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Guidance Modules on Antiretroviral Treatments

Module 8

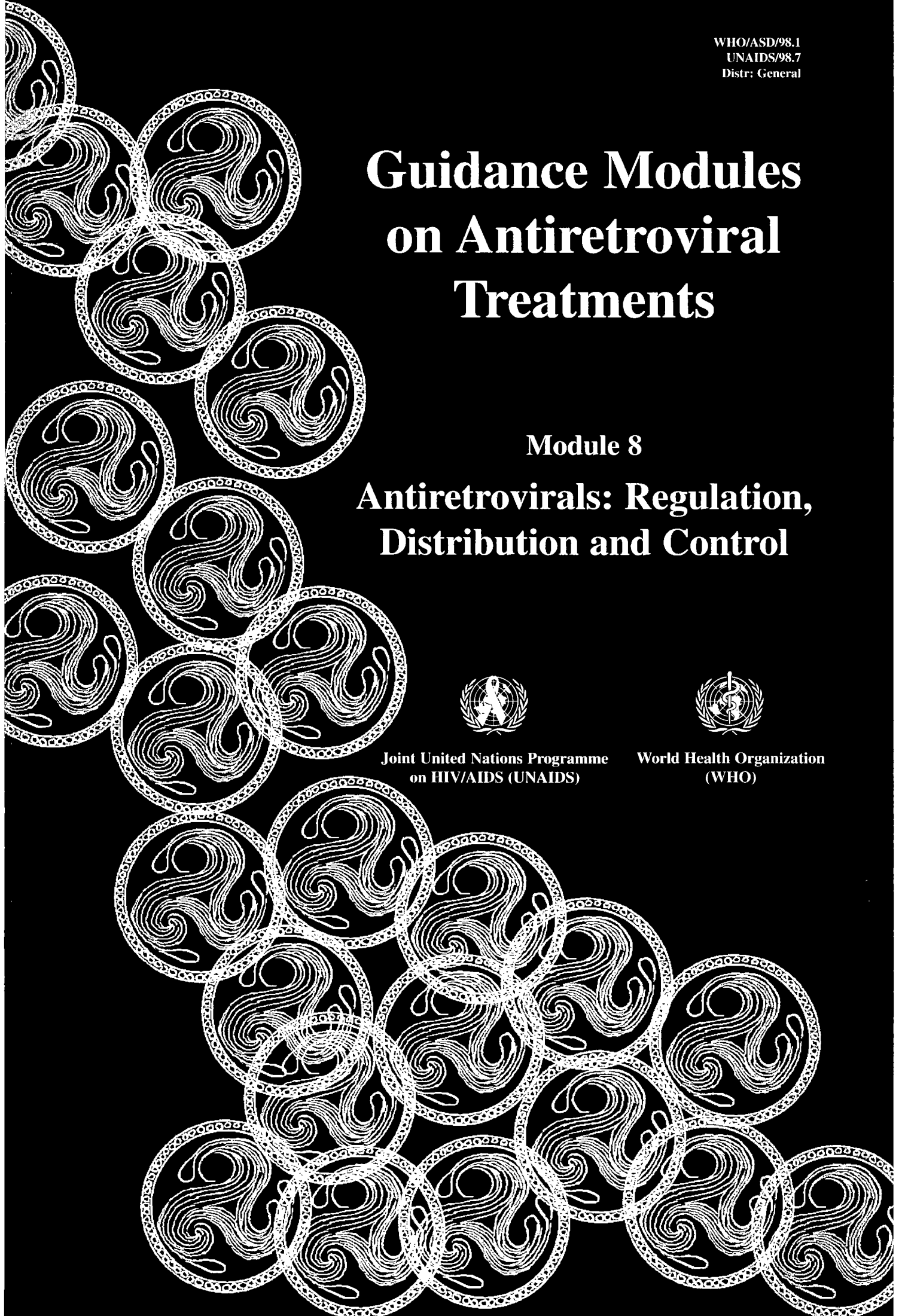
Antiretrovirals: Regulation, Distribution and Control



Joint United Nations Programme
on HIV/AIDS (UNAIDS)



World Health Organization
(WHO)



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Module 8

ARVs: Regulation, Distribution, and Control

The objective of this module is to provide guidance to policy-makers and senior managers on the effective management of antiretrovirals (ARVs) so as to ensure their safety, efficacy, and quality from procurement to end-use. It is intended to provide support at two different points in time:

- Before a decision is made to introduce ARVs, the module can assist senior managers to check if minimum structures, systems and policies are in place and to evaluate additional resources and investment needed to make ARVs available, and ensure their rational use.
- Once the decision has been made to introduce specific ARV treatments for certain target groups, the module provides support in troubleshooting, improving the efficacy and reliability of the pharmaceutical system, and building a consistent and sustainable ARV supply.

