Economic benefit:** the molecules included in the stock have been selected according to cost/efficiency criteria within a National Essential Medicines List (NEML), therefore they are easily accessible and cheap.
- **Therapeutic benefit:** practices in the association have been harmonized through the use of a common list and through meetings of the Medicines Committee leading to regular dialogue between doctors and pharmacists.
- **Additional space:** selecting a limited list of medicines means that it is possible to anticipate the space needed to store them.
- **Time benefit** by simplifying orders and inventory checks: the list serves as a reference and guarantees that no medicinal product will be forgotten.
- **Logistics benefit** by simplifying relations with suppliers: the order, based on the medicinal products on the list, will be similar each time.
- **A more reliable and easier circulation of information:** the list of medicines is the reference for all information on the community pharmacy's stock. This is an advantage for the association and for external partners who will appreciate having access to the list of medicines available in the pharmacy.

a. Recommendations for Creating a Formulary

- This list is the **starting point** for rational management of drugs.
- It is advisable to **base it on the current National Essential Medicines List (NEML)** or on the WHO list of essential medicines (latest version dating from March 2007). From this reference, a **formulary adapted to the dispensing outlet's needs and priorities** will be established (**generally shorter as it focuses on pathologies associated with HIV/AIDS**).

Comments on the NEML: The Ministry of Health in every country in Africa must establish a list of essential medicines, which it will define as being priority medicines, based on the WHO list. These medicinal products can then be exempted from import duty and they will be used in negotiations to obtain international aid for the health care system.

- **Reliable prices and local availability** must exist for each medicinal product when the formulary is being drawn up. This information features on **updated lists of medicines available at the national procurement agency and with local private wholesalers**.
- The formulary must be **exhaustive and drawn up in a concerted manner by all players concerned** (pharmacy staff, doctors, administration) **and then circulated and easily consultable in prescribing, dispensing and administrative services**.
- The formulary must then be **respected** by these same players:
 - Doctors should refer to it for their prescriptions.
 - Pharmacists should also refer to this formulary when managing their orders.
 - Administration services should use it to validate purchase order forms.
 A meeting with all these players (Medicines Committee [10]) will enable them to draw up this formulary in a concerted manner. This **Medicines Committee will meet at the outset to draw up**

this formulary, then it will agree on regular meetings (quarterly, biannually or annually) to update it.

- If a person wishes to modify the formulary quickly (*e.g. a pharmacist realizes that doctors regularly and justifiably prescribe a molecule not on the formulary*), it is necessary to have an extraordinary meeting to make a joint decision.
- After an update or modification, a new formulary should be circulated to replace the previous one.
- When new employees join the team (*e.g. new doctors or pharmacists*), this formulary should be given to them and it is necessary to highlight the importance of respecting this reference tool.

b. Specificities of the Formulary of ARV drugs

As is the case for opportunistic infection (OI) drugs, a formulary of ARV drugs must be drawn up and serve as a framework for everyone concerned in the dispensing outlet.

However, the choice of ARV molecules is often made beforehand by the Ministry of Health (regarding the National AIDS Council), based on the latest WHO recommendations.

As this national formulary is limited, the sorting is rarely necessary: doctors and pharmacists apply national recommendations for first and second-line ARV treatment.

Furthermore, the economic argument that applies to OI drugs rarely concerns first and second-line ARV drugs recommended by the National AIDS Council, as today they are free in several countries.

In certain countries (*e.g. in Mali in 2005*) the National AIDS Council has specified consumption percentages for each treatment line on this formulary of recommended ARV molecules. This information should be mentioned in the formulary of ARV drugs since these percentages often determine ordering and storing quantities.

The work of drawing up the **formulary of first and second-line ARV drugs** therefore consists of keeping informed of **WHO and National AIDS Council recommendations** and using the formulary as a reference for the dispensing outlet.

It is essential to **update** and **circulate** this list to those concerned.

Comments

It is often necessary to add **second and third-line** ARV drugs to the reference formulary. The molecules indicated for patients experiencing therapeutic failure after a first line treatment, such as lopinavir, abacavir or didanosine, are not always freely accessible via the national program. African populations have great difficulty in accessing these drugs due to the slow progress of registration in certain countries or due to their high cost as certain molecules are not available in generic form. Despite these setbacks, care centers are doing everything in their power to finance the purchase of these ARV drugs in small quantities for some patients. If an ARV medicine is registered in the country, these drugs can be bought locally or through international humanitarian associations' procurement agencies.

Decisions are often made on an individual basis **for certain specific patients not receiving "ordinary" treatment**. These **additional molecules need to be chosen in a concerted manner**: during meetings of the Medicines Committee or during specific meetings concerning care of patients on ARVs.

The following **criteria** need to be taken into account:

- the potential **resistance** to ARV treatments developed by the patient;
- the **availability** of these molecules in the country;
- the monthly **cost** of these drugs for a patient;
- the **conditions for use** of these drugs (*e.g.: the combinations of IP containing Ritonavir in soft capsule form not advised for patients who do not have access to a refrigerator to store it*).

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5

Selecting Suppliers and Managing Donations

Objectives

The creation and the implementation of procedures to select suppliers and manage donations allow the pharmacist to:

- identify the most reliable, practical and economic supply solution;
- react appropriately when faced with proposals of donated medicines.

a. Supplier Categories

National Procurement Agencies (NPA):

They are the most reliable, practical and economic supply solution. The risk of long lead times is, however, their main disadvantage. National procurement agencies offer a catalogue of medicines including all essential medicines as well as other medicines. Each NPA has its own catalogue. They use international calls for tenders and take into account the quality and cost of medicines when incorporating them into their stock. The list of WHO prequalified ARVs, anti-malaria and anti-tuberculosis medicines offers an additional guarantee of quality to the head of pharmacy purchasing (a list of prequalified medicines and websites is available on the Internet: http://mednet3.who.int/prequal/lists/hiv_suppliers.pdf)

Local, private pharmaceutical wholesalers:

This supply solution offers prices that are globally higher than those of national procurement agencies. It can be a step solution in case of slow lead times or stock shortage announced by an NPA. The choice of molecules available is often similar to that of an NPA. The reliability of the wholesaler's quality assurance procedures needs to be checked before dealing with the wholesaler.

International humanitarian procurement centers:

These suppliers ensure reliable supplies of very good quality (reliable internal quality assurance system). The disadvantage, however, is that they are more expensive than local suppliers (transport costs), and their lead times are quite long (15 days minimum due to transport).

In France (and in Nairobi in Kenya):

- **the CHMP** (*Centrale Humanitaire Médico-Pharmaceutique*). More information (lists of products, prices and delivery times) available at <http://www.chmp.org>
MSF Supply: proposes non-ARV medicine supply to humanitarian organizations, Non-profit organizations or organizations pursuing a social goal. These organizations must be able to prove their independence from any political or military organization. Further information is available at: <http://www.msfsupply.be/index.html>
- **In the Netherlands (and in Mumbai in India): IDA** (International Dispensary Association). More information (lists of products, prices and delivery times) available at <http://www.idafoundation.org>

b. Strategies for Choosing Suppliers

Community pharmacies, contrary to hospital pharmacies, do not operate through contract procurement with a supplier for a long time period. The most suitable purchasing procedure for community pharmacies is through purchase against pro forma invoice [11] which consists in getting suppliers to compete with each other for each order, so as to select the most competitive. Since the NPA usually offers the best deal, this process is often used for the medicines which are not available at the NPA.

Another option consists of asking for the NPA's help to launch an international call for tenders when ordering large quantities.

The steps of this procedure are as follows:

1. Choice of medicines to be bought and calculation of the quantities required.
2. Preparation of the purchase order.
3. Submission of this purchase order to the different suppliers listed by the pharmacy.
4. Receipt of a pro forma invoice from each supplier contacted.
5. Submission of quotations to the administrative and financial service and concerted choice of supplier for this particular order.
6. If one supplier has the best offer for the whole order but is out-of-stock for certain products (which is often the case for the national procurement agency), it is possible to select their proposal and to go to another supplier (wholesaler or international center) for the missing products.

This procedure implies the work of previously selecting local pharmaceutical suppliers:

- **Creating** an extensive list of local pharmaceutical suppliers (NPA and private wholesalers). When listing prices, the transport fees of packages must be included.
- **Classifying** these suppliers in relation to the following criteria: reliability of their quality assurance systems (proven by a legal certificate), list of OI drugs available, list of ARVs (WHO prequalification is a bonus) and competitive prices.

Remember: the choice of suppliers should take the pharmacy's financial partners' demands into account!

- **Solution:** create a **list of all financial partners supporting the supply of medicines**, by specifying the medicines provided, the sum of money allocated and the procedures imposed. It is then easy to distinguish two supply channels:
 1. **Backers which impose a supplier:** grouping together partners sending medicines directly and those sending a sum of money while imposing a supplier.
 2. **Backers which allow the organization to freely choose a supplier:** grouping together partners sending a sum of money for supplies directly to the pharmacy without imposing a supplier. These sums of money can be grouped together to pay for orders made after selection of and negotiation with suppliers.

c. Recommendations for Managing Drug Donations

Supplying the pharmacy through drug donations should be avoided [12]. Despite the gratuitous and therefore attractive nature of the pharmaceutical products received, the advantages for the pharmacy accepting these donations are nil or insignificant (*e.g. the advantage of adding a few tablets gratuitously to the stock is mainly overridden by the time lost in destroying useless or expired tablets*). By taking a clear stance against receiving irrational donations, the pharmacy team avoids encouraging parallel supply channels that illegally compete with the national pharmaceutical channels and slow the process of consolidation (the proportion of drug donations misappropriated and resold on black markets is progressing dangerously in Africa).

Several structures agree on this principle today, such as the WHO or ReMeD (*Réseau Médicaments et Développement*) and **recommendations exist to learn how to react rationally when faced with multiple proposals of donated medicines. These should be respected.**

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6 Drug Management

Objectives

Drug management makes it possible to:

- Know the current **stock** of drugs at all times;
- Know the **consumption rate** of each type of drug;
- Efficiently manage the generation, tracking and reception of drug **orders**;
- Ensure the traceability of prescriptions dispensed;
- Ensure the effective therapeutic care of pharmacy **patients**.

a. Keeping Track of Stocks

1. Reception of a medicinal product = stock entry

▶ **1 entry: quantity received is entered on the stock records and the new stock is calculated.**

Tool = Stock records:

- **1 stock record per medicinal product;**
- **1 line filled in for each entry of medicine units;**
- **1 line filled in for each issue of medicine units.**

Stock management of medicinal products is based on the correct and regular use of stock records. They must therefore be adapted to the context and the staff must be well-trained in using them. They can be bought through the NPA or typed on a computer and printed on index cards. From a blank model it is easy to create a card for each product (always keep a blank model and photocopy it for each new product entering stock).

Each card should then be placed on the current stock shelf, where the product is stored. The card should be protected by a transparent plastic pocket.

The ideal solution is to create these cards using a spreadsheet program on a computer (e.g. Excel). The use of formulas should then enable fast, reliable and error-free calculations. In this case each product card should be printed, manually filled in on a daily basis, and then regularly updated by computer (i.e. on a monthly basis) in order to save the data on stock movement and to check the manual calculations.

Name (INN): Cotrimoxazole Form: Tablet Special storage conditions: Current supplier: CAMEG Average Monthly Consumption (AMC): 6,000				Strength: 480mg Products remaining in store: X Unit price: Minimum Stock: 12,000 Maximum Stock			
Date of Movement	Quantity Received	Quantity Issued	Theoretical Stock	Physical Stock	Expiry Date	Lot Number	Comments
12/07/2006	36 000		48 000		11/2008	R4567	
13/07/2006		60	47 940				
14/07/2006			47 940	47 940			Inventory

Sample stock record

2. Issue of a medicinal product = stock issue

▶▶ 2 entries:

- issuance of the prescription is entered in the dispensing register (detailing each medicinal product dispensed to the patients);
- the quantity issued is entered on the stock record of each medicinal product dispensed and calculation of the new theoretical stock is made.

Tool = dispensing register or prescription ledgers:

1 line filled in for each prescription dispensed.

January 2006					
No. Order	Date	Patient Code	Patient Name	Prescribing Doctor	Products Issued (INN, dosage, dosage form, number of units delivered)
1	11/01/06	AA05	A	Dr. O	Paracetamol, 500mg, tablets: 50 Cotrimoxazole, 480mg, tablets: 60
2	12/01/06	BB06	B	Dr. O	Paracetamol, 500mg, tablets: 25 Cotrimoxazole, 480mg, tablets: 60
3					
4					

Sample dispensing register or prescription ledger

b. Recommendations for Reception of Orders

1. Anticipate the arrival of orders by posting a list of orders expected. This list enables the pharmacist to plan the arrival of orders and to re-contact the supplier if the expected delivery is late.
2. Prepare a clear area to receive the packages (in the storeroom or the dispensing outlet, depending on the space available).
3. When the packages arrive, check that:
 - the number of packages corresponds to that indicated on the delivery order;
 - that the contents of each of the packages correspond to those on the delivery order (open each package and check the contents. It may take some time but it is necessary);
 - that the medicines are in good condition (appearance of the packaging and the pharmaceutical products themselves) and that their remaining shelf life is sufficient for the products to be used before the expiration dates.

▶ Any problems (*i.e. missing products, products that were not ordered, etc.*) should be immediately reported to the supplier and the unwanted items should be returned. The maximum period for reporting these problems depends on each supplier, and is specified in the initial contract. The pharmacy staff should be familiar with this contract and respect its clauses.
4. Archive the delivery order in a folder for tracking orders. The folder should be organized in chronological order (containing purchase orders, invoices and delivery orders). The delivery order must be kept for a minimum of 3 years (legal provision).
5. Clean the storage areas and dispose of any damaged or expired products before storing the new products.
6. Store the new products received and enter the quantities on the stock records for each medicine.
7. Respect the first-to-expire, first-out policy by arranging the boxes with the closest expiration dates to the front of shelves.

8. Logically divide the medicines between the current stock and the storeroom (*e.g. place the quantity required for 1 month on the current stock shelves and place the rest in storage*). This is particularly advisable for bulky items (liquids, perfusion solutions, consumables, etc.).

c. Recommendations for Managing Orders [13]

1. **Safety Stock (SS) of each medicinal product.** This depends on the pharmacy's supply means. The more reliable the supply time and the more regular the patients, the smaller the amount of safety stock required.

