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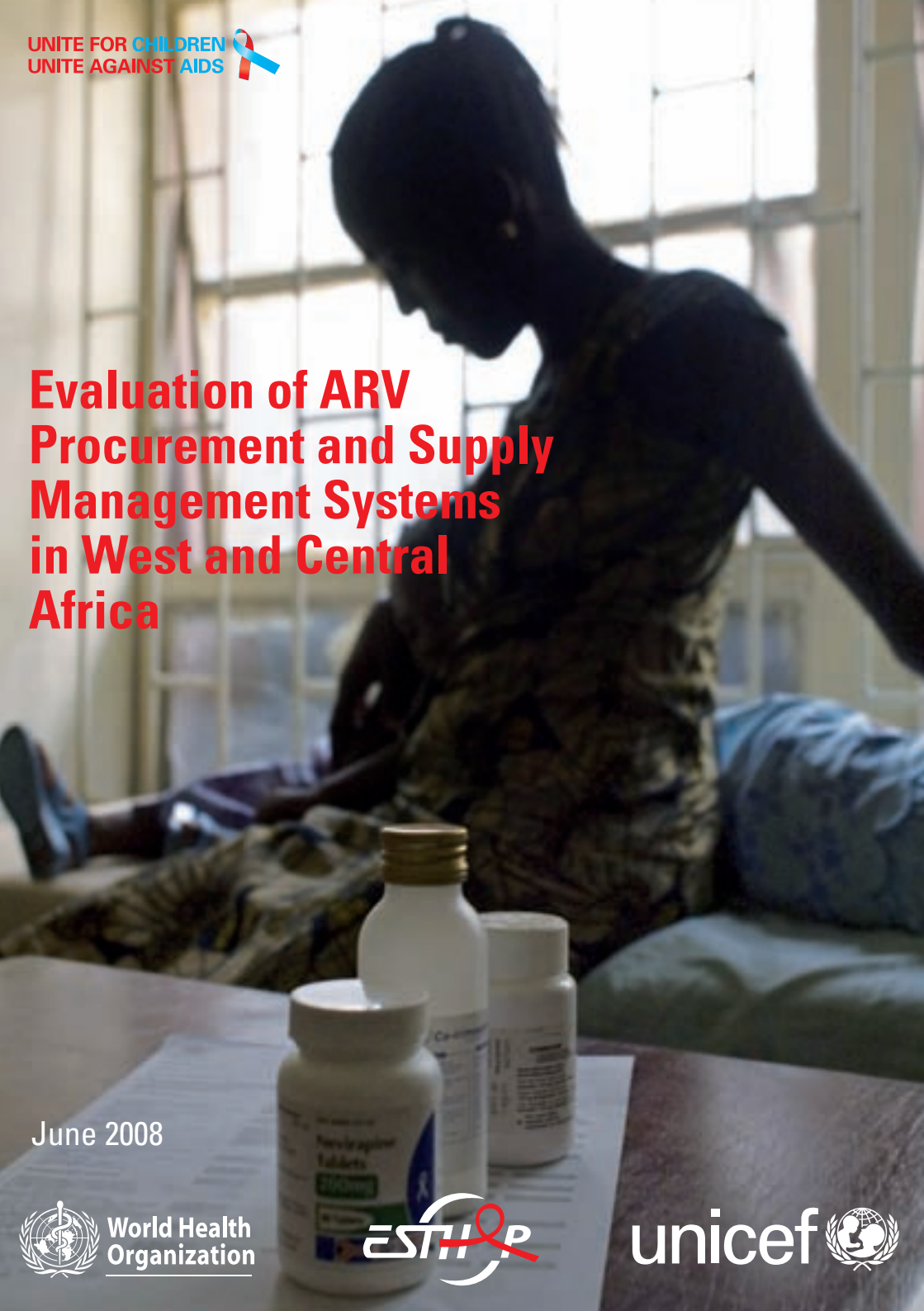

Evaluation of ARV Procurement and Supply Management Systems in West and Central Africa

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World Health Organization

ESTHER

unicef

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CONTENTS

LIST OF ACRONYMS

ACAME	Association des Centrales d'Achat de Médicaments Essentiels (Association of Essential Medicines Central Medical stores)
AMDS	AIDS Medicines and Diagnostics Service
ART	Antiretroviral Therapy
ARV	Antiretroviral Drug
CAMEG	Centrale d'Achat des Médicaments Essentiels (Essential Medicines Central Medical store)
DPL	Direction de la Pharmacie et des Laboratoires (Pharmacy and Laboratory Department)
DPM	Direction de la Pharmacie et du Médicament (Pharmacy and Medicine Department)
EMEA	European Medicine Agency
FDA	Food and Drug Administration
GDF	Global Drug Facility
GIP ESTHER	Groupement d'Intérêt Public : Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau
JSI	John Snow International
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
OI	Opportunistic Infection
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PLWA	People living with AIDS
PMTCT	Prevention of Mother To Child Transmission
PNLS	Programme National de Lutte contre le Sida (National Aids Control Programme)
PSM	Procurement and Supply Management
SCMS	Supply Chain Management System
TCM	Department of Technical Cooperation for Essential Drugs and Traditional Medicine
USAID	United States Agency for International Development

SUMMARY

The UNICEF Regional Office for West and Central Africa[1], in partnership with WHO (TCM[2], AMDS and the AFRO Office) and GIP ESTHER[3] undertook an assessment of Procurement and Supply Systems (PSM) for Antiretroviral (ARV) drugs, medicines for opportunistic infections (OI) and diagnostic means (reagents and other consumables)
The evaluation was sequenced in three phases: (i) review of documentation available on the issue in the 24 West and Central African countries covered by UNICEF (ii) field surveys, in sample countries and (iii) submission, discussion of results and development of proposals during a regional feedback workshop held in Dakar in April 2008.

Phase 1 : The literature review has helped to identify a number of interrelated constraints in the PSM issue commonly faced by almost all countries :(i) Recurrent stockouts in health facilities mainly due to inadequate forecasting and inadequate information flow between stakeholders, (ii) the high number of stakeholders involved working with complex and rigid scenarios (iii) inadequate consultation between donors and medical stores, (iv) fractioning of the supply cycle (v) the multiplicity and lack of flexibility in supply procedures. The analysis also revealed that the volume of information on PSM in documents reviewed was generally of very poor quality and was hardly useful to establish a typology of problems encountered. This is accounted for the fact that beyond topics addressed, the level of relevance of documents if highly variable, ranging from mission reports for a period under a week, conducted by one single person without using a confirmed working methodology, to cumbersome studies and evaluations conducted by pluridisciplinary teams over one month based on a validated methodology.