1. Introduction

For many PLHA, ARVs represent the only hope and the best available treatment which may increase survival and quality of life. Understandably, obtaining ARVs is likely to be a major preoccupation of many PLHA all over the world. However, at government level, the decision to introduce ARVs is a complex one, as ARVs are very expensive, the treatment is difficult to adhere to, and requires efficiently functioning health and social services. Governments can decide not to permit the importation and use of ARVs in the country, or to permit the distribution of ARVs only in the private sector or to provide them through public health services. Individual countries need to analyse their own situation before making any decision. (See Modules 2 and 3 for further discussion of this issue).

When a government decides to introduce ARVs, a reliable and regular supply of good quality ARVs must be assured. For a variety of reasons, ARVs pose a particular challenge in this respect:

- (1) The development of resistance is “just around the corner”. It has been shown that minor lapses in adherence may lead to the development of resistance and thus interfere with efficacy.
- (2) It is almost certain that given a treatment which is perceived as life saving, but that is very expensive, a black market will form; counterfeit and substandard drugs will start to circulate and a parallel drug supply system will operate.

The procurement, distribution and dispensing of ARVs require therefore functioning national quality assurance and supply systems. In the following pages, we will try to describe what should be done in developing countries to ensure that ARVs are of acceptable quality, are in continuous supply, and appropriately dispensed.

2. Characteristics of pharmaceutical systems

Measures in a particular country to ensure that ARVs are well controlled and managed are closely linked to the structure of its pharmaceutical sector, the capacity of the drug regulatory agency, the level of training of its personnel and its pharmaceutical pricing and financing policies.

In low income countries, health services are in general in a poor state; trained pharmacists are few especially in the public sector, drugs are supplied through public and private health facilities, pharmacies and drug outlets. Drug regulatory authorities have limited capacity to enforce legislation and regulations. Expenditure on drugs is low (between 1 and 10 US\$ per capita) and mainly financed directly by households. Shortages of essential drugs in public health facilities are common and prices in the private sector are unaffordable for the majority. These countries face major problems when introducing ARVs as the minimum conditions required to ensure their rational use cannot be met. However, in a number of countries ARVs are already available in private pharmacies. The extent of the problems, which include black markets, is not yet well known.

In middle income countries, health services are often better organized; drugs are supplied by public and private providers (pharmacies and drug outlets); the regulatory capacity of governments tends to be greater; pharmaceutical expenditures are higher in absolute terms with a higher proportion of public financing and still a large out of pocket share. However, in many middle income countries drug supplies in the public sector are uneven; financial access remains a problem; regulations are poorly enforced; and irrational use of drugs is rampant. In these countries, a variety of ARV dispensing strategies are in place which are closely linked to ARV financing strategies. In Brazil, for example, ARVs are fully subsidized and available free to HIV-positive individuals from the Unified Health System through governmental health services, whereas in Thailand, people with HIV/AIDS are included in a network for clinical trials in selected hospitals. In South Africa, on the other hand, there is no public expenditure on ARVs.

In industrialized countries, health care coverage is almost universal, health care delivery systems are well organized; drugs are supplied by public and private providers (pharmacies); regulations are comprehensive and well enforced. Therefore, access to and quality of ARVs is a less important issue than in other countries. The main concern is how to ensure maximum adherence to treatment. The way distribution of ARVs is organized has an influence on this adherence. Distribution varies considerably according to the organization of public health systems: from dispensation restricted to hospital pharmacies, to "double dispensation" wherein the hospital pharmacy is responsible for initial prescribing with subsequent dispensing entrusted to private outlets, to dispensing by both hospital and private pharmacies.