A quantity corresponding to 1 month of consumption is the minimum to apply to safety stock. This is in a context where the orders are made at least every month, and where the lead times are fast and respected.

**Safety Stock (SS) = stock necessary to avoid shortages,
in case of a long delay in lead times or an unexpected increase in the number of patients.**

2. **Quantity of each medicinal product to order** to avoid stock shortages between 2 orders (for ARV drugs refer to Part 7 as specific quantification techniques apply).

- **Calculate the Average Monthly Consumption (AMC) of each medicinal product**

Average Monthly Consumption (AMC) = consumption of past 6 months ÷ 6.

This AMC should be recalculated every 3 to 6 months (according to the level of activity and the increase in consumption as the AMC increases at the same rhythm as the active patient file).

E.g. if a pharmacy dispenses 600 paracetamol tablets in 6 months, the AMC is $600/6=100$ tablets per month.

Comments on assessing consumption at the beginning of the pharmaceutical activity: initially, when previous consumption statistics are not available, a reliable solution is to refer to another local structure that is comparable in terms of frequentation and conditions treated. If this is not possible, begin by making estimates based on the number of patients expected and the breakdown of conditions treated, then adjust as you go along (after 3 months of pharmacy activity an estimate of the AMC is possible).

- **Calculating the Running Stock (RS) of each Medicinal Product**

Running Stock (RS) = stock consumed between 2 supply deliveries.

E.g. if the orders are placed quarterly, the running stock will be $AMC \times 3$.

- **Calculating the quantity of the product to be stored on receiving the order**

Quantity to store on receipt of order =
RS to avoid stock shortages before receiving the next order
+ **SS** which can be used in case of an emergency

*E.g. if the orders are placed quarterly, on receiving the order, total stocks should correspond to the quantity needed for 3 months of consumption (AMC x 3) + Safety Stock (AMC x 1)
 → on delivery, the stock of each medicinal product will be AMC x 3 + AMC x 1 = AMC x 4.*

■ **Calculating the quantity to order for each type of medicine**

$$\begin{aligned} \text{Quantity To Order (QTO)} = & \\ & \text{Quantity to store on receipt of order} \\ & + \text{Running Stock} \\ & \text{(required during lead time - time between placing an order and receiving it)} \\ & - \text{Stock On Hand (SOH)}. \end{aligned}$$

E.g. If the quantity to be stored on receiving delivery is AMC x 4, the lead time is 1 month and the quantity on hand is AMC x 2 → QTO = AMC x 4 + AMC x 1 – AMC x 2 = AMC x 3. On receiving the delivery there is AMC x 1 in stock and the new total stock is AMC x 4. This running stock is sufficient for 3 months (AMC x 3) with a safety stock of 1 month (AMC x 1) in the case of unexpected events.

3. Placing an order: when the Minimum Stock (MS) level is reached

When stock levels reach the “Minimum Stock” level (or “reorder level”) this corresponds to the level of stock that calls for placing an order. The “Minimum Stock” level means that medicines can be issued normally during the lead time, without having to use the safety stock.

$$\text{Minimum Stock (MS)} = \text{SS} + \text{RS}$$

E.g. MS = AMC x 2 = AMC x 1 (SS) + AMC x 1 (1 month between placing an order and receiving it).

It is therefore necessary to regularly check the stock levels of each product, on the stock records. If stock levels become lower than AMC x 2 = MS when orders are placed every 3 months, it is time to place an order for this product. This gives 1 month to place the order and receive it before having to use the safety stock.

Comment 1: Minimum Stock can also be called Reorder Level.

Comment 2: It can often be difficult to visualize the Minimum Stock. It is useful to separate the Minimum Stock from the rest using a rubber band, a ribbon or any other sort of visible barrier. When this barrier is reached, the next order should already have been placed or should be done so very quickly

4. Carefully use the budget allocated by the organization’s management to purchase the medicinal products (for ARVs refer to part 7 as there is often a difference in financing ARVs and OI drugs).

E.g. If the budget is defined for a 12-month period and the orders are placed every 3 months, divide the total amount by 4 in order to ensure a balanced distribution throughout the year.

5. **Rigorously monitor orders**, step by step, in order to guarantee respect of the budget, deadlines and quality (the right products, in good condition and in the right quantity) of the orders delivered.

- ▶ Determination of quantities and preparation of the order
- ▶ Choice of most competitive supplier
 - ▶ Reception of the pro forma invoice
 - ▶ Validation by the organization's administrative and financial body
 - ▶ Confirmation of the order to the supplier
 - ▶ Monitoring of the preparation of packages by the supplier (deadlines must be respected)
 - ▶ Preparation for receipt of the packages
 - ▶ Reception and validation of the order shipped.

d. Physical Inventory of Stock

Advantages of a physical inventory

- ▶ **Validation of theoretical quantities** of medicines in stock in the pharmacy (reserve stock + current stock) in order to then guarantee the management of stock based on exact quantities.
- ▶ **Disposal of expired or damaged medicinal products** (see Part 3 dealing with disposal of pharmaceutical waste).
- ▶ **Assessment of the pharmacy team's capacity** to manage its stock. If there are differences between the real and theoretical quantities after the inventory, this shows a deficiency in stock management (problem of method or application of the method by staff) which needs to be corrected.

Method [14]

- Suspend dispensing outlet activities during the inventory (no stock movement).
- Count the number of usable products (physically present, undamaged and unexpired) among all medicinal products in the pharmacy and write this number in the "Physical Stock" column of the stock record.
- If there are 2 storerooms in the pharmacy, count the medicinal products stored in current stock and in the reserve stock and then add these 2 quantities to obtain total physical stock.
- An inventory should ideally be carried out once a month or at the very least twice a year.

NB: the **role of the inventory audit** is very useful to improve the pharmacy's management techniques.

- If stock management errors are detected (differences between theoretical and physical stock), bring the team together to try to understand the causes of this malfunction and to correct it.
- If on the other hand the inventory shows that the theoretical stock is exactly the same as the physical stock, this is a positive factor and the entire team should be congratulated.

Bibliographical references for further information on this subject

- “Optimiser les activités de la pharmacie - Guide en organisation hospitalière dans les pays en développement”, La Documentation Française. November 2005. Pages 69 to 84, 168 to 169, 190 to 191. Available upon order from ReMeD (www.remed.org) or from the Documentation Française (www.ladocfrancaise.gouv.fr) or downloadable from the following website: <http://www.remed.org/versionweb.pdf>
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Publication available upon order from the WHO or downloadable from the following website: <http://www.who.int/medicinedocs/collect/medicinedocs/pdf/s4885e/s4885e.pdf>
Latest access on 15 January 2008.
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Publication available upon order from AIDES (www.aides.org) or downloadable from the following website: <http://www.reseauafrique2000.org/docs/Documents/guide%20RA2000%20fr.pdf>
Latest access on 15 January 2008.

7

ARV Management

Objectives

ARV management makes it possible to:

- always know what is in storage (number of units of each drug);
- **know how much is used for each ARV;**
- efficiently manage the supply chain and reception of ARVs;
- **prevent stock shortages of ARV;**
- prevent over-stocking (risk of expiration if large quantities of ARVs are stored for too long);
- be able to track prescriptions dispensed through the dispensing outlet;
- insure pharmaceutical follow-up of the patients on ARVs.

The basic rules of managing drug supply and storage in the dispensing outlet are applicable to all medicines (keeping track of what, and how much is in stock at all times; order, track and receive and re-order; monitor stock by taking inventory...) but there are certain guidelines specific to ARV management because:

- these are medicines to treat a chronic illness, taken on a continual basis: a patient starting ARV therapy needs their prescription refilled each month for an extended period of time. That means that each time ARVs are purchased for a dispensing outlet a thorough assessment of the amount needed is extremely important because it is based on the number of patients treated;
- if patient adherence is < 95% perfect, these drugs can lead to resistant strains, which require ARVs whose access is limited in developing countries: everything should be done to absolutely prevent stock shortages of ARVs because stock shortages are a major cause of reductions in adherence;
- sources and procedures of funding ARVs are often quite specific and more limited than that of other medicines (non-ARVs).

In Western Africa, the supplying of ARVs in dispensing outlets involved in the fight against HIV/AIDS remains in large part ensured by international funding institutions (the Global Fund, for example), which provide ARVs directly to dispensing outlets (quite often, this ARVs' procurement is managed by a managing organization and supply and distribution are covered by the NPA).

A small portion of ARV medicines is bought by the community dispensing outlets, through the NPA or from International Wholesalers if a budget is available for this purpose.

In these two cases the budget for purchasing the ARVs in bulk is sent only if the organization is capable of precisely describing its needs by submitting meticulous documentation describing the population of patients receiving treatment.

The pharmacy has to be able to describe its consumption and its exact needs at each request to its partners. This means rigorous tracking of the patient list receiving or waiting for treatment.

a. Recommendations for assessing ARV needs

It is essential to set up a **general tracking chart of the patient list on ARVs** showing:

- complete active patient list on ARVs;
- different programs funding the ARVs;
- breakdown by ARV drug combinations of patients enrolled in the program;
- cost of each drug combination as well as the total cost for the fund provider depending on the number of patients being followed on each of the drug combinations.

Necessary documentation to be gathered from the medical team in order to describe the needs for the upcoming period (steps required by funds providers to order drugs or transfer funds necessary for purchase) is [15]:

- number of patients already on ARV therapy and who tolerate their current drug combinations = those who need their prescriptions to be **renewed**;
- the number of patients on ARVs who are not tolerating their current drug combination = they need to continue treatment but must **change their ARV combination** (this is a “switch”), they need to be counted as new patents in the new combination therapy and be subtracted from the list of patients on the old combination;
- patients waiting for ARVs (who fulfill the clinical and biological criteria required for them to be placed on ARV therapy and who have been waitlisted by the medical team) need to be counted in the list of **patients to include in the total ARV treatment population**. The doctor must also forecast their therapeutic combination.

Chart n° 5: Example of follow up chart of patient list on ARV (the treatment costs and numbers of patients are fictitious).

Financing program	ARV combinations	Monthly cost of drug combination (in Fcfa)	Number of patients to continue on current combination	Number of patients to include (including 'switchers')	Total monthly cost for the upcoming period (in Fcfa)	
Global Fund	d4T 30mg + 3TC + NVP	8 000	230	35	2 120 000	Total: 3 240 000
	d4T 30mg + 3TC + EFV	12 000	55	5	720 000	
	AZT + 3TC + NVP	10 000	35	5	400 000	
Foundations	AZT + 3TC + IDV	20 000	15	0	300 000	Total: 360 000
	AZT + 3TC + ABC	20 000	2	1	60 000	
TOTAL for the upcoming period			337 renewals	46 switches & inclusions	3 600 000 Fcfa / month	

Note: Using a computer program (i.e.: basic Excel) largely facilitates this management of the general list of patients on ARVs. Using the “automatic filter” on the spreadsheet program it is possible to tally useful information like the total number of patients on a particular ARV combination (all funds providers combined) or a tally of ARV drug combinations that involve at least 50...

b. Recommendations for ARV drug orders

In the case of funds providers who just transfer funds to the organization and leave it up to the organization to effectuate its own orders, it is useful to set up **a chart documenting the essential quantification information:**

- What drugs must be purchased? (Fixed-dose combinations / simple doses)
- What is the recommended monthly dosage and how many pills are required for a month's worth of treatment?
- How many pills are contained per box?
- How much does each drug cost (price per box)?
- How many patients will need each kind of drug?
- What is the length of each time between orders?
- What is the safety stock for each treatment?

This information should be calculated by the pharmacy or gathered from the medical team and from ARV drug providers.

Here are two suggestions to help avoid using complicated tables and complex calculations:

- Start by calculating quantities to order by the number of units (number of pills) then create a final summary chart that helps you tally the number of boxes to order and the order price.
- Create a separate chart for patients starting a treatment that includes NVP, by dividing it in three parts which correspond to the phases of initiation (Day 1 to Day 14), the stabilization phase (Days 15 to Day 30), and regular treatment (Month 2, Month 3, etc.).

This chart can then be filled out following the model below. This model can and should be adapted to the habits of each dispensing outlet/pharmacy (type of drugs purchased, timing of orders, and choice of drugs to be kept under extra security.) The examples given in this chart are completely fictitious.

Chart n° 6: Example tally chart of ARV quantities to order (*cost of treatments and numbers of patients are entirely fictitious*)

Prescriptions to be renewed + new prescriptions
(except for new prescriptions of Nevirapine)

In the example below:

100 patients are on the combination d4T+3TC+NVP

35 patients are on the combination AZT+3TC+NVP

60 patients are on the combination d4T+3TC+EFV

Drugs to order	Number of pills / month	Number of patients	Time period (months between orders)	Quantity to order for the time period	+ Security Drugs (1 month)	Order (number of units)
NVP 200mg	60	35	3	6 300	2 100	8 400
EFV 600mg	30	60	3	5 400	1 800	7 200
d4T 30mg	60	60	3	10 800	3 600	14 400
3TC 150mg	60	60	3	10 800	3 600	14 400
AZT 300mg + 3TC150mg	60	35	3	6 300	2 100	8 400
d4T 30mg + 3TC + NVP	60	100	3	18000	6000	24000

New prescriptions of drug combinations that include Nevirapine

In the example below:

40 patients start the combination d4T+3TC+NVP

30 patients start the combination AZT+3TC+NVP

Drugs to order	Number of pills / month	Number of patients	Time period (months between orders)	Quantity to order for the time period	+ Security Drugs (1 month)
D1 to D14: initiation phase to NVP					
d4T 30mg + 3TC + NVP	15 (1 pill in the evening)	40	600		600
3TC 150mg	15 (1 pill in the morning)	40	600		600
d4T 30mg	30 (1 pill morning)	40	600		600
NVP 200mg	15 (1 pill in the evening)	30	450		450
AZT 300mg + 3TC 150mg	30 (1 pill morning and evening)	30	900		900
D15 to D30: stabilization phase to NVP					
d4T 30mg + 3TC + NVP	30 (1 pill morning and evening)	40	1 200		1 200
AZT 300mg + 3TC 150mg	30 (1 pill morning and evening)	30	900		900
NVP 200mg	30 (1 pill morning and evening)	30	900		900
M2 and M3: maintenance of regular treatment					
d4T 30mg + 3TC + NVP	120	40	4 800	2 400	7 200
AZT 300mg+ 3TC 150mg	120	30	3 600	1 800	5 400
NVP 200mg	120	30	3 600	1 800	5 400

Order summary for the upcoming period (3 months between 2 orders)

Drug	Commercial name	Number of units/ box	Price/ Box (Fcfa)	Number of units to order	Number of boxes to order	Total price (Fcfa)
NVP 200mg		60	6 000	15 150	253	1 515 000
EFV 600mg		30	10 000	7 200	240	2 400 000
3TC 150mg		60	5 000	15 000	250	1 250 000
d4T 30mg		60	4 000	15 000	250	1 000 000
AZT 300mg +3TC 150mg		60	7 000	15 600	260	1 820 000
d4T 30mg + 3TC + NVP		60	8 000	33 000	550	4 400 000
Total					1 803 boxes	12 385 000 Fcfa

c. Note on management of pediatric ARVs

The recommendations in this chart do not apply to the management of pediatric ARVs. Management is very specific because both the formulations (pills and liquid) and dosages of pediatric ARVs vary for each child (depending on weight and age). Order forecasts should be calculated for each child. There are manuals and computer programs to help calculate these quantities for children.