Phase 2 : The second Phase aims at conducting field surveys on a sample of 8 countries identified in Phase one (Benin, Burkina Faso, Cameroun, Central Africa Republic, Congo, Ivory Coast, Democratic Republic of Congo and Ghana) which account for 43% of the population, 48% of PLWAs and 58% of children affected by AIDS in the region. These field surveys are intended to collect and analyse in countries part of the sample information needed to review PSM systems for ARV drugs, medicines for OI and diagnostic means in the region.

Based on the literature review conducted during Phase 1, a survey questionnaire was developed to collect objective information on PSM issues. This questionnaire was tested in November 2007 in

[1] Benin, Burkina Faso, Cameroon, Cape Verde, CAR, Congo, Côte d'Ivoire, Gabon, the Gambia, Ghana, Guinea, Guinea Bissau, Equatorial Guinea, Liberia, Mali, Mauritania, Niger, Nigeria, DRC, Sao Tomé, Senegal, Sierra Leone, Chad and Togo.

[2] Department of Technical Cooperation for Essential Drugs and Traditional Medicine.

[3] Public Interest Group : « Ensemble pour une Solidarité Therapeutique Hospitalière En Réseau ».

Gabon and modified as needed. It is structured in four chapters and 17 mains sections : (i) 3 sections on general information on the context, (ii) 10 sections covering all aspects on procurement and management, (iii) 3 analytical sections (visits to three health facilities, description of the procurement and supply management cycle of ARVs and major weaknesses and disruptions in the procurement and supply management system and (iv) 1 section on resource persons contact details.

The survey methodology focused on three aspects : (i) Review of literature available based on documents submitted to consultants, (ii) completion of the survey questionnaire through working sessions and structured interviews with key individuals working in AIDS Committees or Programs, either in national organizations and institutions or from multilateral, bilateral organizations and institutions technically or financially involved in AIDS control activities and (iii) a visit in each country of 3 health facilities, where care, support & treatment are provided to PLWAs, to assess their level of functionality.

Data thus collected is analyzed in two respects: (i) Quantitatively concerning figures on various global domains (organization mode of the pharmaceutical sector, organization of disease management, price analysis, contribution by patients to the cost of treatment, etc. (ii) Qualitatively, concerning data related mainly to the review of the procurement and supply management cycle and information collected during visits to health facilities.

Major results highlighted by surveys are as follows:

- Resources mobilised vary considerably in terms of both the proportion of eligible patients among people living with HIV/AIDS who receive ARV treatment but also for the number of health facilities, the geographical distribution of such facilities and functionality of equipment for testing and immunological follow up of patients, especially in view of the low number of PCR machines available for early diagnosis in children.

- On regulatory aspects, all countries covered by the sample have passed legislations regulating the pharmaceutical policy, registration procedures and the list of essentials medicines including antiretroviral. However, the situation is much more contrasted with essential and generic medicines (EGM): only half of the countries have a fairly complete regulatory and legislative framework, including a set of texts promoting the use of generic medicines (promotion policies, specific registration policies for EGM, right of substitution and establishment of operational quality control laboratories adequately equipped to control the quality of ARVs.

- Purchase prices: Significant deviations are noted from one country to another: 1.20 for Didanosine 200 mg. 30 tab. (lowest price: 19.5 USD, highest price 23, 5 USD) to 2.96 for Abacavir 300 mg. 60 tab. (lowest price: 30, 5 USD, highest price 90, 5 USD). Such deviations seem to be related to supply modalities (land, air, sea) and purchase techniques used rather than to

the geographical situation of purchasing countries because the highest prices are not restricted to landlocked countries as would have been expected.

- Free treatment, testing, CD4 count and biological follow up are only enforced in one country. In all other countries, highly variable amounts are requested from patients for one of these expenditure lines and can reach for all cumulated expenses, an annual total exceeding 150$, which represents three months salary for the least skilled civil servant in Sub-Saharan countries.

- The analysis of the 9 activities which make up the PSM cycle (forecasting, procurement, monitoring of orders, reception of products, conformity checks, storage, quality control, settlement of suppliers' bills and distribution) shows that the number of players per funding source is high, ranging from 11 to 16. The number of players per type of activity ranges on average from 3.3 (1-8) for estimation of needs to 0.5 (0-2) for quality control. This multiplicity of funding sources and actors generates additional costs without any technical or logistical counterpart and makes the issue more complex.

- The outcome of visits conducted in 24 health facilities in the 8 countries globally shows quite poor situations in some aspects : storage conditions are not satisfactory, stock managers are not sufficiently trained, management tools, even basic ones (stock cards) are not systematically used, along with non systematic supervision. However, availability rates are satisfactory, even though all centres report stockouts during the period before surveys are conducted.

The analysis points to 4 recurrent difficulties faced by all countries:

- Lack of reliability in quantifying needs
This is the major problem of the procurement chain and the first cause of stockouts or drug expiry. It has several cumulative origins : the difficulties encountered by the staff of the health facilities in correctly counting the number of patients per protocol or molecule, omissions in those health facilities to report on patients loss to follow up or on newly enrolled ones, reports of new patients on the basis of the percentage of the objectives of the care and not on the reality, and the forecasting technique based on the epidemiological profile and not on the real consumption.

- The multiplicity of stakeholders in the procurement chain and fragmentation of its essential functions (estimation of needs, procurement and monitoring, management of orders placed with suppliers and drugs warehousing) among all these stakeholders are factors affecting the efficiency of the procurement function. In such scenarios, information flows bottom up ; thus, central medical stores regularly report on their activities but they are not informed in return about suppliers programming or delivery dates or corresponding quantities, which may seriously affect their operations and demotivate their intervention.

- Many difficulties identified result from incompatibility between, on the one hand, inadequately expressed demand owing to its dynamic nature due to constant variation in the number of patients, non compliance with therapeutic protocols and lack of forecast reliability, and on the other hand, enforcement of procurement techniques poorly adapted to

demand specificities : sometimes insufficiently informed operators with poor knowledge of both the issues related to HIV/AIDS and procurement, too lengthy and inflexible procurement procedures with suppliers being slow in responding.

- Frequent stockouts sometimes generated by lack of flexibility of procurement procedures adopted at central level and in health facilities though disruptions in the supply channels, delayed or under-estimated orders and various management constraints ; no satisfactory and sustainable response has yet been found. Emergency stocks positioned in some countries in the region are under used resulting in stockouts of some drugs, which preclude health care providers to abide by the national protocols; the consequences are drug resistance or lower effectiveness of the treatments.

- In many countries, forecasting, ordering and receiving of ARVs drugs, OI medicines and diagnostic means are conducted by national AIDS programmes without the involvement of central medical stores or authorized operators. They latter know of the existence of drugs and materials only when they are already warehoused.

The general lesson to be drawn from this evaluation exercise is that, in view of the complexity of the PSM issue within developing countries where difficulties of all kinds accumulate, calling for appropriate and flexible responses, existing systems responsible for ensuring efficient drugs procurement and diagnostic means are too vertical, hierarchical, too rigid, not efficient, which negatively impacts on the efficient use of funds committed.