In view of the wide disparities between countries, solutions to ensure availability of good quality ARVs have to be tailored to country characteristics. However, there are a number of minimum structures/systems/policies which need to be in place, before any ARVs are made available in a country.

The next chapters will highlight some of the challenges and the various measures, actions and procedures which are essential and which cannot be ignored by governments. These measures are the most important ones and should be considered as the bare minimum. Indeed the supply, distribution, and provision of ARVs require a national commitment to implementing quality assurance systems, keeping in mind that:

- Access to and use of ARVs must be integrated within a continuum of care comprising home, community, and hospitals.
- Non-discrimination and equity in access should be ensured for individuals in ARV target treatment groups.
- There must be a comprehensive policy on ARVs which should be part of the national drug policy and should be based on the concept of essential drugs.

3. Ensuring that ARVs are of acceptable quality

Many of the measures which are described in this chapter apply to all drugs. For example, a legal and administrative framework must be in place in all countries to regulate, and control the pharmaceutical sector in order to ensure that only drugs of acceptable quality are available. However, these measures are particularly important for ARVs as the presence of substandard or counterfeit ARV can lead to a number of problems.

Risks of low quality ARVs:

- Therapeutic failure
- Development of resistant strains
- Health threats (toxic or adverse reactions)
- Waste of already meager resources

Maintaining quality of ARVs during procurement

In most developing countries ARVs will be procured from outside and not produced in the country. Whatever the situation is, it is important to use some simple procedures to ensure that ARVs conform to acceptable standards of quality, safety and efficacy when procured. These procedures apply for ARVs distributed in the public or in the private sector.

➤ **Register ARVs:**

Even in least developed countries where the drug regulatory authority has limited capacity, the Ministry of Health should ensure that a product license has been granted by the drug regulatory authority before allowing any pharmaceuticals, including ARVs, into the country.

Small regulatory authorities do not have the capacity to undertake the multidisciplinary assessment needed for ARVs, they should therefore rely primarily on information provided by well developed national drug regulatory authorities; this can be done on a country to country basis or through the network of national information officers established by WHO.

Where no formal system of drug licensing has been established, importation of ARVs can be most effectively controlled by issuing permits in the name of the drug regulatory authority to the authorized importing agency.

➤ **Make full use of the WHO Certification Scheme on the Quality of Pharmaceuticals Products Moving in International Commerce:**

This scheme constitutes a formal agreement between participating Member States to provide information on any product, notably on its registration status in the country of origin and whether or not the manufacturer complies with WHO's guidelines on good manufacturing practices (GMP) for pharmaceutical products.

➤ **License importing agents and distributors:**

All transactions relating to the importation of pharmaceutical products including ARVs should be conducted either through the government drug procurement agency or through independent importing agents and distributors specifically designated and licensed by the national drug regulatory authority.

➤ **Deal directly with ARV manufacturers:**

This allows for checking the exporting source and buying only from known ARV suppliers (all ARVs are single-source drugs).

➤ **Include detailed product specifications in drug procurement contracts:**

- Indicate accepted pharmacopoeia standards when they exist.
- At time of delivery, at least two years or 75% of shelf life should remain to avoid early expiry.
- Contract terms should require standard labelling and proper packaging of ARVs.

Maintaining the quality of ARVs during importation

The WHO Scheme and the above mechanisms need to be complemented by administrative and other safeguards aimed at ensuring that consignments of imported ARVs are in conformity with the import license. All formalities undertaken on importation should be coordinated by the customs service which need to work closely with the drug regulatory authority. It is therefore extremely important to have a well functioning drug inspection system and to use the most trained personnel for the activities related to importation and distribution of ARVs.

Most important measures include:

- **Require key documents from the importer before customs clearance:**
 - Certified documents attesting that the importer is duly authorized by license to undertake the transaction..
 - A batch certificate issued by the manufacturer in line with the requirements of the WHO Certification Scheme.
- **Specify designated customs posts.**
- **Carry out effective control at specified entry points:**
 - *Inspection:* visual and physical examination checking for compliance with the contract conditions concerning drug type, quantity, presentation, packaging, labeling, and any special requirements, and reporting of suspect products.
 - *Routine sampling and independent drug analysis* to validate product content and drug concentration, in case the product has deteriorated, or is of doubtful authenticity. If no facility exists at national level, organizing quality control with outside laboratories may be a solution.
- **Formulate and supplement procedures for donations of ARVs:**
 - Use the guidelines for Drug Donations developed by WHO and other agencies (WHO/DAP/96.2) to define national guidelines for donations of ARVs
 - Define administrative procedures for receiving donations of ARVs.
 - Define administrative procedures for receiving donations of ARVs.
 - Specify the needs for ARVs (in terms of the kind of drugs and the quantities).
 - Manage ARVs donations as other ARVs.