Source on managing pediatric ARVs

- 'GROWING UP Info' website (information on comprehensive care of children living with HIV): link <http://www.grandir.sidaction.org/US>
Latest access on 15 January 2008.
- WHO recommendations for care and treatment of children living with HIV: <http://www.who.int/hiv/pub/guidelines/paediatric020907.pdf>
Latest access on 4 March 2008
- Dosing chart for pediatric ARVs: link: <http://www.grandir.sidaction.org/2-13/publications-growing-up/toolkits.htm>
Latest access on 15 January 2008.

Bibliographical references for further information on this subject

- « Optimiser les activités de la pharmacie - Guide en organisation hospitalière dans les pays en développement », La Documentation Française. November 2005. Pages 84 to 87.
Available upon order from ReMeD (<http://www.remed.org>) or from the Documentation Française (<http://www.ladocfrancaise.gouv.fr>) or downloadable from the following website: <http://www.remed.org/versionweb.pdf>
Latest access on 15 January 2008.

8

Dealing with Stock Shortages

Objectives

The creation of a procedure concerning stock shortage makes it possible to:

- quickly propose an appropriate solution to the patient;
- limit risk for the patient;
- change or postpone treatment with the prescriber's agreement.

a. What to do in case of a stock shortage

Whatever the context and immediately on noticing a stock shortage:

1. Report this shortage to the pharmacy on the notice board and in the logbook.
2. Notify prescribers and the healthcare facility connected to the pharmacy of the shortage.

If the shortage concerns a non-ARV drug

Propose a solution to the patient

- ▶ If there is a medicinal product with a similar therapeutic indication in stock, offer it as a substitute. **Contact the prescriber** and ask if the prescription can be modified.
- ▶ If there is no medicinal product with a similar therapeutic indication in stock:
 - if the beginning of the treatment can be delayed for a few days, contact the prescriber and ask for authorization to delay the prescription, then propose that the patient return to the dispensing outlet a few days later to collect the medicine once the emergency order is delivered;
 - if the treatment must be started immediately and the patient has the means to pay for it in another pharmacy, suggest that the patient obtain it at another pharmacy at his own expense (the fastest solution);
 - if the treatment must be started immediately and the patient does not have the means to purchase the medicine in another pharmacy and if social services are connected to the pharmacy, suggest that the patient obtain the treatment at a partner pharmacy. The social service should check the patient's financial situation in order to give him a voucher to obtain free medicines in the partner pharmacy. The pharmacy will be reimbursed at the end of the month/quarter, by presenting a list of medicines dispensed on free vouchers to patients.

Contact the usual supplier to place an emergency order

- ▶ If the medicine to be ordered is available with the usual supplier:
 - estimate the quantity required and ask for an emergency pro forma invoice;
 - contact management and the financial service for validation of the pro forma invoice and issuance of an emergency check;
 - pay the supplier and quickly collect the medicine.
- ▶ If the medicine to be ordered is not immediately available with the usual supplier:
 - find another local supplier who can quickly supply the medicine;
 - if the lead times proposed by the local suppliers are clearly defined as being between 3 and 15 days: place the order with the supplier offering the best lead time/price ratio;
 - if the lead times proposed by the local suppliers are uncertain or exceed 15 days, order the medicine with an international procurement agency (*i.e. the CHMP or IDA*).

If the shortage concerns an ARV drug

Remember!

An ARV molecule should never be eliminated from an ARV combination, or spontaneously replaced by another ARV molecule, even if it belongs to the same class. Molecules of the same class are different (toxicity, teratogenicity, administration prescribed, etc.) and a sudden change is dangerous for the patient.

The only modification possible at the pharmacy would be to replace a fixed-dosage combination by its equivalent in the form of separate treatments.

E.g. 1 pack of (d4T+3TC+NVP) = 1 pack of d4T + 1 pack of 3TC + 1 pack of NVP

Specific Recommendations

- ▶ Notify prescribers and the organization's management of this shortage.
- ▶ Estimate the number of patients concerned by this shortage (by using the general care table of patients under ARV treatment).
- ▶ Place an emergency order using the same procedure as for non-ARV drugs with an extreme degree of emergency (at the national procurement agency, with a wholesaler or an international procurement agency).
Be sure to note the lead time given.
- ▶ If the ARV drugs are being dispensed to the patient for the first time:
 - ask the prescriber for agreement to postpone beginning ARV treatment until the order has been received;
 - ensure that the patient is protected against opportunistic infections by cotrimoxazole prophylaxis;
 - tell the patient about the delay before beginning ARV treatment, and reassure him/her that delaying the beginning of treatment for a few days bears no serious consequences.
- ▶ If the patient is already on ARV treatment:
 - ask him/her about the quantity of ARV drugs remaining in his/her home;
 - if there are enough ARV drugs left to ensure continued use until the order has been received: explain the situation, reassure the patient and tell him/her to come back when the order is due to be delivered;
 - If the patient has no more ARV drugs to continue treatment until the order has been delivered: find a structure dispensing ARV drugs (NGO, hospital, etc.) that will accept to help out the dispensing outlet by providing a batch of ARV drugs while awaiting delivery of the order.
- ▶ If no other solution is found:
Discuss the situation with the ARV prescribers and the staff in order to find a temporary treatment solution for the patients concerned by this stock shortage.

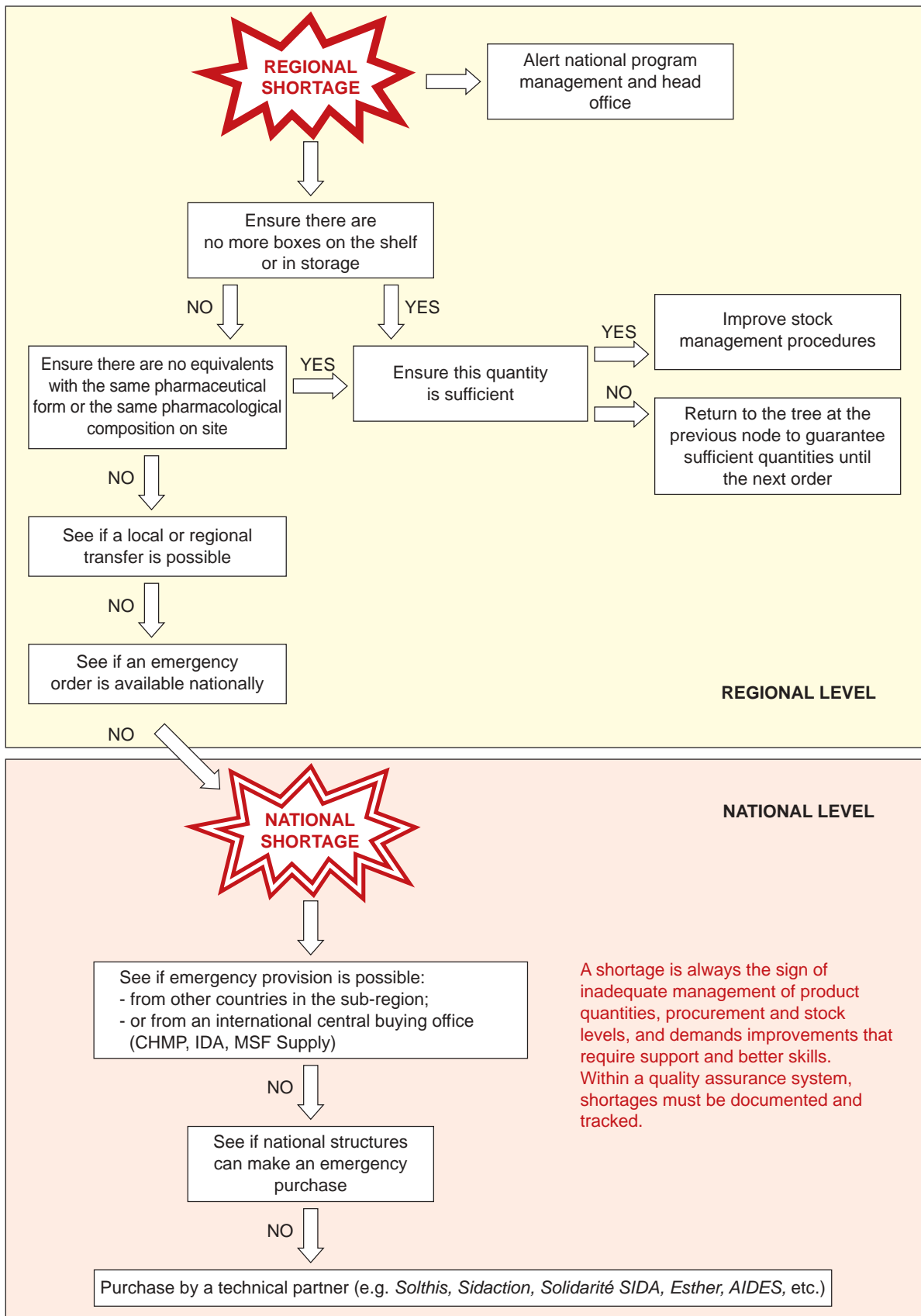
Reminder of recommendations based on technical documentation, useful for avoiding stock shortages:

- ▶▶ Create a **formulary of medicines to be stocked**. This is the keystone for the concerted work of all players involved.
- ▶▶ **Communication with suppliers** is essential for keeping track of orders efficiently.
- ▶▶ Good **communication within the pharmacy**: procedures to be respected on a daily basis for efficient work.

Flow chart suggesting courses of action in case of a stock shortage

(Source: Solthis Association, France)

DECISION TREE IN CASE OF MEDICINE AND REAGENT STOCK SHORTAGE



b. Solutions for Supply Difficulties

Remedial Solutions

Two situations are often the cause of stock shortages:

1. A blockage in the logistics chain at the national level, leading to shortages at the national procurement agency, with repercussions on the country's health structures.
 - The solution consists of finding an alternative to the national procurement agency: a supplier capable of quickly delivering the medicinal product, most often at a higher price than that of the national procurement agency. This requires having the necessary funds.
2. A delay in the health structure's cash flow.
 - The solution is to find a supplier who will accept to supply the merchandise in advance of payment.

Example [16]

Since 2005, the ESTHER network member countries can call on ESTHER and the CHMP for ARV drugs in an emergency situation (unexpected stock shortages). These ARV drugs can be paid for afterwards (at Accelerating Access Initiative prices), thus allowing the health structure to wait for an inflow of cash before paying. This emergency stock has been set up in order to overcome shortages at pharmacy or national levels. However, after one year of existence, it is evident that emergency provision of ARV drugs has its limits, as it encounters the same purchasing problems as those of procurement agencies in developing countries:

- Purchase of brand-name drugs through the Accelerating Access Initiative (proposed by pharmaceutical laboratories):
 - complex administrative procedures;
 - stringency (business agreements, just-in-time delivery, candidacy files, refusal of logistics intermediaries, etc.);
 - ▶ it is sometimes easier to purchase WHO prequalified generic medicines.
- Necessary reliable quality control.
- Difficult negotiations.
- Complex need assessment.
- Restrictive pre-payment.
- Uncontrolled lead times.
- Inter-country exchanges that are not advocated by the Global Fund and brand-name laboratories.

Preventive Solutions

- The objective is to react to shortages by setting up a **quality assurance system** identifying the malfunctions leading to shortages and dealing with them so that they do not reoccur.
- This quality assurance approach is based on **anticipating** shortages. Tools and procedures used on a daily basis are meant to prevent shortages and to diminish the seriousness in case they do occur.
- This approach should be systematic whatever the degree and source of the shortage, as patients' health is in danger each time.
- If this quality assurance system is efficient, the stock provision process is better controlled: purchase procedures and stock management are delineated, assessed (guidelines implemented) and evolutionary (techniques for resolving expected problems).

Bibliographical references for further information on this subject

- ASHP Guidelines on Managing Drug Product Shortages:
www.ashp.org/s_ashp/docs/files/BP07/Procure_Gdl_Shortages.pdf Latest access on 22 July 2008.

9

Management of Patient Care Files

Objectives

A general table, grouping together the characteristics of patients frequenting the pharmacy allows for:

- an overall view of these patient files;
- an overall estimate of the needs in medicinal products;
- data collection in order to make reports and to calculate statistics.

a. Overall Monitoring of Patient Files

Recommended tool: A general table summing up the characteristics of each patient regularly frequenting the pharmacy. This should be created when the pharmacy begins its activities.

This table is easiest to use if the pharmacy team creates it using a spreadsheet program (e.g. Excel).

- ▶ If it is created on a pharmacy computer, it can be filled out in real time and regularly saved on a CD-ROM. In this case it is not necessary to create a paper version.
- ▶ If the pharmacy does not have its own computer but has access to a 'shared' computer on a daily basis in the organization (to record new data daily), it would be prudent to create a manual table in a notebook to record new data directly by hand and then to transfer the information to the spreadsheet file every evening.
- ▶ If there is no computer available, this table can be created manually in a notebook. It will give an overall view of the patients frequenting the pharmacy. Filtering of the data with the spreadsheet program, which allows users to easily generate statistics, will be impossible however.