Therefore, it is important and urgent to improve the efficiency of the PSM system to meet the challenge of scaling up HIV/AIDS care support and treatment programmes.

WARNING

The term «evaluation» should not be understood in this context in its usual acceptation, as an approach using a specific methodology and intended to give a value judgement on a given situation using indicators. The purpose is therefore not to judge the specific situation of the Procurement and Supply Management issue (PSM) in countries where surveys were conducted or to perform an in-depth analysis of the process. We rather intend to perform an assessment to identify jointly with countries involved major recurrent or systemic difficulties, to determine causes and suggest and implement at regional level, coordinated and adapted responses in the next years.

1 BACKGROUND TO THE EVALUATION CONTEXT

Initially commissioned by the UNICEF West and Central Africa Regional Office, the evaluation of Procurement and Supply Systems (PSM) for Antiretroviral drugs (ARV) for opportunistic infections (OI) and diagnosis equipments was finally conducted through a formalized partnership between WHO (initially the TCM Department joined later on by AMDS and the AFRO) and the GIP ESTHER.

The idea of conducting this tripartite evaluation was justified for two major reasons : the WHO TCM Department had commited since 2007 in several countries of the AFRO region to «launch an in-depth evaluation of the procurement and supply management chain in essential medicines in the public sector» ; in this context, collaboration between UNICEF and WHO seemed therefore relevant because these two UN agencies have always entered into technical cooperation and it was necessary to coordinate their interventions to avoid duplication and generate synergy. On the other hand, GIP ESTHER was since a recent time involved (in 6 of the 8 countries surveyed) in the analysis of the PSM issue, the objective being to improve access to quality treatment.

The evaluation is sequenced in three phases : (i) review of documentation available in WCAR on the issue (ii) field surveys, in a sample of 8 countries selected based on specific criteria and on the analysis of survey questionnaires and (iii) submission and discussion of results and development of recommendations during a feedback workshop held in Dakar in April 2008 with the attendance from partners (donors and operators) representatives of programmes, national departments and projects involved in HIV/AIDS control in this geographical area.

2 ACTVITIES CONDUCTED DURING PHASE 1 OF THE EVALUATION PROCESS

Three main activities were conducted (ref. Report of Phase 1[4] , which this report completes)

2.1 Interviews with officers from institutions and organizations involved in HIV/AIDS interventions

These interviews were intended to introduce to these institutions and organizations the evaluation process (objectives, methodology and expected outcomes), to collect additional information and to suggest them to collaborate in the process in order to broaden the initial partnership and create a sustainable trend.

Interviews were conducted with officers in charge in the following bodies : The French Foreign Ministry, DGCID-DPDEV[5], the Ministry of Foreign Affairs (Paris), The Global Fund Secretariat (Geneva), Supply Chain Management System (Geneva), WHO AMDS (Geneva) and the UNITAID Secretariat (Geneva).

Generally, people met were quite enthusiastic about the evaluation process because they believe that better knowledge of PSM systems for procuring medicines and diagnosis tests as well as disruptions faced by operators on site will contribute to improve the efficiency of current and future initiatives and operations. On the other hand, the evaluation process would facilitate consultation between donors and operators and thus improve the visibility of initaitives and operations in the HIV/AIDS sector in Africa (which is quite weak now) at the end of the process.

2.2 Literature Review

a. Major Findings

This has helped to identify a number of often inter-related constraints in the PSM issue common to almost all countries. The following can be highlighted :

- Frequent stockouts are noted in health facilities, their causes being multiple. Among these, two are recurrent : (i) difficulties encountered by national programmes in assessing their needs, with adequate estimation of margins. This is due to lack of an actual information management system on consumption patterns and on care to be provided to new patients [26, 27, 36, 47][6] and (ii) the very low level of feedback from health facilities to entities responsible for procurement [11, 32, 39]. However, situations encountered are not all similar. In Burkina Faso, CAMEG has identified original solutions to address stockout problems [6, 7] : anticipation of donor authorization to place orders from suppliers[7], stock swaps in dispensation centres when drugs are three months away from expiry, permanent consultation with

[4] Phase 1 report includes: A summary of documents reviewed (annex 1), score cards 2), Terms of reference of consultants recruited to conduct Phase II surveys (annex 3) and the questionnaire used for data collection in countries covered (annex 4).

[5] Direction des Politiques de Développement.

[6] Numbers in brackets refer to bibliographical references at the end of the report.

[7] The World Bank and other donors: A « non objection » notice is required before orders are placed from suppliers, whose delivery time can sometimes take months.

prescriptors, regular stock monitoring. This mechanism has significantly contributed to reduce the number of stockouts. Other medical stores have also witnessed a reduction in the frequency of stockouts (such as the Côte d'Ivoire Public Health Pharmacy in 2006 [16]).

- The number of players in the PSM cycle (donors, national programmes and operators) is very high in some countries; organizational mechanisms are numerous, complex and not always rational, while communication, information sharing and consultation amongst them is poor; if not non-existent [8, 40].
- Donors are not aware, or they underestimate the financial costs and workload generated by their support, which heavily impacts on medical stores' operations.
- Underestimation by donors of tasks to be accomplished in the countries within the PSM process.
- Multiplicity of programmes and procedures, hence the need for various partners involved to harmonize their administrative procedures to facilitate programme implementation

b. Limitations of the literature review

This literature review revealed that the volume of information on PSM contained in the documents reviewed was generally low and hardly useful to allow rigorous assessment of PSM systems: in some cases, they are just brief and incomplete descriptions and the six crucial components in the procurement and supply management chain (forecasting, funding, supply, stock management, distribution and quality assurance system) are not systematically addressed. Therefore, it is difficult, if not impossible, to develop a typology of constraints. At most, it may be possible to state that in 4 countries (Burkina Faso, Côte d'Ivoire, Ghana and Senegal) difficulties encountered are less important and that achievements in terms of numbers of patients under care and attainment of objectives are better than in other countries. This is accounted for the fact that beyond topics addressed, the level of relevance of documents if highly variable, ranging from mission reports for a period under a week, conducted by one single person without using a confirmed working methodology, to cumbersome studies and evaluations conducted by pluridisciplina. This is accounted for the fact that beyond topics addressed, the level of relevance of documents is highly variable, ranging from mission reports for a period under a week, conducted by one single person without using a confirmed working methodology, to cumbersome studies and evaluations conducted by pluridisciplinary teams over one month based on a validated methodology (all of them conducted by large US agencies (MSH, JSI/DELIVER and Tulane University).

The volume of documentation available is only significant for 5 countries, which together detain half of documents compiled. This absolute lack of documents for such a critical issue as the PSM supply chain, which determines to a large extent access to cheap and quality treatment, seems to point to some lack of communication between partners, operators and national institutions involved in HIV/AIDS control interventions. This is a barrier to information sharing.