Maintaining the quality of ARVs through the distribution chain

The ARVs should remain secure within the distribution chain. This distribution can be done by the government procurement agency or by private wholesalers; the precautions are the same in the two channels and are basically the same as for other pharmaceuticals. However, as ARVs have a number of characteristics described above, it is advisable in countries with limited resources to give more attention to the management of these drugs at all levels of the chain.

Most important measures include:

➤ **Appropriate transportation and storage conditions:**

Ensure compliance with maximum allowable temperatures. During transportation the maximum temperature for most of the ARVs is +30°C; it is only +8°C for Ritonavir. The same applies for storage: Ritonavir should be kept in a refrigerator set between +2°C and +8°C; the other ARVs can be stored in dry, clean, well ventilated storerooms maintained between +15°C and +25°C.

➤ **Special attention to the management of ARVs:**

Distributors whether public or private should have reliable records of ARV stocks and in certain cases keep ARVs in a separate locked area. In addition, the most experienced and competent staff should be made aware of the specific importance of ARVs and assigned the task of supervising the ARV distribution chain.

At dispensing level, consumption reports showing the time, date, patient, dose, and remaining stock levels should be kept by the hospital pharmacy.

Essential measures to ensure quality of ARVs:

- Allow only registered ARVs on the market.
- Allow only licensed importers to import ARVs.
- Use the WHO Certification Scheme.
- Designate customs posts for importation of ARVs.
- Physically inspect all consignments.
- Respect transportation and storage conditions for ARVs.
- Give special attention to the management of ARVs at all levels of the distribution chain (inventory control, storage, etc.).

4. Ensuring a continuous supply of ARVs

Ensuring a continuous supply of ARVs is a key issue in the management of ARVs. Adherence is particularly critical in relation to ARV treatments. There is evidence of drug resistance resulting from minor lapses in adherence. Many factors influence

adherence to treatment and obviously, unreliable supply is one of them. Unreliable supply may be due to problems in financing ARVs (discussed in Module 2) or to poor drug management.

Risks of unreliable supply and distribution of ARVs:

- Decreasing treatment efficacy or treatment failure
- Increasing risks of emergence of resistance
- Compromising patients' commitment to adherence
- Demotivating health professionals
- Increasing unregulated supply and distribution of ARVs

National systems vary with respect to public and private roles in procuring, distributing, and dispensing drugs. In organizing the supply of ARVs, governments can:

- Assume the responsibility to provide publicly-funded ARVs
- Leave the financing and supply of ARVs to the private market
- Develop a combined public/private supply strategy.

Regardless of the approach selected, public health authorities must make sure that there is no shortage of ARVs at the agreed points of dispensing.

ARV supply management

➤ **Develop group purchasing:**

Regardless of how the drug supply system is organized, a centralized procurement system in which one procurement office, whether publicly or privately managed, negotiates ARV supply contracts, offers several potential advantages:

- Larger procurement volume, even for single-source drugs, creates the conditions for reduced prices and favourable contract terms.
- With only one procurement unit to staff and manage, it is easier to maintain the rational procurement of ARVs and a constant supply to distributors, thereby ensuring the sustainability of the programme. This centralized procurement system can cover the provision of ARVs for the public and the private sector.

➤ **Calculate ARV requirements carefully:**

ARV orders should be based on reliable estimates of actual need so as to avoid stock-outs or overstocks (AIDS pattern, morbidity data, consumption records).

➤ **Specify divided ARV deliveries in terms of contract:**

Even when ARVs are ordered only once a year, divided deliveries allow reductions in inventory holding costs, ease cash flow constraints, and result in increased ARV shelf life.