Data included in the general table could be as follows:

Chart 7: Sample general table of all patients (*these data are fictitious examples*)

No	File No. or Patient Code	Date	Surname	First Name	Sex	D.O.B.	Address	Date of ARV inclusion	ARV Combination	ARV Finance Program
1	M1	07/08/2004	A	a	M	1960	Town X	01/12/2004	d4T 30 mg/3TC/ NVP	Global Fund
2	F2	04/10/2004	B	b	F	1980	Town X	01/03/2005	d4T 30 mg/3TC/ NVP	Global Fund
3	F3	04/10/2005	C	c	F	1978	Suburb C			
4	M4	14/10/2005	D	d	M	1983	Town X	01/12/2005	AZT/3TC/ EFV	Private Partner Z
5	F5	17/02/2006	E	e	F	12/12/2002	Suburb D			

By using the automatic filter in the spreadsheet program (in which commands can be personalized) it is possible to 'sort' the data on the active patient file according to various criteria:

- display and count the number of patients registered from 01/01/2005 et le 31/12/2005
- display and count the number of male patients
- display and count the number of patients under 18 (children frequenting the pharmacy)
- display and count the number of patients whose ARV treatments are financed by a defined sponsor
- display and count the number of patients treated by a defined combination of ARV drugs, etc.

b. Individual Pharmaceutical Files

Recommended tool: An **individual therapeutic care file** containing the patient's therapeutic history (ARV and OI treatments), treatment and adherence difficulties [17].

The keeping of such a file is facilitated by computer tools (certain specialized software can automatically generate a patient's medical history, or simply a spreadsheet program and a word-processing package can help to create tables very easily). This can be done manually however, although it requires more time to record the information daily by hand on the patients' files.

Chart 8: Sample individual therapeutic care file

<p>Patient Identification Patient code to identify the patient. Demographic data (age, sex, etc.). Social data (work, address, social status group, nutritional status).</p>
<p>Clinical data (from the medical file +/- discussions with the patient) Weight. WHO stage of HIV-related illness. Medical context associated with HIV (tuberculosis, pregnancy, serious psychiatric disorders). Signs and symptoms observed and linked to the side effects of certain treatments. Appraising adherence. Biological data available (at least: CBC and transaminases +/- CD4 +/- viral load, etc.).</p>
<p>History of Hospitalizations <i>For each hospitalization episode:</i> Date and duration. Reason for hospitalization. Name of hospital. Treatment during this hospitalization.</p>
<p>Therapeutic data: history of dispensations by highlighting major events: ARV: History of dispensations by highlighting the combinations taken by the patient and the inclusion dates + history of adherence monitoring (counting of tablets, visual scale, etc.). Add, if applicable, written reports about ARV adherence errors that have been identified. Non-ARV Treatments: history of dispensations by highlighting the important occasional treatments and chronic treatments (contraceptive, antihypertensive, antidepressant, etc.). Other medicinal products taken elsewhere (including traditional medicine).</p>
<p>Patient Education Written reports about patient (or third-person) interviews. These reports should include topics covered as well as level of patient understanding.</p>
<p>Psychosocial Data Participation in a support group for people infected with HIV/AIDS. Participation in an adherence club and/or individual discussions for adherence support. Participation in nutritional education sessions. House calls already carried out to the patient's home (for nursing care or psychological or social discussions). Social support provided. Nutritional support given provided. Dependent children provided.</p>

10 Installation of computers in the pharmacy

Objectives

The installation of computers in the pharmacy makes it possible to:

- **centralize** data in a suitable database;
- get a source of **information that is easy to access (nevertheless secure), reliable and transparent;**
- **easily collect data** concerning the activities of the patients (helps with monitoring);
- produce regular **backups** of data (*bimonthly on CD-Rom, for example*);
- improve **confidentiality** of data as computer databases are more secure than manual registers (*e.g. a password may be needed to activate the computer*).

a. Limits of manual management

Three pharmaceutical management channels benefit from the use of computers:

1. Computerized management of medicine stocks (OI and ARV) [18]

- avoids manual entry errors;
- avoids multiple reception/issue records for medicines in manual registers, by centralization of records in a single computer file;
- enables secure data storage and backup (*e.g. on CD-Rom, securely stored in a different room of the pharmacy*);
- enables easy and rapid collection of certain key data, such as the stock of a product or the consumption of a product over a previous period;
- facilitates printout of reports on consumption of medicines and supply needs.

2. Computerized management of patient files (general monitoring of patient files and individual tracking)

- enables centralization of the general table showing the active patient file and individual patient records in a suitable computer file system;
- enables rapid collection of key data concerning one or more patients at any time;
- enables use of data to generate statistics on active patients for the purposes of internal tracking and production of reports.

3. Computerized inventory management

Information technology can facilitate inventory by printing out the complete list of medicines and materials in the theoretical stock. This can then be compared to the actual stock on the day of inventory and any differences can be quickly corrected.

b. Pre-requisites for installing computers in the pharmacy

- Have at least one computer in working order reserved for use by the pharmacy and installed in the pharmacy itself.
- If power cuts are frequent: install an uninterruptible power supply for each computer or a generator for all the computer equipment.
- Skills: at least one person in the team must be trained in using computers and be able to use the word-processing package and the spreadsheet program without supervision. This person will be trained in computerized management and designated as the person to whom IT-related questions in the pharmacy should be addressed. The designated person may then train the other team members should they desire.
- Necessary precautions: Recorded data must be backed up on average every two weeks in at least two different formats (external hard drive, USB key, CD Rom) to minimize the probability of loss.

c. Practical examples

Several choices must be made before the computer system is installed, in order to decide which software is to be installed:

- **Choice of channel to handle:**
Only the pharmacy channel (medicines and patients who transit via the pharmacy) or a wider coverage of the organization (for example the channel of a patient throughout the different sections of the organization).
- **Choice between a single workstation and a network**
The existence of a network between several computers (linked by cables to enable data sharing between them) will allow the installation of specific software designed to function over a network. Without a network, it is possible to install simple software on a single station or on several non-connected stations, but in this case data will not be automatically shared between them.
- **Choice of functions needed**
The statistical and operational requirements for use of the data (notably for ordering stocks or drawing up activity reports) will determine the type of software to install.

Chart 9: Characteristics of various pharmacy management software

Means, specific features and requirements	Type of software to install	Functionalities of this type of software	Drawbacks of this type of software
<ul style="list-style-type: none"> – Fairly low level of team IT skills – No network (single station) – Patient population < 500 – Molecule list < 150 – Simple search requirements 	<p>Spreadsheet program (e.g. Excel) [19] [20]</p> <ul style="list-style-type: none"> – pre-designed spreadsheets for community pharmacies can be configured to your activities; – or you can configure an electronic spreadsheet yourself with the assistance of a person with sufficient knowledge of the application. 	<ul style="list-style-type: none"> – Define and update the list of medicines in stock at the pharmacy. – Ensure monitoring of receipts and issues of medicines (computerized inventory control files). – Monitor dispensations (computerized prescription register). – Monitor the patient population frequenting the pharmacy (computerized patient files). – Use the data to make simple searches and include results in reports. 	<ul style="list-style-type: none"> – Limited use of data. – Inventory planning (e.g. sophisticated quantification) difficult to implement. – Risk of errors spreading throughout the file and leading to completely false data (rigor required in usage). – Modifications to the application difficult to implement (adding a line or column can disturb the whole spreadsheet if the user is not well-trained).

Chart 9: Characteristics of various pharmacy management software

<ul style="list-style-type: none"> - Good level of team IT skills - No network (single station) - Patient population <> 500 - Molecule list <> 150 - Higher search requirements 	<p>Specific software for pharmacy management</p> <p>Examples: LOGONE (free and accessible on the internet) ADAGIO [21] (fee-paying) QUANTIMED [22] (fee-paying)</p>	<p>Same functionalities as Spreadsheet program with in addition:</p> <ul style="list-style-type: none"> - The software has a more user-friendly interface that is simpler to manipulate and which generates less errors than the spreadsheet program. - More sophisticated use of data with possibility of complex searches. 	<ul style="list-style-type: none"> - Needs configuration and training by a specialist when learning to use the software. - More complex maintenance than the spreadsheet program as a person with specific knowledge of the software must be called in if problems arise.
<ul style="list-style-type: none"> - Good level of team IT skills - Presence of a computer network between the different departments of the organization - Patient population <> 500 - Molecule list <> 150 - Higher search requirements 	<p>Software for global management of a care structure for HIV/AIDS patients, integrating the management of pharmacy activities</p> <p>Example: SANTIA (free and accessible via Internet) [23] [24]</p>	<ul style="list-style-type: none"> - Global monitoring of patient population in all departments of the organization (social, medical, pharmacy). - Real-time information sharing (secure access to certain parts of patient files dependent on user authorizations). - Highly sophisticated use of data with possibility of generating customized activity reports. 	<ul style="list-style-type: none"> - Dependence on network: if the network malfunctions the software is not usable. - Complex initial installation and training of users, carried out by a software specialist. - Heavy maintenance (network and software) as an expert in networks or the software must be called in.

Bibliographical references for further information on this subject

Excel-based applications:

- Software inspired by a model supplied by the French Red Cross organization and adapted to community pharmacies is available on request to Sidaction: by email j.langlois@sidaction.org
- Software used by the French NGO Solthis was developed in Niamey, Niger and enables quantification of ARV medicines over a chosen period (1 month, 3 months, 6 months). It is available over the Internet via the following link: http://www.remed.org/JCavagnoud_RE.xls
- Further information can be obtained from any person with sufficient skills in Excel to build a spreadsheet, depending on the needs of the pharmacy.

Specific pharmacy management software:

- LOGONE software allows computer-based management of ARV stock and dispensation. It was developed by the French organization *Entrepreneurs du Monde*. Easy to use and install, it can be downloaded free of charge via the following link: <http://www.entrepreneursdumonde.org/logiciels/setupLogone.exe>
- The ADAGIO software (assistance for out-patient prescriptions and automated prescription management) enables computer-based management of dispensation of ARV drugs and OI medicines to out-patients and also management of the active patient population. Its presentation is based on an Access database, so it has a simple interface and is user-friendly. A fee must be paid for this software and it requires intensive basic training for at least one person in the pharmacy. It can be used on PC and Mac computers, either on single workstations or over a network if a 4-D server tool is acquired. Currently it is mostly used in France but has been installed in Phnom-Penh in a hospital pharmacy, where it is functioning well - one person from this pharmacy came to France to receive training in Adagio at Bichat Hospital, in the framework of an inter-hospital partnership (ESTHER). A description of

Adagio and details of the Adinphorm association, developer and publisher of the software, are available on the association's website: <http://www.adinphorm.org/ADadagio.html>

- The American software Quantimed enables the quantification and estimation of costs of pharmaceuticals on varying scales: for a health facility, a region or even a country. It is published in the USA by MSH and its description is available on: http://www.msh.org/projects/rpmpplus/pdf/Quantimed_Flyer_2006.pdf. It is currently used in Kenya, Namibia, Rwanda and Zambia in the framework of the PEPFAR program. For further information about the product and to obtain it, contact MSH: Quantimed@msh.org

NB: We could identify no examples of pharmacy management software specifically designed for developing countries, either in France or via Internet searches, nor in several reference works. This does not signify a total absence of these applications but reveals a lack of centralized information concerning the use of computers in pharmacies in Africa. Each association works with its own African partners without taking the time to communicate and share the precious tools designed for field work.

Global management software for organizations caring for HIV-infected patients:

- The SANTIA software is available for download free of charge on the site www.santia.org. Information and contacts concerning the installation and use of Santia are also available on the site. Training of trainers in the SANTIA software took place in Ouagadougou in April 2006, organized by the association ELSA (*Ensemble Luttons contre le Sida en Afrique* – “Fight Aids Together in Africa”). Copies of the training guides and supports are available via <http://www.pplateforme-elsa.org/guideLogiciel.php>

Regular information about pharmaceutical management software suitable for developing countries

- ReMeD website: www.remed.org

11

Best practices in dispensing

Objectives

Best practices in dispensing allow the pharmacists to:

- know the **medicines**;
- know the **patient**;
- **locate quickly and easily the medicines** in the stockroom;
- know how to **substitute** an equivalent for the prescribed product if it not available;
- dispense the **exact number** of units (tablets, ampoules etc.) indicated on the prescription;
- dispense medicines with **packaging** that will help conserve and identify them;
- provide complete and appropriate **information** to the patient;
- ensure that the patient has **understood** the information given.

a. Example protocol for dispensing a prescription [25] [26]**Welcome the patient, analyze and prepare the prescription**

- check that the patient has a double-copy prescription and take the original from them, leave them the duplicate (if the prescription is not in duplicate, make a photocopy if possible and keep the original in the pharmacy, give the copy to the patient);
- read the patient number provided by the doctor on the prescription:
 - if the patient is new, enter their details in the patient register and create a new file in their name,
 - otherwise locate and retrieve the patient's file.
- analyze the prescription: Who wrote the prescription? Date of prescription? Weight of patient? Dosage prescribed? Medicines prescribed (INN)?
- if the prescription complies with regulatory requirements, accept it. Otherwise contact the doctor to obtain any missing information or to rectify any errors, until the prescription is compliant;
- calculate the necessary quantities of each product for 1 month's treatment (except in certain cases where the patient is authorized to receive 2 or 3 month's treatment);
- remove the products from the stock shelves and record the quantity of each medicine issued on the inventory control cards.

Communicate with the patient and dispense the medicines.