2.3 Phase 1 closing meeting

After this first evaluation phase, a meeting was held at WHO Headquarters in Geneva in October 2007 with the following objectives: (i) presentation of the preliminary report of phase 1 and review of its content, (ii) identification of countries to be surveyed during phase 2 of the evaluation, (iii) finalization of the methodology to be used during phase 2 and, (iv) adoption of an implementation timeline.

3 PHASE 2 : FIELD SURVEY

3.1 Reminder of PHASE II terms of reference

The second Phase aims at conducting field surveys on a sample of 8 countries identified during Phase one. These field surveys are intended to collect in countries the information needed to review PSM systems for ARVs, OI and diagnostic tests, to analyse data collected and to produce an assessment.

3.2 General methodology

Surveys were conducted in 8 countries: Benin, Burkina Faso, Cameroon, Central African Republic, Côte d'Ivoire, Congo, Ghana and Democratic Republic of Congo[8].

a. Justification for the selection of countries

The sample was selected based on three major criteria: (i) avoid duplication of similar activities already implemented in the field within the evaluation currently being conducted by WHO AFRO and WHO/TCM Department; (ii) take into account the level of advancement of country programmes and (iii) give priority to countries with the highest prevalence rates.

These 8 countries account for 43% of total population, 48% of PLWAs and 58% of AIDS orphans[9].

b. Conduct of surveys

Surveys were conducted by a team of 4 consultants during short term missions[10] in January and February 2008. Consultants also benefited from technical and logistical support by UNICEF offices in the 8 countries and by ESTHER project coordinators in 6 countries (Benin, Burkina Faso, Côte d'Ivoire, Cameroon, Central African Republic and Ghana).

[8] Despite the importance of its population (131 millions inhabitants, of which 3 millions living with HIV/AIDS), Nigeria was not included for three reasons : JSI/Deliver is currently conducting a study on PSM, PMTCT program is being reviewed and some elements are already available.

[9] Report on the Aids global epidemy, Special issues, 10th UNAIDS Anniversary. Geneva 2006.

[10] 10 days per country, or two calendar weeks.

c. Survey methodology

The survey methodology focused on three aspects:

- Review of literature available based on documents submitted to consultants completed by those collected on site.
- Working sessions and structured interviews with key individuals working in AIDS Committees or Programs, either in national organizations and institutions or from multilateral, bilateral organizations and institutions technically or financially involved in AIDS control activities and (with key individuals in AIDS control entities and working, depending on countries, either for national organizations and institutions (Ministry of Health, ministry in charge of AIDS control, central medical stores, national AIDS Council, Pharmacy department, Ministry of Trade, Quality control National Laboratory, a few health facilities providing ART) or for multilateral or bilateral organizations and institutions technically or financially involved in AIDS control activities (World Bank, Global Fund, WHO, UNICEF, UNAIDS, UNFPA, UNDP, JSInc/DELIVER, GIP ESTHER, Clinton Foundation, European Union, MSF, West African Heath Organization, bilateral cooperation services and health projects, etc.).
- Visit in each country to three health facilities providing ART to determine whether or not there are discrepancies between information collected at central level during working sessions and the field reality, which is often more prosaic.

d. Survey questionnaires

Based on the literature review conducted during Phase 1, a survey questionnaire was developed to collect objective information on PSM issues. It is structured as follows:

- 3 sections on general information: (i) population, economic and epidemiological data, (ii) ARV purchase price and, (iii) financial contribution of patients to the cost of treatment.
- 10 sections covering all aspects on PSM : (i) mode of organization of the pharmaceutical sector, (ii) organisation of AIDS control interventions, (iii) patient management programme (iv) customs and taxes, (v) supply cycle, (vi) purchase modalities, (vii) bulk purchase, (viii) forecasted financial flows, (ix) distribution of funding and (x) activities funded per source of funding.
- 3 analytical sections: (i) visit to three health facilities, (ii) description of the procurement and supply of ARVs, OI, reagents and tests and (iii) major loopholes and disruptions identified in the PSM chain.
- 1 information section: contact details of people appointed as focal point or resource person.

The review of all these domains should contribute to provide adequate feedback to countries concerned.

e. Material, method and limitations of the study

Information discussed in this chapter is first of all derived from the processing of questionnaires used during field surveys. However, in some cases, they were completed by data gathered during interviews with professionals involved in AIDS control interventions in countries surveyed and also from the content of presentations made during interventions by the Global Fund and UNITAID, during the «Seminar on National Pharmaceutical Policies» held by WHO in Geneva from 10 to 14 March 2008.

Such data were processed under two prospects:

- Quantitatively concerning figures on various domains: mode of organization of the pharmaceutical sector, organization of disease management, price analysis, contribution by patients to the cost of treatment, etc.
- Qualitatively, concerning data related mainly to the review of the procurement and supply cycle and information collected during visits to care centres.

Finally, as field surveys conducted in one round were of a declarative nature (ref. supra chapter § 3.2b and c), information thus collected may not always truthfully reflect the reality of situations in the field. Each country was thus asked, after the feedback workshop, to validate their data and to correct apparently erroneous ones. If that is the case, corrective measures recommended were mainstreamed and the related tables bear: «Corrected data».

3.3 General findings

a. The existence of efficient procurement and supply systems is a prerequisite to cover increased number of patients.

Between 2001 and 2005, HIV/AIDS programs in Sub-Saharan Africa has markedly amplified and the number of patients under ARV in low or middle-income countries have been multiplied by over 5, increasing from 240,000 to 1.3 million. Over the same period, in Sub-Saharan Africa, the reported number of PLWAs under ARV treatment was multiplied by 16, going from 50,000 to about 800, 000[11].

In the 8 countries surveyed, significant achievements were made to broaden access to treatment. It should be noted that the situation has changed quite quickly though in a disparate manner: between 2004 and 2007, the reported number of PLWAs under ARV treatment was multiplied by 5 or 6 and even more in countries least advanced in this area such as Congo and Central African Republic (Table 1).

National AIDS programmes forecasts indicate that the number of women who will benefit from prophylactic treatment within PMTCT programmes by 2010 will have at least doubled and has been most often multiplied by four or five[12].

[11] Report on the Aids global epidemics, Special issues, 10th UNAIDS Anniversary. Geneva 2006 . Page 170.