Distribution of ARVs through the public sector

Deciding to provide ARVs through the national public health system implies a commitment to guarantee a regular and long-term supply to a number of dispensing points. Public health authorities have two options for achieving these demanding objectives: integrating ARV distribution into the existing drug distribution system or creating a specific distribution for ARVs. The choice must be made after a careful assessment of the existing drug supply system, with the long term goal of an integrated drug distribution system.

➤ **Integrated distribution:**

The relative strength and weakness of current distribution systems can be assessed by using some simple key indicators such as percentage of inventory variation in stock record-keeping, percentage of expired drugs in stock, stock-out frequency for indicator drugs or delivery delay at different levels of the distribution chain. Relevant activities aimed at redesigning the existing system can then be planned, in line with the following objectives:

- Maintaining a constant supply of ARVs.
- Ensuring the timely delivery of ARVs to chosen dispensaries.
- Ensuring that ARVs are properly stored, with minimal expiration or other losses.

➤ **Vertical distribution:**

If the existing national distribution system is ineffective, implementing an ARV-specific distribution system -- which implies mobilizing new resources and establishing a new management structure -- can be a temporary alternative, particularly initially, where only a few distribution points have been identified. Designing a new organization allows for planning ARV distribution, setting up an efficient network of storage facilities with the fewest number of levels appropriate to the country's geography and ARV treatment needs, and achieving more rational use of transportation facilities.

Table 1: Integrated versus vertical distribution system		
System	Advantages	Disadvantages
Integrated	<ul style="list-style-type: none"> • Option of choice if chosen dispensary is easy to reach by existing distribution system • High quality requirements of ARV supply pulling forward the whole supply chain • Challenge of ARV introduction stimulating staff and helping changes in management • Less costly: use of existing resources 	<ul style="list-style-type: none"> • Risk of disrupted supply and stock-outs when there are structural weaknesses in the system • Difficult to implement strict quality assurance procedures • Storage points may not suit the needs of ARV distribution
Vertical	<ul style="list-style-type: none"> • Establishment of central unit in MoH with overall responsibility • Long-term planning, coordination, supervision, and monitoring of ARV supply facilitated • Easier to prevent unexpected events • Homogeneity of quality assurance procedures • Reliable information system for coordinating distribution network easier to implement 	<ul style="list-style-type: none"> • Higher management costs • Developing a new vertical programme for ARV supply is not a rational measure in countries where a national drug procurement and distribution system exists

Dispensing

Selecting where to deliver ARVs is closely linked to who is to receive antiretroviral therapy. Choosing dispensaries is also conditioned by several other factors:

- ARV financing strategies
- HIV/AIDS prevalence in the country
- Selected target group (PEP (post exposure prophylaxis), MTCT (mother to child transmission), AIDS, HIV patients)
- Need to monitor efficacy and toxicity of ARV treatments.

Based on these factors and the existing situation in the country, governments will decide that ARVs will be available in the public, in the private or in the two sectors.

➤ **Dispensing through public health services:**

When deciding where ARVs should be dispensed, the following guidelines should be taken into consideration:

- Conceding priority for ARV supply to existing facilities for AIDS medical care
- Ensuring that chosen ARV dispensing facilities can be easily and regularly supplied (reliable transportation and scheduled deliveries)
- Ensuring inclusion of retail points in clinical, laboratory, and social support network
- Taking into account the educational levels of dispensing facilities' personnel
- Involving pharmacists in multidisciplinary teams of ARV therapy monitoring
- Guaranteeing joint and convenient access to dispensaries and laboratory facilities
- Ensuring that targeted patients will be able to come to the same dispensing facility for follow-up purposes.

The main concern in choosing the adequate level for dispensing facilities is their degree of technical expertise and specialization. Since full coverage is not currently achievable in most countries, one approach might be to ensure access to ARVs in a limited number of facilities where clinical, laboratory, and social support can be guaranteed.

The pros and cons of centralized and decentralized ARV dispensing level are listed in the following table.