- if it concerns a renewal of an ARV prescription: note the date the patient comes to the pharmacy (in the ARV patient treatment planner) and verify that the patient does not show adherence problems (i.e. if the date of their last visit is over one month ago). In the event the patient has delayed their visit, discuss this adherence problem with them (detailed in sheet 7 dedicated to ARV treatments). Then note the theoretical date of their next visit, taking into account the quantity of medicines dispensed;
- ask the patient about other medicines potentially used;
- discuss methods of administering the medicines and decide with the patient how to organize their treatment according to their usual schedule;
- write the times that medicines are to be taken on the boxes in indelible ink (numbers or symbols depending on the patient's level of literacy);
- check that the patient has correctly understood by asking them to repeat and to mime how medicines will be taken throughout the day;

- clearly explain to the patient the importance of always adhering to the treatment schedule, explain why the medicine must always be present in a certain quantity in the body, and that they must never stop or modify the schedule without coming to discuss matters with the doctor or at the pharmacy;
- advise the patient to come back and ask any questions they need to if they have any doubts or problems;
- log the patient's adherence problem in their treatment file;
- if a discussion group concerning the treatments or an adherence club exists in the organization, tell the patient about it and propose that they join;
- note the date of dispensation on the prescription, the start and end dates of the treatment and sign;
- record this issue in the dispensing register;
- offer the patient the chance to ask any questions if certain points do not seem clear;
- say goodbye to patients and see them out;
- file away the documents accordingly;
- welcome the next patient.

This protocol is a good model for dispensing, in a 2-part approach

- firstly the pharmacy staff concentrates on the prescription and there is little communication with the patient (greetings are nevertheless exchanged, an invitation to be seated, etc.): the pharmacy employee uses their knowledge to analyze the prescription and prepares the contents to be dispensed;
- the next stage involves much more communication with the patient (in a confidential area) during which the dispensing staff must be capable of providing the patient with the information they need and collecting any information needed for correct monitoring of the patient's treatment (tolerance of drugs, observance, etc.).

Sharing the workload

If the influx of patients to the pharmacy is high, it is useful to assign two members of the team to dispensing. This enables faster dispensing and stronger controls by double validation:

- the first staff member can welcome the patient, retrieve the prescription and locate the prescribed medicines. This person could be the pharmacy manager or a non-pharmacist assistant;
- the second staff member can then validate the prescription, verify the products issued and dispense them to the patient with all the advice necessary for correct adherence to the treatment schedule. If a pharmacist works at the pharmacy, they could have this role, as this person is responsible for validating the prescription and ensuring the patient takes the medicines correctly. Otherwise this role could be assumed by a staff member trained in dispensing treatments to HIV/AIDS patients.

Another method of dividing tasks between staff is possible in the event of a massive patient population receiving ARV treatments: perform the dispensing of OI medicines and that of ARV treatments at two different counters, with a person in charge of each counter (assisted or not by a person who will retrieve the stock from the shelves).

A patient with a prescription for both OI and ARV drugs will therefore visit two counters consecutively in order to receive all their medicines. In this case the channel must be clearly indicated.

Sharing the workload in this way enables the staff member with more training in dispensing ARV drugs and monitoring adherence to manage this part and to enable another member trained in dispensing OI drugs to manage prescriptions of this type. There is however greater risk for not detecting interactions between OI and ARV medicines. The person dispensing the ARV drugs must therefore have adequate knowledge of possible interactions¹ and request that the patient presents all their prescriptions, in order to verify that there is no risk of dangerous interactions between the OI and ARV medicines prescribed.

1. A very practical grid exists, showing the principal interactions between common ARV and OI medicines. The grid is available free of charge on request from "Actions Traitements" or can be downloaded at the following address: <http://www.actions-traitements.org/reglette/>

Cooperation with other health professionals

To facilitate communication between the pharmacist and the doctor, the pharmacist may use a patient tracking file where the difficulties encountered are noted, in particular concerning the adverse effects, interactions between medicines, adherence problems, irregular visits by the patient and non-compliance of their care schedule, etc.

The pharmacist may need to contact other health professionals involved in the care of the patient (psychologist, nutritionist, social worker, etc.) or encourage the patient to consult these professionals. The pharmacist must therefore know their partners well and have defined a communications and orientation circuit beforehand.

b. Analysis and preparation of the prescription

Is the form of the prescription compliant [27]?

To ensure conformity of prescriptions, it is useful to define a standardized prescription model with the medical team (better legibility, no omission of information: drugs with INN identifier, dosage, posology).

It is then up to the organization team (prescribers, dispensers and management) to validate the model used by prescribers. Double- or triple-copy prescriptions are recommended (1 copy for the pharmacy, 1 copy for the patient and sometimes a copy for the doctor, to be kept in the medical file).

Provided here is a prescription model, containing the information that is indispensable for a prescription to be deemed compliant:

Name of prescriber (health care professional)	Date
Doctor or nurse.	
Patient:	
Identification number + last name and first name (unless anonymity is to be respected, in which case only the identification code is provided).	
Sex, Age, Weight (mandatory for children, recommended for adults).	
Type of HIV (1 or 2), CD4 rate, viral load.	
Prescription:	
INN name of medicine, dosage, pharmaceutical form.	
Posology: dosage, number of administrations, length of treatment.	
Additional information if required (possible secondary effects, cause of stoppage of treatment, etc.).	
+/- Advice on diet, lifestyle.	
+/- Remarks concerning the patient, considered important for pharmaceutical analysis (pregnancy, diabetes, allergies, adherence problems, patient living far from the dispensing outlet, etc).	
Date of next appointment	
	<i>Signature and stamp of doctor or nurse</i>

If the prescription presented by the patient is incomplete, the prescriber should be called to complete the information.

Is the content of the prescription acceptable [28]?

- is the prescription suitable for the state of the patient's health? (age, weight, pregnancy, allergy history, kidney failure, etc.);
- are all the medicines in the prescription on the list of medicinal products kept by the pharmacy? (If this is not the case read the note below on prescriptions for "off-list" medicines);
- are all the medicines in the prescription useful, or are any redundant?
- are some prescribed products out of stock? If yes, is it possible to deliver an equivalent medicine?
- are any interactions between medicines detected? does the degree of interaction justify modifying the prescription or is it simply necessary to take note and monitor the presence of a low-risk interaction?
- is the posology of the treatments correct? (Total dose/24h must respect therapeutic limits);
- what are the adverse effects and precautions for use of these treatments?

Again, if the content of the prescription does not seem valid to the pharmacy team, it is appropriate to contact the prescriber to discuss the problem and modify the prescription together.

In order to gather all the information required for correct analysis, the following must be done [29]:

- retrieve the individual patient file (whether physical file or computer file) to have all information about them at your disposal (profession, home, clinical and therapeutic history);
- it is important that the patient presents all their prescriptions in case the prescriber wrote several during the consultation, in order to detect any risk of medicine interactions. If the prescriptions for ARV drugs and non-ARV medicines are separate, the patient must present them at the same time (e.g. *the doctor may staple them together at the end of the consultation*);
- **Important:** each time the patient presents a prescription it must be possible to know if they are receiving ARV treatment by referring to the ARV patient tracking file;
- rapidly ask the patient if their state of health is particularly accentuated at this time (weight loss, extreme tiredness, depression, etc.) and if they are following another course of treatment (e.g. *delivered by another structure or a traditional therapist*);
- for female patients, it is useful to know whether they take oral contraception (or if they have an internal contraceptive device) and if they are pregnant or planning a pregnancy.

Remark on prescriptions not respecting the list of medicines available in the pharmacy ("off-list" prescriptions):

the problem of prescriptions that do not respect the pharmacy list is frequent. The prescriber must be consulted, either to modify their "off-list" prescription or to justify this prescription.

if the "off-list" prescription is kept, as it is considered exceptional and necessary, the pharmacy staff must know how to react towards the patient:

- either the organization considers that any off-list prescription will be filled at the patient's expense in a private pharmacy (includes the risk that patients will not buy drugs that are too expensive),
- or the pharmacy places an exceptional order with a wholesaler and asks the patient to come back and obtain their prescription free of charge once the order has been received,
- or a special fund reserved for exceptional "off-list" prescriptions exists within the organization and enables patients to fill these prescriptions free of charge in a neighboring pharmacy. This implies an agreement between the organization and the neighboring pharmacy for them to accept the credit system for off-list medicinal products. At the end of each period (month, quarter, etc.) the pharmacy must supply the list of products sold to patients covered by the organization who presented a prescription containing an off-list product. A pharmacy employee verifies that this list of products indeed corresponds to the total of off-list products prescribed by the organization, and its management then pays the pharmacy.

This last solution is the most equitable for patients but it is neither simple nor economic, as the products sold in regular pharmacies are more expensive (high margins compared to wholesalers). If this system is used, the organization must be vigilant and negotiate discounts with them and regularly update the list to include certain medicinal products.

If a product is expensive but indispensable: it is better to include it in the list and order small quantities from the wholesaler, than to pay very high unit prices at the private pharmacy!

Dispensing the treatment to the patient

- current stocks must be perfectly arranged and organized so that it is easy to access medicines [30];
- the final packaging of the medicinal products must be in a good condition and enable correct conservation of the product for the duration of the treatment;
- the medicine label must enable its identification;
- the instructions for use must be indicated on the packaging (e.g. in indelible black marker, to avoid being erased during the treatment period) and understandable by illiterate patients (in this case, symbols should be drawn and explained to the patient);
- packaging of tablets in “blister” form rather than in bulk means that products do not have to be re-packaged, thereby limiting the risks of errors and contamination, and enabling better conservation. Also, as long as the blister pack is not cut up, it enables better traceability of products dispensed (name of product, batch number, expiry date clearly indicated on each blister strip);
- bulk packaging remains widespread as it is very economical and the re-packaging stage is often necessary. It can be done in advance or at the time of dispensing [31], however if the pharmacy has a large patient population and there are not many staff members, it is recommended to pre-package medicines that are regularly prescribed with an identical posology for each patient (e.g. Cotrimoxazole, multivitamins, iron tablets, etc.):
 - the most practical packaging is reclosable plastic bags; they can be ordered at the same time as generic medicinal products in African procurement agencies;
 - a label must always be stuck or stapled to the bag indicating the name of the medicine, its posology and expiry date;
 - basic hygiene rules must be respected: clean hands and bags, use of sterile gloves if needed, use of sterile tongs to handle tablets, etc;
 - to re-package large quantities of tablets, manual tablet counters can be used.

c. Dialogue with the patient to provide correct information on the administration of the treatment

In order that the patient adheres to the treatment procedure, he/she must assimilate the following information [32]:

- **how** to take the medicine;
- **how many** units to take each time;
- **at what time and for how long**;
- what is the **purpose** of the treatment: why take ARV drugs for their whole life, antibiotics for ten days, or analgesics until pain stops;
- what **precautions of use** must be taken to ensure maximum efficiency (conserve the medicine in the refrigerator, no consumption of alcohol, etc);
- what are the **possible adverse effects**, which should not cause alarm nor cause the patient to stop the treatment (drowsiness, benign digestive problems, tiredness, etc.);
- **what to do in the event of unexpected adverse effects** (do not stop the treatment but come to see the doctor or speak to the pharmacy staff as soon as possible).

To ensure that the patient has correctly understood, it is often useful to [33] [34]:

- ask if he/she has already taken this treatment, before starting to provide explanations;
- after providing explanations, ask him/her to repeat back the information and mime the administration of one day's treatment.

NB: this information is to be adapted to the patient's profile:

- administration schedule for one day: it is useful to jointly identify with the patient some easily remembered times during their daily activities that can be used as reference points (e.g. the first prayer of the day, the first cup of tea in the morning, sunrise, etc.);
- adverse effects: warn the patient of possible reactions to the medicines (digestion, skin-related, etc.) and when they might arise (days, weeks, months). Explain that he/she need not worry nor modify how they take the medicines but that they should immediately come to see the doctor or the pharmacy staff. If the patient lives at a great distance from the organization, ask if there is the possibility of consulting a doctor in the vicinity of their home and advise him/her to visit this doctor in the event of non-severe adverse effects.

The Military and Emergency Pharmacy Section of FIP proposes pictograms to give health professionals a means of communicating medication instructions to people that have no language in common with and/or who may be illiterate. More information on the internet at http://www.fip.org/www2/practice/index.php?page=pharmacy_practice&pharmacy_practice=pp_sect_maepsm_pictogram

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12 Education and training

Objectives

Education and training should allow the team to:

- know which prescribers are authorized to start ARV;
- know the specificity for financing treatments and how to adapt the management of the treatment accordingly;
- inform and motivate the patient about his/her treatment;
- develop therapeutic education programs to ensure good adherence of the patient to the treatment;
- detect late deliveries, intolerance to ARV treatment;
- detect signs as toxicity, health status to be referred to the medical team.

a. Methods for Prescribing and Dispensing ARV Drugs

The circulation of the ARV drugs should be well-known among all the players involved in order to guarantee effective patient care. The following two tables illustrate the information required and should be adapted to each dispensing outlet's particularities:

Chart 10: Example of prescribing and dispensing methods for ARV treatments
(data in italics are fictional examples)

Specific prescription model for prescribing ARV drugs?	<i>Model to be implemented after mutual consultation between the prescribers, the dispensers and the organization directors, which respects the directives of the national HIV/AIDS programs</i>
Prescribers authorized to start ARV treatments	<i>Names of the doctors who initiate ARV prescriptions</i>
Prescribers authorized to renew prescriptions when the treatment has been well tolerated	<i>Names of the nurses who have been trained in caring for patients infected with HIV/AIDS and are qualified to renew ARV prescriptions*</i> <i>* having completed a recognized training program in caring for patients with HIV and those undergoing ARV treatment</i>
Rate for prescribing ARV drugs	<i>From 1 to 3 months</i>
Rate for dispensing ARV drugs	<i>1 month except in exceptional cases (to be defined after mutual consultation)</i>
Payment methods for ARV drugs for the patients	<i>Completely free-of-charge or fixed contribution (+exemption conditions to be defined)</i>

The methods and quality of managing and dispensing ARVs depend on the particulars of each program for financing ARV treatments. Therefore, it is necessary for the pharmacy team to be aware of these particulars. The directors and the financers of the organization should acknowledge that the pharmacist is thus an indispensable and reliable link in the chain.