[12] Except Benin and Ghana, values noted in the 2007 survey are all below (variations range from -4% to -46%) those in the joint UNICEF, UNAIDS and WHO report published in 2006 : « Children and AIDS : second stocktaking report, action and progress » pages 39 and other pages. (Table 1)

The same applies to the expected increase in the number of children to be provided with treatment[13].
As concerns mobilization of leadership and advocacy for universal access[14], these trends will continue and intensify within the scaling up process and will result in a proportional increase in quantities and volumes of ARV and OI medicine and diagnosis tests.

a. Table 1 : Evolution of adults and children HIV positive receiving ART (% represent the proportion of PLWAs under ARV compared to the total number of PLWAs)

	PLWAs under ARV				Pregnant women receiving Arv to reduce the risk of Mother-to-child transmission			Children under ARV		
	2004		2007		2007	2010	Δ	2007	2010	Δ
	Nb.	%	Nb.	%						
Benin	1 500	1,3%	9 768	11,2%	3 447	7 057	2,0	667	2 500	3,7
Burkina Faso	3 200	6,9%	15 417	10,3%	1 380	n.a.		629	n.a.	
Cameroon	9 000	5,1%	45 605	8,9%	6 263	28 800	4,6	1 700	n.a.	
Centrafrique	200	0,4%	8 300	3,3%	1 857	3 750	2,0	731	1 300	1,8
Congo	350	1,8%	7 426	6,2%	175	n.a.		n.a.	n.a.	
Côte d'Ivoire	3 500	2,0%	21 907	2,9%	1 890	3 010	1,6	2 531	6 272	2,5
Ghana	n.a.	n.a.	11 065	3,5%	109 334	297 000	2,7	769	2 700	3,5
RDC	n.a.	n.a.	17 161	1,7%		3 435	n.a.	n.a.	n.a.	

Sources : ReMeD-ESTHER Survey(2004) ; PSM Survey (2007 et 2010)

Efficient and sustainable procurement and supply systems will then be needed to improve both the quality of care and efficiency of funds pledged in view of the increase of the number of patients under ARV. In its annual report[15], UNAIDS underlines that though the unprecedented increase of the level of Aids funding is a new opportunity, all players should in turn commit to launch a coherent response aligned on efforts deployed and led by countries.

b. The current mode of organization of the supply chain cannot accommodate scaling up care for patients

The increase in the number of patients on ART for is mainly accounted for by the availability of new funding which strongly contributed to increase the volume of resources mobilized.
However, such increase often came as an addition to existing parallel financial systems but also through overlapping of

[13] As for the number of children under ARV treatment, values noted in the 2007 survey are coherent (ranging from 8 % for Burkina Faso to 530 % for Ghana) with those in the joint UNICEF, UNAIDS and WHO report published in 2006 : « Children and AIDS : second stocktaking report, action and progress » pages 39 and other pages. Ref. Comparative table appended

[14] Declaration of Commitment on HIV/AIDS signed in June 2001 by Heads of State and Representatives of Governments at the United Nations General Assembly Special Session dedicated to HIV/AIDS, reaffirmed in New York in 2006 in the Final Declaration of the General Assembly High Level Meeting on AIDS. Making the Money Work. UNAIDS, Geneva 2007. Page 57

[15] Ibid. footnote 14.

new funding and procurement sources practically working in isolation, without any coordination with national budgets and operators, which leads to an increasingly complex and less and less transparent.

Additional funding was not always accompanied by prior evaluations to highlight the complexity of the supply cycle, specifically some of its components: estimation of needs, capacity and warehousing conditions especially in health facilities, distribution, monitoring of supplier orders, quality control and feedback from the periphery to the central decision-making level.

This situation led sometimes at central level but particularly at peripheral level within health facilities stock levels poorly correlated with the needs, which leads either to stockouts or expiration of overstocks. This in turn translates into the interruption of treatments with the related risk of pharmaco-resistance.

3.4 Survey results

a. The general context of HIV/AIDS control

Resources mobilized

Resources mobilized vary considerably according to countries in terms of both the proportion of eligible patients receiving treatment, the number of health facilities (testing, care and PMTCT centres), distribution of such facilities (central and periphery level) and functional equipment for immunological monitoring of patients (Table 2).

As for the proportion of PLWAs receiving ARV treatment out of the total number of PLWAs, three categories of countries exist : (i),countries with an average 10% : Benin 11%, Burkina Faso 10% and Cameroon 9%, (ii) another group where this proportion is half of the first group : CAR 6% and Congo 6% and, (iii) a third group where the proportion is equal or below 3% : Côte d'Ivoire 3%, Ghana 3% and DRC 2%.
The proportion of health facilities providing testing, treatment and PMTCT in the periphery (outside the capital city and in important towns) gives an order of magnitude of the level of decentralization of such activities at national level. Once again, large gaps are noted from one country to another with fairly comparable gradients : 16% to 97% for screening centres, 39% to 100% for care centres and 16% to 97% for PMTCT. Mean values (53%, 58% and 58% respectively) if data are accurate[16] reflect that decentralization is actually a reality except perhaps in the case of Côte d'Ivoire where the mean value of the three indicators is 28%. However, these high percentages are due to the little number of health facilities surveyed (Table 2)

The ratio of patients receiving ARV treatment per health facility is more homogeneous, to the exception of extreme values : Cameroon : 461, Ghana: 122 and DRC : 103 (for these two countries, these low figures are due to the low proportion of PLWA receiving treatment); in the other two countries, the high figures are close to the median value (210).

[16] Value noted in Ghana are indeed surprising (87% to 97%) and should be validated by the National Aids Committee.

Equipments (CD4 counting equipment and PCR machines[17]) are generally inadequate. The ratios $\frac{\text{Nb. equipments}}{\text{Nb. patients}}$ for CD4 counting machines vary significantly from one country to another : from 1 (Ghana : 138) to 12 (CAR: 1 660). The number of PCR is obviously inadequate (from 0 in Benin to 5 in Burkina Faso and Cameroon) considering its role in early screening of young children[18].

Table 2 : Resources mobilized for HIV/AIDS programs

	Benin	Burkina Faso	Cameroon	CAR	Congo	Côte d'Ivoire	Ghana	DRC	Mean (%) or medians
PLWAs (x 1 000)	87	150	510	146	133	750	320	1 000	
Nbr.of patients under ART (x 1000)	9,8	17,3	45,6	8,3	7,4	21,9	11,1	17,2	
Nbr. of patients under ART in % of Nbr, of PLWASs	11%	12%	9%	6%	6%	3%	3%	2%	4%
% of health facilities providing HIV testing in the periphery	35%	33%	16%	86%	80%	22%	97%	n.a.	53%
Nbr.of PLWAs under treatment per testing centre	935	1 240	461	6 636	2 463	5 102	760	5 988	1 851
% of health facilities providing ART in the periphery	72%	70%	100%	50%	79%	39%	87%	n.a.	58%
Nbr.of PLWAs per health facility	208	228	411	208	265	213	122	103	210
Number of health facilities providing ARVs for PMTCT in the periphery	183	55	700	62	28	147	407	296	
% of health facilities providing ARVs for PMTCT in the periphery	19%	91%	16%	65%	79%	22%	97%	79%	58%
Nbr of patients under ARV per CD4 machine	376	444	894	1 660	530	487	138	n.a.	487
Nbr. of PCR machines	0	5	5	1	2	4	2	3	3