Table 2: Centralized versus decentralized ARVs dispensing		
Dispensing level	Advantages	Disadvantages
Specialized (regional level) <ul style="list-style-type: none"> • Selected centres • Hospital pharmacies 	<ul style="list-style-type: none"> • Close relationship with hospital clinicians • Hospital pharmacists' expertise • Faster and safer ARV supply • Easier ARV quality monitoring • ARV adverse reactions surveillance and reporting facilitated (team monitoring) • Easier constitution of a therapeutic file for treatment monitoring • Training workshops easier to implement (key staff from provincial hospitals, for instance) • Regular updating of treatment standards and recommendations facilitated (know-how of a few specialists) 	<ul style="list-style-type: none"> • Decreased ease of access • Difficult for community to participate in ARV therapy supervision
Decentralized (district level) <ul style="list-style-type: none"> • Hospitals • Health centres 	<ul style="list-style-type: none"> • Better equity in access • Use of local social and familial resources to ensure treatment adherence and follow-up • Possible to integrate with TB care systems 	<ul style="list-style-type: none"> • Lack of available human resources and local infrastructure, lack of expertise and suitably trained staff • Increased costs of distribution • Risk of decreasing ARV quality • Increased risk of thefts • ARV treatment supervision more difficult; increased risk of inappropriate use, bad compliance, and resistant strains emergence • ARV adverse reactions monitoring limited

➤ **Dispensing through private pharmacies:**

Governments may decide to allow ARVs to be sold in the private sector, considering that patients with sufficient disposable income have the right to obtain these therapies. Governments should be aware that regulations and their enforcement are very important to ensure that ARVs are distributed appropriately in the private sector. This means that the system for regulatory drug control including inspection and drug quality laboratory has to function properly. Ideally the same principles as for dispensing in public health services should be adhered to. In addition:

- Limitations should be placed on the number of drug outlets allowed to sell ARVs in a given town or district. The quality of ARVs sold by a few well known retailers is easier to monitor.
- To protect patient health, it would be important that patients who buy their ARVs in the private sector do so only if the drugs have been prescribed by an authorized source and the treatment is monitored under strict medical, laboratory and care conditions in a designated centre.
- Private outlets should be licensed for ARV sales only if located near clinical, laboratory, and social structures for treatment supervision.
- Pharmacists should be trained in ARV dispensing; training sessions could be jointly organized by public health authorities and ARV producers.

Essential measures to ensure continuous supply of ARVs:

- Give special attention to the management of ARVs.
- Encourage group purchasing to reduce ARV prices.
- Assess the distribution system before deciding on an integrated or a vertical approach.
- Select carefully the places (public or private) where the ARVs will be dispensed to patients.
- Give special attention to the inspection/supervision of dispensing outlets.

5. Ensuring correct dispensation of ARVs

Dispensing ARVs correctly is an important step in ensuring adherence to treatment. Problems concerning ARVs do not end once these drugs become accessible. The counselling process at the dispensing point should be able to partly address the factors that adversely affect adherence.

Combination therapy is complicated. ARVs have to be taken many times a day. Some have unpleasant side effects which may become difficult to accept by the patient. When ARVs are dispensed in public health facilities, pharmacists are usually part of a team responsible for information on drug taking. When ARVs are dispensed in private pharmacies, they should be able to address issues which will maximize adherence to the treatments. This implies additional responsibilities for pharmacists.

Risk of incorrect dispensing of ARVs:

- **Incomplete or bad adherence to ARV treatments**
 - Less effective regimen, possibly leading to treatment failure
 - Development and transmission of ARV-resistant viral strains
 - Waste of valuable resources
- **Toxicity of ARV treatments (side effects and interactions)**

- **Pharmacists or other health staff involved in dispensing need to be trained to provide information and to improve their communication skills:**

Appropriate training is very important; the training should associate all health care providers dealing with HIV/AIDS and include issues related to information and to communication, including dealing with the stress which may occur in patients when drugs are not available or treatment has not been adhered to. This training can be organized at regular intervals and cover an increasing number of pharmacists and other personnel. Pharmacists also need to know where and when to refer patients for counselling.

- **ARVs should be issued to patients with clear instructions and advice:**
 - As far as possible, ARVs should be given directly to the named patient.
 - Every effort must be made to confirm that the patient understands the complexity and duration of ARV treatment (patients' commitment to ARV therapy).
 - Pharmacists should make sure that the patient understands the dosage and course of therapy. Advice should concentrate on when and how to take ARVs and how to store them.
 - Written or symbolic instructions could accompany ARVs (detailed timetable, pictograms, etc.).
 - Warnings about possible side effects should be provided.
 - Instructions should be organized: patients remember best the first instructions provided.