Chart 11: Example of the specifics of the funding programs for ARV treatments
(data in italics are fictional examples)

<i>Global Fund</i>	Payment of funds	<i>No funds are paid. The Global Fund requires that needs be reported on a quarterly basis and attends to ordering and supplying the organization via the national procurement agency. (time required: 1 to 2 months).</i>
	Type of ARV drugs financed	<i>First-line treatments recommended in the national protocol of the National Program in the Fight Against AIDS.</i>
	Current number of patients	<i>Ex.: initially approx. 100 patients followed by an increase of approx. 30 patients every quarter.</i>
	Max. number of patients	<i>No limit defined.</i>
	Funding schedule	<i>Ex.: 2005-2007</i>
<i>Foreign or international NGO</i>	Payment of funds	<i>Ex.: half-yearly</i>
	Purchasing of ARV drugs by the organization	<i>Ex.: Half-yearly order with the national procurement agency (supply time: 1 week) or with the international procurement agencies (supply time: 2 months).</i>
	Type of ARV drugs financed	<i>Ex.: Every type of ARV drug available at the national procurement agency or the international procurement agencies.</i>
	Current number of patients	<i>Ex.: 15</i>
	Max. number of patients	<i>Ex.: Budgetary limit of 200 000 FCFA/year for purchasing ARVs. No recruitment currently possible.</i>
<i>Local private donor</i>	Payment of funds	<i>Ex.: Quarterly</i>
	Purchasing of ARV drugs by the organization	<i>Ex.: Quarterly order with the national procurement agency</i>
	Type of ARV drugs financed	<i>Every type of ARV drug available at the national procurement agency or the international procurement agencies</i>
	Current number of patients	<i>Ex.: 20</i>
	Max. number of patients	<i>Ex.: 20</i>
	Funding schedule	<i>Ex.: For 2006, non-renewable → these 20 patients are to be integrated in the Global Fund active files at the end of the year</i>

b. Good Dispensing Practices for ARV Treatments

ARV treatment is a chronic treatment, which could promote resistant mutations of the virus if the patient is not sufficiently compliant [35] [36]. It should only be started when all patient constraints have been ruled out: financial problems, nutritional problems, not understanding the lifetime principle of the treatment (risk of discontinuing treatment once condition has improved), not understanding the treatment regimen, lack of motivation to get better and to undergo medical care, etc.

Several tools, complementary to medical and psycho-social care, should be implemented in the pharmacy in order to ensure that patients are carefully observed and any possible abnormality is detected.

►► **At inclusion:**

ensuring that the patient adheres to and perfectly understands the treatment

The first meeting with the patient, before ARV drugs are started, is crucial. The patient should come away having perfectly assimilated the treatment regimen and with a real sense of motivation to undergo the treatment for life.

▶▶ Treatment information for the patient

Every person who dispenses treatments at the pharmacy should know the following:

- The ARV molecules: name, chemical class.
- The forms, dosages, etc. that are available locally.
- Administration conditions that must be respected (times, meals, etc.).
- Main contraindications.
- Main side effects.
- Interactions with other ARV molecules.
- Interactions with other non-ARV medicinal products.

This pharmaceutical knowledge must be acquired firmly at the outset (training specific to the dispensing of ARV drugs) and maintained continuously through the consultation of publications and articles. It is recommended that the pharmacy create a binder containing one file per ARV molecule used at the pharmacy. These files can be either photocopied or created by the team itself to form a resource that the head of the pharmacy deems comprehensive and appropriate. They are to be updated regularly according to official recommendations and new information. This binder should be kept in good order and within reach of the dispensing area (every staff member who dispenses ARV drugs should be able to access it quickly).

▶▶ Therapeutic education from the outset to ensure good adherence to the treatment

Adherence is the effective administration of the right medicinal products, at the prescribed dose, at the right time, at the desired intervals, over the necessary length of time and according to the advised dietary practices.

Thus, it is advisable to [37]:

- **Ensure that the patient wants to take the treatments:** if the patient is not ready, it would be better to wait than to begin a treatment against his/her will (since the patient risks not being compliant and will develop a resistance to the first-line ARV combination).
- **Ensure that the patient is able to take his/her treatments:**
 - verify that the patient's daily living conditions (housing, family, work conditions, etc.) will allow him/her to take his/her medicinal products;
 - guarantee a regular supply for the patient (anticipate when there will be a disruption in administration): pharmacy personnel should make patients responsible for coming every month to receive their medicinal products. In order not to discourage patients, pharmacy personnel should adapt the supply to the patient's lifestyle.
Ex.: if a patient lives far from the dispensing outlet or travels frequently, explain to him/her that once the treatment has been started and is well-tolerated, it would be possible to supply 3 months worth of treatment at a time.
- **Ensure that the patient knows how to take his/her treatments:**

Has the regimen been well-understood?

 - ask the patient to reformulate and demonstrate how the treatments will be taken over the course of a day;
 - write the treatment regimen in a simplified manner on the package (in permanent marker);
 - if needed, use a small reference card to note the daily regimen (if the patient cannot read, use easily understood symbols for administration times).
- **Could the patient's eating habits interfere with the correct administration of ARV drugs?**
 - ask the patient about his/her eating habits – what foods and at what times does the patient usually eat;
 - try to integrate the administration of the medicinal products into the patient's eating schedule;
 - inform the patient of the nutritional rules that must be respected in order for the treatment to be well-tolerated and effective;

- advise the patient on eating habits that will enable him/her to stay healthy;
- should a financial problem be detected inhibiting the patient from buying food, refer him/her to social services so that he/she can receive support and obtain information on community meal programs and nutritional advice (refer to part 13 on nutritional advice from the pharmacy).

Remark concerning inclusion of treatments containing nevirapine:

The first month of treatment containing nevirapine (15-day inclusion phase with a half dose of NVP followed by the stabilization phase with a normal NVP dose) is often difficult for patients to understand. One solution to the problem is to supply the patient with the 15 NVP tablets required for this phase and to make another appointment for 15 days later (after the medical consultation that verifies NVP tolerance). This requires some special organization by pharmacy staff who must:

- store the remaining tablets (45 if the package contains 60 tablets) in a small bag or blister pack on which the patient's name is well-indicated;
- take note that the patient is in the initial phase and thus, should return to the pharmacy in 15 days to pick up the remainder of the treatment;
- reassure the patient and explain that as of the 15th day, the regimen will be fixed at 2 tablets/day;
- ask the patient to return with the ARV-drug packages in order to count the tablets and verify that the regimen has been followed correctly for the first 15 days.

▶▶ Detecting late deliveries

Tool: a schedule for monitoring patient ARV deliveries.

- create a new line for each new patient undergoing ARV treatment;
- take note at the time of each distribution of: the date of distribution and the theoretical date of next distribution according to the number of treatments issued;
- every evening: go to that month's column and verify that all of the remaining theoretical dates are later than the current day's date → if a theoretical date is not confirmed by a visit to the pharmacy once the day has passed, it means that the patient has not come for his/her supply and could be in risk of interrupting treatment in the coming days. It would therefore be advisable to contact the patient (either by telephone or by offering to make a house call) to discuss the reason for being late and ask him/her if a house call would be desired in order to deliver the medicinal products and/or provide health care.

Chart 12: Example of a schedule (using a spreadsheet program) enabling the detection of late deliveries (data are fictional examples)

First and last names	Patient code	Patient contact	ARV protocol	Jan 06	Feb 06	Mar 06	Apr 06	May 06
S O	0106M	70 30 23 47	AZT + 3TC + EFV	13	10	08	05	
N P	0206M	70 56 76 34 (sister)	AZT + 3TC + IDV	12	OK	05	02	
B P	0306F	70 90 67 45 (mother)	AZT + 3TC + NVP	0	26	23	20	
G I	0406F	none	d4T + 3TC + EFV	0	0	31	27	
Z F	0506F	70 35 45 89	d4T + 3TC + EFV	0	0	31	27	

- the **dates in black** correspond to the validated dates of actual distribution to the patients;
- the **dates in red** correspond to the theoretical dates for the next distribution;
- the **dates in green** correspond to the dates of the first ARV distribution (initiation of treatment);

- when the patient comes to pick up his/her ARV drugs, the dispensing staff member finds the patient's line in the table (using the patient's name or code) and verifies the date in red (theoretical):
 - If the red date has not already been passed, it means that the patient is not late. The red date is erased and replaced by the actual date of the patient's visit. Then, the theoretical date for the next delivery is entered in red in the column for the next month.

If the ARV supply is for 2 months worth of treatment, the theoretical appointment is made for 2 months later and the agent enters 'OK' in the box for the following month, which signifies that the treatment quantity is sufficient to ensure adherence for the entire month.

 - If the red date has already been passed, it means that the patient is late. The staff member can suspect that the patient may have been non-compliant and can thus inquire about the reason for being late and if the patient has stopped taking his/her ARV treatment or taken a smaller dose.

In the above example:

- *if the current date is 1 April 2006: none of the patients are late;*
- *however, if the current date is 2 April 2006: patient NP 0206M is late for his/her appointment and risks not having enough medicine for the days to come.*

► Detecting when a patient does not understand his/her ARV-drug regimen

Several methods exist for evaluating the degree of patient non-adherence:

Chart 13: Individual evaluation methods for ARV-treatment adherence

Non-adherence evaluation methods applicable to the pharmacy	Advantages & disadvantages
<p>Counting the tablets remaining in the packages brought by patients each time they come to pick up their medicinal products.</p>	<p>Constraint for patients: bringing their ARV-drug packages with them at each visit.</p> <p>Low reliability since it is difficult to prove that the tablets not in the package were actually taken by the patient at the correct times.</p>
<p>Asking the patient about treatment administration over the past week</p> <p>Enquire whether the patient remembers skipping any doses or not taking any at the proper times over the past week.</p> <p>"Over the past week, how many doses have you skipped: none, 1 dose, more than 1 dose, more than 3 doses?"</p>	<p>Reliability: medium.</p> <p>Interesting method that requires patient honesty though in order to be reliable.</p>
<p>Patient evaluation of adherence on a visual scale of 1 to 10</p> <p>0 = 0% compliant 10 = 100% compliant</p> <p>The patient must simply make a mark on the scale to represent his/her level of adherence.</p> <p>Question to ask the patient: "On a adherence scale of 0 to 10, 0 meaning that you took none of the prescribed medicine and 10 meaning that you took it all, where would you situate yourself for the past 7 days?"</p> <p>0 1 2 3 4 5 6 7 8 9 10 * * * * * * * * * * (0%) (100%)</p> <p><i>In this example, the patient evaluates adherence at 7, which means that according to the patient, he/she has taken 70% of his/her ARV drugs.</i></p>	<p>Reliability: rather high.</p> <p>Interesting and reliable method since even if patients do not precisely remember forgetting doses, they can often visually estimate their overall adherence.</p> <p>The visual scale makes it possible to get around the problems of illiteracy and patients' own feelings of guilt since they do not have to admit their non-adherence outright.</p> <p>If a patient estimates adherence to be lower than 9 (90%), it is then time to have a discussion with him/her about the reasons behind forgetting doses or not taking them at the proper times.</p> <p><i>Remark:</i> this method is not always suitable to the African context. The concept of a visual scale is not always well understood nor communicative to patients. It is therefore important to present it first to the pharmacy team and to collect their opinions on the use of this tool with the patients they are accustomed to seeing.</p>

When the patient has been assessed as non-adherent, it is important to seek out the causes of their non-perfect adherence:

- possible financial problems;
- real cause of forgetfulness;
- patient ignorance and insufficient information about the treatment;
- religious beliefs;
- laxness often observed after the 6th month of treatment when the patient's condition has improved.

The patient should consequently be re-educated and re-motivated to accept the treatment. The pharmacist will verify the manner in which the patient takes their medicines and will interview them about the place where medicines are stored in their home (difficulties sometimes encountered for reasons of confidentiality).

► Detecting an intolerance to ARV treatment

A distinction should be made between the early and usual side effects of ARV drugs, for which information should be given at the outset, and the unexpected effects, which:

- may appear abruptly and require urgent care (early adverse effects);
- or may start slowly and occasionally develop to an acute stage requiring urgent care after a few weeks or several months.

The pharmacy is a place for regular dialogue with the patients. The team should be able to detect the adverse effects of the treatment and alert the medical team if necessary.

The pharmacy personnel should also inform the patient to this regard. Its role is to [38]:

- for less anxious patients who request details on starting the treatment;
 - inform them very gently and reassure them of the low risk involved, the side effects which may appear in the early stages;
 - describe the warning symptoms in order to have the patient consult a professional quickly, if necessary;
- know how to handle adverse effects as well as know which structures the patient must be referred to according to the degree of severity.

Interventions on part of the pharmacy team must correspond to 3 levels of urgency [39]:

Chart 14: Role of pharmacy personnel regarding the adverse effects of ARVs

Degree of urgency for ARV side effects and role of pharmacy personnel	Side effects and molecules involved
<p>Urgent (first days) → the pharmacist must be able to determine the severity of the side effect, know how to quickly explore the circumstances surrounding its appearance, inventory the patient's treatments and be able to contact the doctor and/or the nearest appropriate hospital.</p>	<ol style="list-style-type: none"> 1. Allergic reactions: ABC, NVP 2. Cardiac disorders: drug interactions 3. Pancreatitis and acute hepatitis: d4T, NVP, ddl 4. Renal colic: IDV

<p>Early disorders (first days, first weeks)</p> <ul style="list-style-type: none"> – uncomfortable but harmless and often temporary; – occurring regardless of eating habits, hygiene and lifestyle habits (sleep, work schedule) and living conditions. <p>→ Pharmacist's role: listen to the patient and rule out any drug reactions while taking all of the patient's treatments into account.</p> <p>→ Discuss with and seek direction from the medical team.</p>	<ol style="list-style-type: none"> 1. Digestive disorders (gastralgia, nausea, diarrhea, constipation, etc.) 2. Neuro-psychic symptoms (fever, headaches, insomnia, pain): EFV
<p>Medium and long-term disorders (first weeks and months)</p> <p>→ Inform, reassure and direct the patient on metabolic disorders that involve changes in appearance and/or overall state of health.</p> <p>→ Discuss troublesome cases with the medical team and encourage the patient to discuss them with the doctor at his/her next appointment. If necessary, the doctor will decide to change the ARV combination.</p>	<ol style="list-style-type: none"> 1. Persistent fatigue 2. Dermatological disorders (dry skin) 3. Neuropathy: d4T, ddl 4. Psychological / psychiatric disorders 5. Sexual disorders 6. Metabolic disorders (hypercholesterolaemia, hypertension and diabetes): PI and NRTI 7. Change in appearance (visual thinning of the thighs and calves, thickening of stomach and breast fat, bulging of the nape of the neck, hollowing of the cheeks): PI

► Changes in ARV combination

Changing or switching the ARV treatment often destabilizes patients. The role of pharmacy personnel includes:

- Knowing the potential causes for changing the ARV combination (specific state of health, toxicity, therapeutic failure) in order to ensure that patient care will be attentive to these precise signs.
- Knowing how to detect and record these signs in order to refer the patient to the medical team should a change in ARV combination be indicated.
- Knowing the changes anticipated by the medical team for the next period of time (*ex.: for the next quarter if ordering is carried out quarterly*) in order to properly evaluate the requirements, which must periodically be given to the sponsors who order the ARV drugs.
- Being able to inform and reassure the patient on the reasons for changing the combination.