PLWA = people living with AIDS. ART =Antiretroviral Treatmentl
Sources : PSM Survey (corrected data) except PLWAs (UNAIDS 2006)

The pharmaceutical sector regulatory and legislative framework

Since the 90s, strengthening the regulatory and legislative frameworks of the pharmaceutical sector in West and Central Sub-Saharan Africa has been one of the priorities of development partners specifically through a tripartite partnership involving WHO (Essential Medicines Department), the European Union (DG VIII) and French Cooperation, with technical and financial support provided to central medical stores. Such support was necessary to resume activities in health facilities especially primary health care

[17] PCR technique can detect faster HIV infection (allowing then a better efficiency of treatments) than rapid tests. PCR technique is the most appropriate technique for the diagnosis of infants and young children (in: AIDS.ORG: http://www.aids.org/atn/a-060-07.html).

[18] The availability of PCR machine does not mean that routine early diagnostic for infants and young child is conducted. Indeed, an article published in the Bulletin of the World Health Organization 2008 ; 86 : 155–160 ("Optimizing pediatric HIV care in Kenya: challenges in early infant diagnosis"), report than even if 4 research centers had the capacity to do early infant diagnostic of HIV through PCR, these PCR machines were just used for research and not as a global practice.

centres in districts and regularly supply health facilities at all levels with quality generic drugs at affordable cost within the Bamako Initiative or through cost recovery mechanisms.

The survey reveals highly contrasting situations (Table 3). Even though most countries have passed texts regulating the pharmaceutical policy[19], registration procedures and the list of essential drugs including ARVs[20], the situation is much more contrasted for generic drugs There is a clear distinction between two groups of countries :

Table 3 : The pharmaceutical regulatory framework

	Benin	Burkina Faso	Cameroon	CAR	Congo	Côte d'Ivoire	Ghana	DRC
Texts regulating the pharmaceutical sector	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Pharmaceutical policy document	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Medicines registration procedures	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
National essential medicines list	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Date last updated	n.a.	2007	2007	2007	n.a	2007	2004	2007
Does it include ARVs	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Esential medicines Promotion policy	Yes	Yes	Yes	No	No	Yes	Yes	No
Procedures for specific registration of EMs	Yes	Yes	Yes	No	n.a.	No	Yes	No
Right of Substitution	Yes	Yes	Yes	n.a.	No	Yes	n.a.	No
Operational quality control laboratory	Yes	Yes	Yes	No	No	Yes	Yes	No
Can ARVs be controlled there	Yes	Yes	Yes	No	No	No	Yes	
The country has signed agreements on TRIPS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
When	1996	n.a.	2000	n.a.	n.a.	n.a.	2005	n.a.
The country has signed agreements on FTAs	No	No	No	No	Yes	Yes	Yes	n.a.
When			On-going		n.a.	n.a.	n.a.	
Percentage of "Yes"I	92%	92%	92%	50%	50%	75%	92%	50%

ARV = Antiretroviral drugs. GEM =Generic essential medicines. TRIPS =Trade-related Intellectual property rights issues.
FTA = Free Trade Agreement.
Source : PSM Survey (2007)

- Benin, Burkina Faso, Cameroon, Ghana and to lesser extent Côte d'Ivoire, which have a fairly comprehensive regulatory and legislative framework including a set of texts favourable to the use of generic drugs: policy for the promotion of generic drugs, specific registration procedures for generic drugs, existence of a substitution right and existence of operational quality control laboratories with advanced equipment to perform quality control. However, for reasons not elucidated during the survey, it seems that such

[19] Except Côte d'Ivoire, which is elaborating the document.

[20] This does not mean that they are realizing these controls.

laboratories are not used in Benin[21], Burkina Faso[22], Côte d'Ivoire and Ghana[23].

- In CAR, Congo and DRC where the regulatory supervision is minimal and where there is no policy for the promotion of generic drugs, surveys indicate that the absence of specific registration procedures, neither substitution right nor operational national quality control laboratories.

These frameworks regulating the pharmaceutical sector are not enough per se because documents must be relevant in relation to the issue. Several reports reviewed during phase 1 of the evaluation reveal that some existing texts do not provide satisfactory solutions to bottlenecks identified. Thus, by way of illustration, in DRC one report [37] recommends in on the one hand the revision of texts (decree creating PNMLS[24], ministerial decision creating PNLS/IST[25]) to clarify the roles and responsibilities of such organs and, on the other the revision of a decree on regulation of imports, supply and use of ARVs. Another report [7] recommends the modification of the text on the mode of organization of Regional Health Divisions in order to specify their role in the management of ARVs.

Lastly, even when these frameworks regulating the pharmaceutical sector exist and are coherent, they are not always followed. Indeed, it came out of the survey questionnaire that more often and for emergency reasons, partners do not always follow national regulation for the importation of medicines and diagnostic means.

ARV purchase price

The price analysis[26] from a sample of most commonly used drugs highlight significant heterogeneity (Table 4).

Mean deviations[27] range from 1.20 for Didanosine 200 mg. 30 tab. (lowest price : 19.5 USD, highest price 23, 5 USD) to 2.96 for Abacavir 300 mg. 60 tab. (lowest price : 30,5 USD, highest price 90,5 USD).

Four other medicines show price deviations above 2.00 : Stavudine 30 mg. 60 tab. (deviation : 2.92 ; lowest price : 1.69 USD, highest price 4.92 USD), Lamivudine 150 mg. 60 tab. (deviation :

[21] The consultant reported that the National Laboratory for Quality Control does not routinely undertake quality control of ARVs, however quality control of ARVs is done during the ARV registration process.

[22] The LNSP (Laboratoire National de Santé Publique) is functional and is equipped with all analytical equipment required (HPLC, Spectrophotometer UV-visible and IR, Dissolutests, etc.). There is an inter-ministry Decree regulating the quality control and the surveillance of imported medicines (Systematic control). However, ARV quality control is not done as LNSP can not procure all referenced products.

[23] Reportedly, the main problem is one of laboratory capacity: lack of space, staff, irregular water and electricity supply (It is to be transferred in new buildings in 2008). In practice, ARVs are procured from viable sources (prequalified by OMS), to mitigate quality risks.

[24] National Multisectoral AIDS Control Programme.