➤ **A personal relationship should be established with patients:**

- Need for confidentiality and privacy when explaining use of ARVs must be recognized.
- Adequate time should be devoted for ARV dispensing.
- Patients should be advised always to come to the same pharmacy.
- As far as possible, the same person from the pharmacy team should follow each patient.

Pharmacists should be able to answer all specific questions and problems encountered by patients related to ARV treatments (side effects, interactions, and so on) and refer to clinicians where appropriate.

➤ **Follow up of non-attenders should be arranged:**

- Participation of NGOs, community groups, and consumer and professional organizations should be sought.
- Regular meetings to motivate patients should be organized.

➤ **Patients self-monitoring should be developed:**

- Involvement of close relatives.
- Self-monitoring procedures to regularly and systematically evaluate treatment adherence should be implemented by mixed physician/pharmacist teams.

➤ **Follow-up the effects of ARV treatment:**

Pharmacists, in collaboration with other health professionals, have a key role to play in following individual patients for adverse reactions and toxicity:

- Pharmacists should recognize side-effects and interactions associated with ARV therapy, and be able to refer patients and inform physicians.
- An individual therapeutic file for treatment monitoring should be constituted at the dispensing facility level to document and trace ARV treatment events for each patient. Details of ARVs dispensed must be entered into this file before being issued to patients (date, patient's name and age, drug name, dosage and amount issued, dispenser's name).

➤ **Health personnel should be alerted to the need to report adverse reactions:**

In the medium term it is important for countries to report adverse reactions to ARVs; a system for reporting to a specific centre may be established step by step.

Essential measures to ensure good dispensing of ARVs:

- Train pharmacists in communication skills.
- Provide clear and simple instructions to patients on use of ARVs and adverse effects.
- Establish a relationship based on confidence between the patient and the pharmacist.
- Ensure through regulations that prescribing and dispensing of ARVs are limited to specific places and persons.
- Ensure that patients are followed by the same pharmacist when ARVs are available through private pharmacies.

6. Supporting activities

Prescribers, pharmacists, and patients must become acquainted with ARVs and learn to use them. They all require information and should not rely only on manufacturers' promotional information. When deciding to introduce ARVs into the health system, governments should consider ways to ensure that independent information is made available; this can be done through the AIDS programme or through the Drug Information Centre when these structures exist. Information should include data on updated recommendations and ARV treatment standards.

Introducing new therapeutics such as ARVs demands new skills and attitudes. This means that time must be devoted to providing training either in basic or continuing education programs. This training needs to be directed at different categories of personnel.

➤ **Inspection services:**

Inspectors should be trained to promptly and accurately identify counterfeit or substandard ARVs. As in many countries the number of inspectors is very limited, it could be opportune at the beginning to select one or two and to provide them with a more intensive training on specific aspects of regulating ARVs.