Chart 15: First and second-line ARV molecule combinations

(Source: WHO Recommendations, August 2006 [40])

Recommended first-line ARV combinations	Recommended second-line ARV combinations
AZT (or d4T) + 3TC + NVP or EFV	ddl + ABC + PI (LPV/r or IDV/r or NFV) or TDF + ABC or 3TC + PI (LPV/r or IDV/r or NFV)
TDF + 3TC + NVP or EFV	ddl + ABC or 3TC + PI (LPV/r or IDV/r or NFV)
ABC + 3TC + NVP or EFV	ddl or TDF + 3TC + PI (LPV/r or IDV/r or NFV)
AZT (or d4T) + 3TC + ABC or TDF	EFV or NVP +/- ddl + PI (LPV/r or IDV/r or NFV)

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13 Best Practices, nutrition

Objectives

Best practices on nutrition allow for:

- an adaptation of the patient's approach to food to meet nutritional modalities related to ARVs or OI drugs;
- counseling the patient in case of vomiting;
- orienting the patient towards nutritional/cooking education groups;
- informing the patient on simple hygiene rules to be respected with food;
- counseling the patient in case of digestive adverse effects.

a. Adapting the administration of medicines to nutritional practices

Based on basic recommendations summarized below, the dispenser must establish with the patient the most natural daily program in order to encourage adherence to treatment. Chart 18 at the end of the sheet lays out the nutritional modalities to respect while taking ARV treatments as well as drugs to treat opportunistic infections.

Rules to apply when taking any medicine [41] [42]: Medicines should be taken with a large glass of water (>150 ml), each day at the same time, while sitting or standing up straight and not lying down for 5 minutes afterwards.

If vomiting occurs: take the pill again only if the vomiting occurred at the same time as taking the medicine (if swallowing the medicine causes regurgitation). If the vomiting occurs later, only take another pill if the first is visible in the liquid vomited (which is very rare and difficult to observe).

If you miss taking your medication:

- If the pill is to be taken once a day: take the pill within the following 20 hours, if not, wait for the next scheduled dose and do not double the dose.
- If the pill is to be taken twice a day: take the pill within the following 8 hours, if not, wait for the next scheduled dose without doubling the dose.

Example: *taking medicines during Ramadan*

It is important to work out a schedule for taking medicines with the patient for this period. Otherwise he may modify on his own initiative how the medicine is taken and take the risk of not adhering to the medication. The pharmacy team and the medical team need to meet to come up with suggestions for patients who will be fasting. Usually patients will continue their medications throughout the day and are advised to continue eating and drinking normally in order to stay healthy. Illness and maintaining immunity constitute a "valid excuse" for breaking the fast. However, this depends on each patient's individual situation: those who take medication only in the morning and the evening (without any requirements for food when they take the medication) and patients whose weight is stable can sometimes be allowed to fast.

b. Nutritional support at the pharmacy

When dispensing medicines, the patient's approach to food is taken into consideration to establish a medicine-taking schedule that best fits the patient's lifestyle (nature and frequency of meals, helping

them choose foods that are good for their health). This exchange makes it possible for the person dispensing the prescription to assess what kinds of food the patient eats, as well as his/her knowledge regarding nutrition.

If the patient respects rules of hygiene and correct diet, these issues are merely brought up during the conversation when the prescription is given out.

If the nutritional situation of the patient seems inadequate and the person dispensing the prescription encounters problems, then there needs to be a more thorough conversation so as to identify the sources of the problem (lack of financial or cooking resources, specific notions about diet) and offer appropriate solutions.

Lack of resources (the patient does not have the means to eat properly):

- refer the patient to the appropriate social services who might be able to give them food staples and inform them of community meals prepared by the organization, depending on the organization (the frequency of community meals depends on the organization: monthly, weekly, daily...);
- create a drug-taking schedule that fits the patient's eating habits;
- let the doctor and social workers know if the patient is encountering difficulties eating/getting the right foods.

Lack of knowledge regarding nutrition/diet (the patient doesn't know how to choose/prepare foods):

- orient the patient towards nutritional/cooking education groups organized by the organization (where patients learn how to cook balanced meals using inexpensive local foods);
- bring personalized advice: simple and balanced recipes, food intake frequency, choosing food adapted to the patient's health...;
- organize an interview with the patient's family (at his home during home based care or at the organization) in order to review the needs of a person living with HIV, to answer their questions, to dispel fears linked to a lack of understanding of the virus;
- let the doctors and social workers know if there are reasons why the patient cannot eat properly (uninformed family, little knowledge regarding food and nutrition on the part of the patient).

Key messages to convey to relatives of the person living with HIV is:

- HIV/AIDS are not propagated in water or food. You will not get HIV from sharing plates and bathrooms.
- There is no reason to avoid physical contact with someone living HIV/AIDS.
- Be encouraging and empathetic to people living with HIV/AIDS, help them to eat well to stay in good health and bring them their food and medicine if they are unable to get it themselves.

c. Nutritional advice to patients living with HIV

Chart 16: Synthesis of main nutrition education in regards to the progression of HIV infection [43]

Progression of HIV Infection	HIV + No symptoms Immune system weakening	Positive nutrition practices; Practical measures to grow/prepare appropriate food; Nutritional advice adapted to the ARV taking; Awareness of the importance of recognizing signs of weight loss and the need for prompt action.
	Progression to clinical AIDS Weight loss Diarrhea Opportunistic Infections Weakening	Continued positive nutrition practices; Nutritional guidelines to prevent weight loss and to regain lost weight; Nutritional advice adapted to the ARV and OI taking; Nutritional advice adapted to HIV-AIDS, symptoms of perturbing food habits (loss of appetite, nausea...)

A healthy diet for a person living with HIV / AIDS includes:

- Starchy foods in every meal (rice, corn, millet, potatoes, plantains...): these provide slow-release sugars, proteins, vitamins and minerals.
- Vegetables every day (dry beans, peas, lentils, groundnuts, soya): associated with starchy foods, they are a source of proteins which make up often insufficient animal protein intake (due to high cost).
- Some meat, some fish, eggs and dairy products as often as patient may buy, according to his financial situation: they provide good quality proteins, vitamins, minerals and energy. Needs in proteins are from 1.2 to 1.5 g / kg / day for a person living with HIV [44].
- Fruits and vegetables every day: they provide fiber, vitamins and indispensable minerals.
- Fats and oil must be associated with the other foods in small quantity: they provide energy and make dishes more delicious; however, they should not be abused, because they may induce metabolic diseases as hyperlipidemia and diabetes. Unsaturated vegetable oil (colza, sunflower, olive...) should be preferred to saturated oil (palm oil...) or (saturated) animal fats.
- The consumption of sweets (drinks, candies, cakes) has to remain occasional but is authorized so that the notion of pleasure is not eliminated and as it may stimulate appetite if necessary.
- Snacking between the meals is to be absolutely avoided.
- Drink a lot of drinking water: at least 8 cups a day (8 x 200 mL = approximately 1.5 liters). If the source of the water is not drinkable, the water must be boiled at least 10 minutes before being consumed. Other boiled drinks such as tea, rice-cooking water or soups are very good alternatives to plain water. On the other hand, alcohol must be limited because it dehydrates and induces interactions with numerous drugs. Coffee and fruit juices are to be consumed with caution as they can induce interactions with some medicines and stomach-aches.

Simple hygiene rules are to be respected with food:

- Wash your hands with water and some appropriate soap, before and after meal making and after going to the toilet.
- Cover any wound (with a glove / bandage) before manipulating food.
- Use clean water or boil it for 10 minutes if its source is not drinkable.
- Wash all fruits and vegetables in clean water.
- Cook on clean surfaces, with clean dishes and utensils (wash them with soap and water after every use).
- Thoroughly cook food, except for vegetables which contain more vitamins when uncooked.
- Avoid keeping food too long in the kitchen, or keep it refrigerated. In that case, always warm them at high temperature before consuming them.

d. Nutritional advice for HIV complications or in regards to HIV treatments

The community pharmacy team should know the complications induced by HIV or its treatments, and have access to the documentation on this subject, to detect them quickly and react in a proper way: by advising the patient at the community pharmacy or by referring him/her to a medical specialist if complications are severe. As soon as an ARV treatment is initiated, it is necessary that adapted nutritional advice is given to the patient, to prevent the outbreak of metabolic disorders induced by HIV and/or ARVs.

Chart 17: Nutritional advice when a patient faces symptoms induced by HIV and/or his treatments

Complications	Specific Nutritional advice (therapeutic advice excluded)
Diarrhea (liquid stools more than 3 times per day)	Do not stop eating and drink a lot to avoid dehydration (all day and night and after each stool). The drink may be water, soups or rice-cooking water. Avoid drinking tea or coffee. Avoid alcohol and tobacco. Eat food facilitating digestion: white rice, bread, cooked carrots, bananas. Avoid raw, spiced or very fatty food and dairy products.
Appetite loss	Eat frequently and in small quantities, preferably food to stimulate the appetite. Drink a lot, especially between meals. Do not take alcohol or tobacco. Avoid food that can cause gas, and carbonated drinks which can cause bloating. Try to take light physical exercise that stimulates good breathing (example: walking). Share meals with family or friends to make it a pleasant time.
Nausea and vomiting	Eat in a sitting position and wait one hour before lying down after the meal. Avoid preparing food whose smell makes you feel sick. Drink a lot, especially between meals, even in case of vomiting. Eat soft food until the vomiting stops. Eat small quantities as soon as hunger is felt. Cold meals as well as dry and salty food are often well tolerated in case of nausea (toast, crackers, cereal...). Eliminate very fatty food and any food which makes you feel sick; they will be gradually reintroduced later. Avoid alcohol and tobacco.
Mouth or throat aches leading to eating difficulties	Prefer soft and easy to swallow food: creams, yoghurts, soups, avocado, gourd, banana, papaya, chopped food. To swallow drinks, use a straw. Avoid carbonated drinks and alcohol. Avoid spicy, irritating (dry) or acid food. Do not swallow very warm or very cold food (keep them at ambient temperature). In case of candidosis, restrict sweet food (sugar, honey and sweet drink) which can worsen patient's health.

Chart 18: Food and HIV infection treatments

Frequently used medicines	Advice related to food habits [45] [46]	
Abacavir, ABC Amprenavir, APV Emtricitabine, FTC Lamivudine, 3TC Nevirapine, NVP Stavudine, d4T Zidovudine, AZT Efavirenz, EFV	To be taken with or without food.	
Non-steroidal anti-inflammatory drugs Aspirin Coartemeter (anti-malaria drug) Iron (ferrous salts) Indinavir, IDV (with RTV) Lopinavir, LPV Nelfinavir, NFV Proguanil (anti-malaria drug), Ritonavir, RTV Saquinavir, SQV Tenofovir, TDF	To be taken during meal.	
Doxycycline		Take your pills during the meal, in a sitting position (to avoid oesophagitis).
Carbamazepine, valproic acids (anti-epileptic drugs)		Do not drink alcohol during all the treatment.

Didanosine, ddl Erythromycin Mebendazole Theophylline	To be taken on an empty stomach = from 45 minutes to 1 hour prior to a meal or from 2 to 3 hours after a meal.	
Indinavir, IDV (without RTV)		Drink a lot of water to avoid urinary lithiasis (that is to say, drink from 1,5 to 2L / day among which 500 mL within the hour following the IDV taking).
Anti-acids (Aluminium hydroxide gels, Magnesium or Calcium carbonates) Charcoals Clays	They decrease the absorption of other medicines if taken simultaneously (as they cover stomach wall). This can be dangerous and facilitate the outbreak of ARV resistances, for example. Activated charcoal is to be banned. If needed, anti-acids and clays are to be taken apart from other medicines, that is to say at least 2 hours before the other medicines being taken.	
Antihistamine (Promethazine)	Do not combine with alcohol as it increases drowsiness risk.	
Aciclovir Co-trimoxazole	Drink a lot of water during all the treatment.	
Griseofulvin (antifungal)	Do not combine with alcohol because it can cause digestive disorders, headaches and cutaneous flushes (antabuse effect).	
Quinolones	Drink a lot of water during all the treatment.	
Métronidazole Tinidazole	Do not drink alcohol during all the treatment.	

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14 Quality Assurance for Pharmaceutical Activities

Objectives

Quality assurance system for pharmaceutical activities allows for:

- an implementation and respect of daily procedures by the pharmacy team;
- an evaluation of the quality of the functioning of the pharmacy to verify whether it fulfils its objectives on the quality of patient care and on the optimal use of human and financial resources.

a. Procedures to Implement at the Outset of Activities

- Draw up a **work schedule of all pharmacy employees (days and hours present) and the tasks attributed to each of them**. Such a chart is very useful for transparent communication within the team and can prevent misunderstandings. It should be posted so that each team member knows which tasks have been assigned and to whom.
- Implement a **correspondence notebook**, which is always filed in the same place. Every staff member should note important information in the notebook during their shift (calls from suppliers, patients requiring house calls, patients late picking up their medicine that should be mentioned to the doctor, stock shortages for a product, etc.). As soon as team members arrive on duty, they should consult the notebook to check whether any urgent tasks await or any information has come in.
- Set up a **box with 2 compartments for the pharmacy mail** – one for incoming, the other for outgoing mail.
- Create a **repertoire of important contacts** for the pharmacy activities (names and addresses of employees, suppliers, doctors, partners, etc.). It should be put away in a specific drawer or shelf (beside the telephone, for example, to provide quick access), organized alphabetically and expanded with each new important contact taken by a staff member.
- Create an **agenda** reserved for use by the pharmacy and available to the entire team, in which important events, tasks and appointments (within the pharmacy and the organization) are noted.
- Mutually decide on a **place to file all the administrative and pharmaceutical documents**. It is recommended to store the administrative documents, stock records and patient files in a lockable cupboard or drawer, inaccessible by the public. A shelf, cupboard or drawer can be reserved for storing documentary sources (pharmaceutical publications, data sheets, medical journals, etc.) and should be easily accessible for the person in charge of dispensing.
- Install a **notice board** for important information (stock shortages, new products integrated in the list of medicinal products, patients to be contacted, etc.).
- Mutually decide which **documents to post** in the pharmacy and the **place to post them**. The posted documents should be protected by a transparent plastic cover to avoid any damage to them.