[25] National Program for HIV/ AIDS and Sexually Transmitted Infections Control

[26] Different INCOTERMS prices were collected with the questionnaire (mainly CIF or CIP). These prices have been recalculated in INCOTERM DDP, adding clearance and taxes and local transaction, depending on each case. All these DDP prices have been changed to USD (1 USD= 435 FCFA)

[27] $\frac{\text{Max Price}}{\text{Min Price}}$

2.88 ; lowest price : 3.72 USD, highest price 9.44 USD), Nevirapine 200 mg. 60 tab. (deviation : 2.74 ; lowest price : 3.77 USD, highest price 10.33 USD) and Zidovudine 300 mg. 60 tab. (deviation : 2.51 ; lowest price : 8.82 USD, highest price 22.14 USD).

These deviations reveal delivery modalities (land, air, sea) and purchase techniques used, rather than the purchasing country's geographical location, specifically their landlockedness which generates additional costs, as confirmed by survey reports. Thus, in the landlocked CAR[28], three drugs can be found with the lowest price in the sample analyzed: Zidovudine 300 mg. 60 tab., Didanosine 200 mg. 30 tab. and Didanosine 400 mg. 30 tab. 2 other drugs present some deviation compared to the lowest price, equal or below 5% : Nevirapine 200 mg. 60 tab. (deviation : 1.04) and the combination of D4T/3TC/NPV, 30 mg. /150 mg. /200 mg., 60 tab. (deviation 1.05). Inversely, Congo and, to a lesser extent DRC, both coastal countries present the highest mean price deviation, 1.92 and 1.90 respectively. This brief analysis reveals that deviations occur where they should not happen.

Comparison of these prices with those on the Clinton Foundation website[29],

Table 4 : DDP ARV purchase price- Adult dosage (index 1.00 for the least highest price)

Nom	Dosage	Pack.	Benin		BF	Cameroon	CAR	Congo	RCI	Ghana	DRC	
EFZ	600 mg	30 cp	1,92	1,08	1,31	1,01	1,37	1,91	2,27	1,00		2,27
EFZ	200 mg	90 cp				1,24	1,54			1,00		1,54
NVP	200 mg	60 cp	1,84		1,38	1,06	1,04	2,74	1,00	1,02	1,51	2,74
ABC	300 mg	60 cp	2,55	1,02	1,29		2,54	1,65	1,00	1,35	2,96	2,96
DdI	250 mg	30 cp			1,20		1,00			1,04		1,20
DdI	200 mg	60 cp		1,00		1,48			1,32	1,24	1,48	1,48
DdI	400 mg	30 gel					1,00	1,32		1,04		1,32
3TC	150 mg	60 cp			1,14	1,20		2,88	1,32	1,00	1,57	2,88
d4T	30 mg	60 cp					1,48	1,91	1,00	1,20	2,92	2,92
AZT	300 mg	60 cp		1,09	1,13	1,10	1,00	2,51	2,19		1,27	2,51
AZT/3TC	300+150	60cp	1,00		1,23	1,06	1,25	1,42	1,05	1,07	1,50	1,50
d4T/3TC	30+150	60cp	1,00		1,35	1,20	1,09	1,42			2,11	2,11
d4T/3TC/NPV	30+150+200	60cp	1,00		1,26	1,04	1,05				1,74	1,74
Cotrimoxazole	480 mg	1000 cp	1,03	1,05		1,00		1,48	1,81			1,81
Mean value			1,48	1,05	1,26	1,14	1,30	1,92	1,44	1,10	1,90	

Source : PSM Survey

[28] For CAR, low prices noted are kinked to the fact that drugs arrived mainly by sea and were then forwarded by road (lead time : 18 months and reception of products at almost expiry date), unlike in other countries where air cargo was used.

[29] http://www.clintonfoundation.org/pdf/chai-arv-price-list-050807.pdf (document not updated consulted in July and December 2007). As the INCOTERM is not mentioned in this list, comparisons should be taken with cautious.

shows that 4 products were brought at prices lower than those proposed by the Clinton Foundation : Stavudine 30 mg 60 tab. (-44% ; 1.69 USD vs 3.00 USD) ; the combination D4T/3TC/NPV 30 mg./150 mg./200 mg., 60 (-33% ; 7,25 USD vs 10,80 USD) ; the combination AZT/3TC 300 mg./150 mg. 60 tab. (-7% ; 9,97 USD vs 10,75 USD) ; Didanosine 250 mg. 30 tab. (- 6% ; 19,48 USD vs 20,65 USD). Finally, the lowest price for Nevirapine 200 mg. 60 tab. is almost similar to that of the Clinton Foundation (+ 1%; 3,77 USD vs. 3,75 USD).

The same analysis conducted on paediatric dosages gives similar results.

Contribution of patients to cost of treatment

Free treatment, testing, CD4 count and biological follow up are only enforced in Benin. In all other countries, variable amounts are requested from patients for one of these expenditure lines (Table 5)

Amounts requested from patients for treatment or laboratory testing are on the one hand extremely variable from one country to another : the highest ratio for the same category is above 4.5 (23USD for CD4 count in Cameroon vs. 5 USD in DRC), and on the other hand, higher in view of the capacity of many patients to pay: 4.5 USD for 1st or 2nd line treatment to 23 USD for CD4 count in Cameroon.

Amounts requested from patients do not seem to be correlated with the level of income of populations :

- In Burkina Faso, patients pay monthly contributions for treatment and bi-annual contribution for CD4 count and biological follow up. Thus, the annual contribution from a patient is 160 USD[30] which is roughly three months salary for the least skilled civil servant and more than twice annual total expenditures of the poorest individuals which account for 50% of the population[31].
- In Cameroon where average income is a bit higher and where only laboratory tests are charged, the amount paid (60 USD) is about three times lower than that of Burkina Faso and represents three month income for the quintile of the poorest populations living in Yaoundé[32].

Such significant disparities between the level of contributions requested and the capacity of patients to pay is certainly one explanation for patients who never turned out again.

Financial ratios

Data collected were often incomplete and should therefore used with much care. This is due to partitioned management of funds to control HIV/AIDS as they are separately and autonomously managed by each donor, lack of centralization within a national entity (AIDS Control

[30] Equivalent to CFA F 70, 000 at the following exchange rate/ 1$ = CFA F 435.

[31] Poverty profile and evolution in Burkina Faso. INSD. Ouagadougou. March 2000.