➤ **Managers and operational staff:**

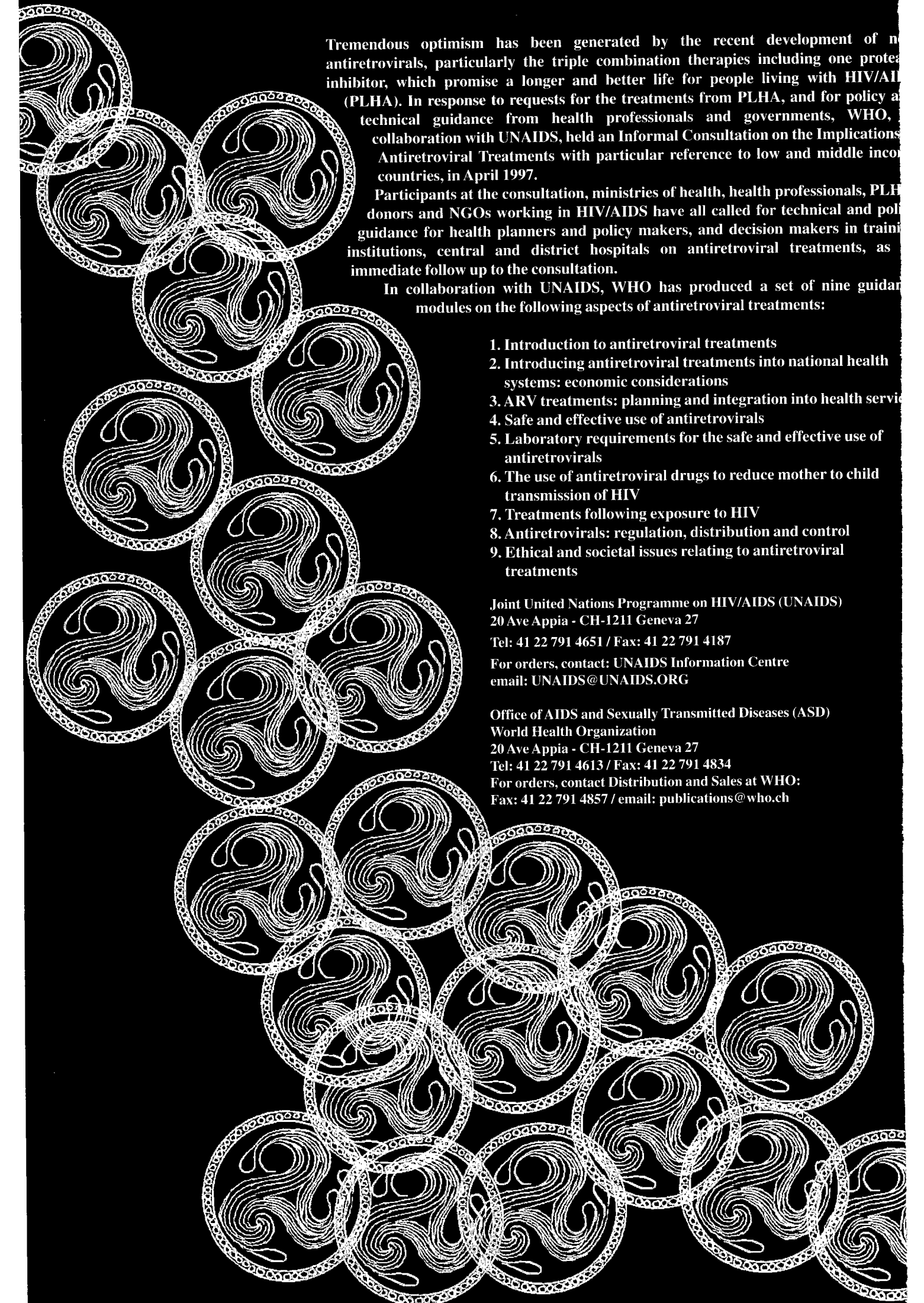
Specific practices developed to manage ARVs should be taught to staff assigned to keep track of them.

➤ **Pharmacists:**

The dispensers play a crucial role in ensuring patient adherence to ARVs therapy. The quality of dispensing may be affected by the training and supervision the dispenser has received and the drug information available to him or her.







Tremendous optimism has been generated by the recent development of new antiretrovirals, particularly the triple combination therapies including one protease inhibitor, which promise a longer and better life for people living with HIV/AIDS (PLHA). In response to requests for the treatments from PLHA, and for policy and technical guidance from health professionals and governments, WHO, in collaboration with UNAIDS, held an Informal Consultation on the Implications of Antiretroviral Treatments with particular reference to low and middle income countries, in April 1997.

Participants at the consultation, ministries of health, health professionals, PLE donors and NGOs working in HIV/AIDS have all called for technical and policy guidance for health planners and policy makers, and decision makers in training institutions, central and district hospitals on antiretroviral treatments, as an immediate follow up to the consultation.

In collaboration with UNAIDS, WHO has produced a set of nine guidance modules on the following aspects of antiretroviral treatments:

1. Introduction to antiretroviral treatments
2. Introducing antiretroviral treatments into national health systems: economic considerations
3. ARV treatments: planning and integration into health services
4. Safe and effective use of antiretrovirals
5. Laboratory requirements for the safe and effective use of antiretrovirals
6. The use of antiretroviral drugs to reduce mother to child transmission of HIV
7. Treatments following exposure to HIV
8. Antiretrovirals: regulation, distribution and control
9. Ethical and societal issues relating to antiretroviral treatments

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