Examples of documents to post:

- Post the **updated list of medicinal products stocked** (list defined in collaboration with the medicinal product committee). This list can be separated into two sections – ARV drugs / non-ARV drugs – and posted near the shelves where the medicinal products are stored.
- Post the **list of ARVs and their specificities** and the **list of possible interactions**.
- Post the **list of routine pharmacy procedures**.

b. Required “Routine” Procedures [47] [48]

Chart 19: Procedures that must be respected in a community pharmacy

Daily	
Maintaining the premises	<ul style="list-style-type: none"> ● Clean the pharmacy: dispose of objects/rubbish that clutter the floors and shelves, sweep and wash the floors, throw out rubbish, clean the rubbish bins and shelves, if necessary. ● Ensure that the fan and/or air conditioning work. ● Verify the neatness and arrangement of the refrigerator and note the temperature on the follow-up chart. ● Ensure that medicinal products are protected from direct sunlight. ● Check that the security cabinets, the pharmacy door and the reserve stock door are properly closed.
Managing the medicinal product inventory	<ul style="list-style-type: none"> ● Catch up on late entries and update the stock records and the prescription ledger over the course of the day. (In this case, take the pile of issued prescriptions and carefully verify against the stock records and prescription ledger that all incoming and outgoing prescriptions have been recorded). ● Should the data be managed both manually and electronically, update the electronic files using those filled out manually over the course of the day. ● Check the inventory level for the medicinal products and stock the dispensing outlet using the reserve stock if necessary.
Respecting good dispensing practices	<ul style="list-style-type: none"> ● Clear, tidy and clean the dispensing outlet office/counter. ● Restock and set out condoms and/or free brochures (or any other object distributed free-of-charge) for patients to help themselves. ● Put away the documents used for dispensing (prescription ledger, product data sheets, literature) in the assigned cupboard/shelf. ● Put away the patient charts and any document containing confidential patient information in the locked drawer/cabinet. ● If necessary, repackage bulk medicinal products (with a high turnover).
Weekly	
Maintaining the premises	<ul style="list-style-type: none"> ● In the reserve stock, ensure that the boxes are stacked correctly (to avoid the risk of crushing, dampness or insect/rodent damage for the bottom boxes). ● Visually check that medicinal products are in the correct place on the shelves. ● Sort out damaged or expired medicinal products and set aside for disposal.
Managing the medicinal product inventory	<ul style="list-style-type: none"> ● If a medicinal product has reached its minimum stock level: <ul style="list-style-type: none"> – If the next general order is to be placed within one month’s time, plan for this product to be included in the order. – If the next order is to be placed in more than one month’s time, place a special order for the missing product.
Communication within the pharmacy	<ul style="list-style-type: none"> ● Weekly internal meeting of the pharmacy team in order to take up the following subjects: <ul style="list-style-type: none"> – Important tasks for the coming week. – New information for the entire staff concerning stock management or following up on active patient files. – Practical remarks (schedule changes, etc.) that staff members would like to remind everybody about. – Updates on pharmaceutical knowledge (theory or practical exercises such as prescription commentaries). <p>At the end of these internal meetings, it is recommended that an account of the meeting be noted in a special notebook that is kept in a specific place and accessible to all employees or evaluators. These meetings should be scheduled in advance and, if possible, made for a specific time of the week outside of public opening hours.</p>

Monthly	
Maintaining the premises	<ul style="list-style-type: none"> ● Inspect the reserve stock for damage of the walls, floors, ceiling. ● Clean the floors, shelves and boxes in the reserve stock.
Communicating with all of the organization staff	<ul style="list-style-type: none"> ● Monthly meeting with the organization staff in order to take up the following subjects: <ul style="list-style-type: none"> – Important tasks for the coming month. – New information for the entire team concerning the organization's activities. – Practical remarks (schedule changes, etc.) that any staff member would like to bring up. ● It is advisable to follow this staff meeting with a meeting limited to those responsible for medical, psycho-social and pharmaceutical care in which specific patient cases from the past month can be discussed. This meeting is similar to a hospital staff meeting and is particularly useful for ensuring effective and coherent patient care. <p>These meetings should be scheduled in advance and, if possible, made for a specific time of the week outside of public opening hours.</p>
Every 6 months	
Maintaining the premises	<ul style="list-style-type: none"> ● Dispose of the expired or damaged products (that have been set aside each week). ● Visually inspect fire extinguishers to ensure that pressures are maintained and extinguishers are ready for use.
Managing the medicinal product inventory	<ul style="list-style-type: none"> ● Conduct a complete physical inventory (reserve and current stocks) and update the stock records for each product.
Managing electronic data	<ul style="list-style-type: none"> ● Make a back-up copy of the pharmacy's electronic data on CD-ROM, which is then archived in the locked cupboard reserved for confidential documents (include the date and contents written in permanent marker on the CD).
Communicating with financial partners	<ul style="list-style-type: none"> ● Be able to provide any financial partner with a report on consumption and medicinal requirements and/or an activity report and/or a financial report for the pharmacy upon request.
Managing team skills	<ul style="list-style-type: none"> ● Organize continuous skills training for team members.
With each order (monthly, bimonthly, quarterly, half-yearly depending on the structures, etc.)	
Managing the medicinal product inventory	<ul style="list-style-type: none"> ● Assess the stock situation for each medicinal product. ● Assess the requirements for the coming period and calculate the quantities of each medicinal product to order. ● Submit requisition form and get a <i>pro forma</i> invoice. ● Submit the <i>pro forma</i> invoice to the organization directors for validation. ● Reduce the order if the budget so requires, then submit the definitive order to the central procurement agency (or wholesaler). ● Receive the medicinal products. ● Store medicinal products according to the pharmacy's categorizing method and to the first-to-expire, first out principle. ● Fill out the stock records for the products received. ● File the order documents (invoice and receiving order) in the assigned file in the pharmacy.
Yearly	
Managing the medicinal product inventory	<ul style="list-style-type: none"> ● Conduct a complete physical inventory (reserve and current stocks) and update the stock records for each product. ● Re-evaluate the minimum/maximum stock levels for each medicinal product (according to the annual consumption) and readjust them if necessary.
Communicating with financial partners	<ul style="list-style-type: none"> ● Be able to provide any financial partner with a report on consumption and medicinal requirements and/or an activity report and/or a financial report for the pharmacy upon request.
Evaluating team skills	<ul style="list-style-type: none"> ● Evaluate the clinical and operational skills of team members.

c. Audit Indicators

A financial partner, an exterior consulting agency, the organization directors or simply the pharmacy team may wish to **evaluate the ratio “resources injected in the community pharmacy (financial, human, etc.) versus patient benefits”**.

Using the indicators mentioned below, it is possible to evaluate the degree to which the community pharmacy objectives have been met and thus, readjust activities.

The evaluation may be internal (self-evaluation by the pharmacy team for evaluating and, if necessary, improving their own performance) or external (initiated by a financial partner or the organization directors in order to guarantee the quality of the pharmacy activities).

Each indicator should be given a score from 1 to 4 according to the degree to which the objectives have been met:

- 1 = entirely; 2 = partially; 3 = answer to question still outstanding;
- 4 = not met; NA = not applicable in this pharmacy.

The **indicators in bold are essential** and should be treated as priority if there is not enough time for a complete evaluation.

Chart 20: Audit indicators for a community pharmacy

Structure indicators [49]
(measure the quantity and quality of the resources available to the pharmacy)

Category	Questions for evaluating the indicator	Score from 1 to 4
Material installations	Is the surface area of the premises adequate for the pharmacy activities?	
	Have the safety and building standards been adhered to?	
	Are the pharmaceutical products stored according to standards?	
Financial resources	What are the financial resources of the pharmacy? Indicate the sum paid to the pharmacy for the current year.	
	If the pharmacy gains its own resources from patient contributions, what is the average monthly revenue? Indicate the average monthly amount of the contributions paid by patients over the last 6 months.	
Human resources	Is the number of persons employed at the pharmacy adequate for its activities?	
	Is there a full-time pharmacist to supervise activities?	
	Is the training of the staff in line with the pharmacy activities?	
	Is employee remuneration in line with their respective scope of activities?	

Process indicators
(measure the level of pharmacy activities)

Category	Questions for evaluating the indicator	Score from 1 to 4
Organization of the pharmacy	Does a detailed procedures manual exist?	
	Is the procedures manual applied?	
	Does every employee have access to the procedures manual according to his/her needs?	
	Does an organization chart exist?	

Does it cover all activities?	
Does it cover the hours of operation?	
Do staff members arrive for work as scheduled?	
Does complete stock management software exist and is it used by staff?	
Does an approach exist for the continued education of staff members?	
Does an employee evaluation for every staff member take place?	
Do hygiene procedures exist?	
Are they applied?	
Do maintenance procedures for the premises exist?	
Are they applied?	
Are anti-theft measures in place?	
Are measures in place to avoid fires?	
Are copies of all stock management tools available?	
Are the tools for stock management put away in the assigned storage location?	
Are the tools for stock management used to 100%?	
Is the stock management software functional?	
Is it possible to calculate the average monthly consumptions with the software?	
Is it possible to calculate the stock situation with the software?	
Is it possible to calculate the expired products, which should be removed from the stock with the software?	
Is it possible to calculate the excess stock, which should be exchanged with the software?	
Do tools exist for manual stock management?	
Does stocktaking take place at least once every 6 months?	
Are weekly controls in place that compare the electronic theoretical stock, the theoretical stock entered on the manual stock record and the physical stock?	
Does the pharmacist carry out internal audits?	
Is there a correspondence form for communicating with the administrative departments?	
What are the average execution times for the administration? (Indicate the average time it takes the administration department to handle a file regarding the pharmacy)	
Is there a meeting notebook in which the minutes of the pharmacy's internal meetings are recorded?	
How often are internal meetings held? (Indicate the number of meetings in the last 6 months)	
Is there a message board for posting important information (stock shortage on a product, new product integrated into the list of medicinal products, patient to contact, etc.)?	
How often are meetings with the other organization departments held? (Indicate the number of inter-departmental meetings in the last 6 months)	
Does the pharmacy subscribe to professional journals?	
Is there a place where recent professional documentation is stored?	
If financial contributions are received, how often is the cash register counted? (Indicate the average over the past 6 months)	

	Is there a balance sheet for revenues? (answer yes or no)	
	Is there a balance sheet for expenses? (answer yes or no)	
Quality of pharmaceutical resources	Is there a functional 'medicinal product committee'?	
	Does the list of the organization's essential and commodity medicines correspond to the national list?	
	What is the percentage of essential medicines (according to the most recent WHO list) in the organization's list of medicinal products? (indicate the percentage)	
Supply and storing functions	Does the purchasing policy for pharmaceutical products follow the decisions of the 'medicinal product committee'?	
	Are requirements estimated correctly?	
	What is the average time lapse between the final order and the delivery of medicinal products? (Indicate the average delivery time over the past year)	
	What is the average time lapse between the estimation of requirements and the final order? (Indicate the average purchasing time over the past year)	
	What is the rate of error for medicinal products when orders are received? (Indicate the % over the past year)	
	What is the percentage of local orders (value of medicinal products purchased locally / value of imported medicinal products)? (Indicate the % over the past year)	
	What is the average time lapse between receiving medicinal products and actually entering them in the stock? (Indicate the average time over the past year)	
	What is the rate of expired items (>1 month) that have not been physically removed from the stock? (= "Number of expired items >1 month / Total number of medicinal products on stock", counted at the time of the evaluation)	
	What is the percentage of items not stored according to procedure (alphabetical order, pharmaceutical form, etc.)? (= "Number of medicinal products stored incorrectly / Total number of medicinal products on stock", counted at the time of the evaluation)	
	What is the percentage of items stored correctly according to the "first-to-expire, first out" principle? (= "Number of products correctly stored / Total number of medicinal products on stock", counted at the time of the evaluation)	
Dispensing practices	What is the average waiting time for patients between arriving at the pharmacy and having received their products? (Indicate the estimated average waiting time over the past 6 months)	
	How often are 'unlisted' medicinal products purchased urgently at the pharmacy? (Indicate the % "Number of 'unlisted' units issued over the past 6 months / Total number of units issued over the past 6 months")	
	What percentage does the purchase of 'unlisted' medicinal products (at purchase value) represent in relation to the total budget for medicinal products? (Indicate the % "Sum spent on purchasing 'unlisted' medicinal products / Total sum spent on purchasing medicinal products", over the past 6 or 12 months)	
	What is the percentage of unlabelled medicinal products issued (mainly products repackaged into bags)? (Indicate the % "Number of unlabelled bags issued over the past 6 months / Number of labeled bags issued over the past 6 months")	
	To what degree are the staff members of external departments (doctors, nurses, etc.) familiar with the pharmacy's stock? (Estimation after consulting these persons at the time of the evaluation)	
	What is the average number of prescriptions issued per month? (Indicate the average over the past 6 or 12 months)	

Results indicators

(measure the results of good resource management and good pharmacy activity)

Questions for evaluating the indicator	Score from 1 to 4
What is the rate of stock shortage at the time of the evaluation? (= "Number of out-of-stock items / Total number of items on stock", at the time of the evaluation)	
What is the rate of non-issued items due to stock shortage? (= "Number of non-issued items due to stock shortage / Total number of prescribed items", over the past 6 or 12 months)	
What is the rate of non-issued 'unlisted' prescriptions? (= "Number of non-issued prescriptions due to unlisted product / Total number of issued prescriptions", over the past 6 or 12 months)	
What is the average waiting time for patients at the pharmacy? (Estimated average waiting time over the past 6 months)	
What is the average cost of a prescription for non-ARV medicinal products for a patient? (Average cost over the past 6 months)	
What is the average cost of an ARV prescription for a patient? (Average cost over the past 6 months)	

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