[32] Household expenditure survey in Douala and Yaoundé (edm2000). National Statistics and Accounts Department. December 2001

Table 5 : Financial participation by patients to cost of treatment (monthly amounts in USD – The letter « G » means free treatment and laboratory testing)

	1st Line Treatment		2nd Line Treatment		Testing		CD4 count		monitoring	
	Adults	Children	Adults	Children	Adults	Children	Adults	Children	Adults	Children
Benin	G	G	G	G	G	G	G	G	G	G
Burkina Faso (a)	11	G	11	G	1	G	7	G	7	G
Cameroon	G	G	G	G	1	1	23	23	7	7
CAR (b)	G à 4,5	G à 4,5	G	G						
Congo	G	G	G	G	2,3	2,3	11	11	G	G
Côte d'Ivoire	7	7	G	G	G	G	G	G	G	G
Ghana	5	5	5	5						
DRC	G	G	G	G			5	5		

Notes : (a) Burkina Faso is considering to reduce fees to 3,5 USD but that decision is yet to be enforced, (b) There are in CAR two categories of patients : the "poor", who do not pay, and others who pay CFA 2,000 MONTHLY, plus CFA 1,000 for visits and OIs medicines.
Sources : PSM Survey

Committee, ministry of Finance, ministry of Health or AIDS ministry if applicable) which is why it is not possible over a given period to compile global amounts allocated to combat the scourge and therefore to efficiently analyse expenditures incurred. In view of this above, it is therefore not likely for these amounts to appear in the State Table of Financial Operations as recommended by public finance rules (Table 6).

Such surpluses correspond to a stock coverage of over 4 years theoretical consumption for Côte d'Ivoire, about 3 years and a half for Congo and 5 months for Burkina Faso. These disparities which are difficult to account for testify to the complexity of measuring financial flows.

b. Analysis of the supply cycle

The PSM cycle has been divided into 9 main activities : forecasting, procurement, suppliers' order follow up, reception of the products, conformity check, storage, quality control, suppliers' invoice settlement and distribution.

For each country, each of these 9 activities and each of the main sources of financing[33], the number of stakeholders[34] were accounted for. The result of this exercise shows a complex and contrasted situation (table7).

[33] Owing to time constraints imposed during the field survey, it was required from investigators to limit the analysis of the PSM cycle to 3 main funding sources operating in the investigated countries even if their number is sometimes much higher if we take into account funding sources or operators of secondary importance.

[34] Donors, operators, programme, service etc.

The first observation suggests that this exercise relates to the number of stakeholders involved by funding source. The average number of stakeholders is 13, with significant variations according to the funding sources[35] : 16 for the PEPFAR initiative in Côte d'Ivoire, for the Global Fund and the World Bank, 13 for national funding, 11 for UNICEF in Benin and for the Global Fund in Congo, CAR and for the State of Côte d'Ivoire.

The second observation relates to the number of stakeholders in each of the PSM cycle, all the funding sources taken together. The average for the 8 countries ranges from 3.3 (1-8) for the estimation of needs, to 0.5 (0-2) for drugs quality control.

Table 6 : Comparison between the annual expenditure declared and the theoretical costs of treatment and the number of patients under treatment (in USD)

	Burkina Faso	Congo	Côte d'Ivoire
1 Annual reported expenditure	4 683 000	7 077 000	21 070 000
2 Number of patients	17 263	7 426	21 907
3 Ratio 1/2	271	953	962
4 Proportion of patients under first line ART	99%	90%	99%
5 Proportion of patients under second line ART	1%	10%	1%
6 Mean treatement cost- first line (a)	180	180	180
7 Mean treatment cost-second line (a)	1 300	1 300	1 300
8 Average weighted cost of treatment : (4x6+5x7)/100	191	207	191
9 Total cost of treatment : 8x2	3 300 686	1 540 152	4 188 618
10 Difference (1-9)	1 382 314	5 536 848	16 881 382

Sources : PSM survey (corrected data).

[35] Ghana, with 23 stakeholders, is not taken into account as this number corresponds to the grouping of two clusters.

b. Table 7 Stakeholders in the PSM cycle by component, funding sources and country

	Benin			Burkina Faso			Cameroon			CAR		Congo		Côte d'Ivoire			Ghana		RDC				Mean
	FM	UNICEF	FC	FM	State	UNICEF	FM	State	FC	BM	FM	State	FM	PEPFAR	State	UNITAID	FM	TSFC	BM	FC	FM		
Needs forecasting	1	1	3	3	3	3	8	7	7	1	4	3	2	8	3	1	1	6	2	2	3	72	3,30
Procurement	1	1	1	1	1	1	1	1	1	2	1	1	1	1	2	1	2	2	1	1	1	25	1,15
Monitoring of orders	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	3	1	1	2	27	1,20
Reception of product	5	3	3	2	1	1	1	1	0	3	1	1	1	1	1	1	3	3	3	2	2	39	1,80
Conformity control	4	2	3	2	2	2	1	1	0	0	1	1	1	2	1	1	2	2	1	1	2	32	1,50
Warehousing	1	1	1	1	2	2	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	24	1,15
Quality control	0	0	0	1	1	0	1	1	1	0	0	1	1	0	1	0	0	2	0	0	0	10	0,40
Settlement of suppliers' bills	1	1	1	2	2	1	1	1	1	3	1	1	1	1	0	1	22	2	1	1	2	7	1,25
Supply	1	1	1	3	2	2	1	1	1	2	1	2	2	1	1	1	1	2	1	1	1	29	1,35
Total	15	11	14	16	15	13	16	15	13	16	11	12	11	16	11	8	14	23	12	10	13		1,46

Note : GF = Global Fund, CF = Clinton Foundation, WB = World Bank, TSFC =Aggregate sources of funding

Sources : PSM survey

Analysis per activity :

- Forecasting : the largest numbers of stakeholders are found in this essential activity[36]. Errors and omission excepted, there are 8 stakeholders in Cameroon for the Global Fund cluster (the DPL of the Ministry of Health, the National Programme of AIDS Control, the medical store, UNICEF, WHO, DPM of the Ministry of Health, UNAIDS) and in Côte d'Ivoire, for the PEPFAR cluster (the PNPEC of the Ministry of Health, the National Programme of AIDS Control, the central purchasing Unit, one NGO, UNICEF, WHO, the DPM of the Ministry of Health, the National Quality Control Laboratory). Since these fragmented forecasts are neither done in a coordinated or concerted way before being materialised into orders validated by a centralised instance, it is not surprising that on the field they are translated into stock outs or drug expiry.

- Procurement, monitoring orders placed with suppliers and payment. These activities being centralized by nature, the limited number of stakeholders in each one of them, (1, 20 : 1-2), (1,30 : 1-3) and (1,30 : 1-3) respectively seems reasonable and does not call for specific comments. There is need to outline however the fact that, to the exception of Congo, central government procurement agencies are only partially involved in these activities which are generally conducted ex cathedra by the operators : in 2 clusters out of 3 in Burkina Faso and Cameroon, and 1 out of 4 in Côte d'Ivoire and are not at all involved in Benin, CAR and the DRC.

- Reception of Goods and conformity checks. The slightly higher average number of stakeholders in these other administrative activities, respectively (1.90 : 0-5) and (1.55 : 0-4), does not pose problem either. These activities, as regards central government purchase, are very often conducted in inter-ministerial committees. There is need to note however the absence of stakeholders for the conformity check activity for the Clinton Foundation/UNITAID cluster in Cameroon, on the one hand, and on the other hand, in the Central African Republic for the World bank cluster.

- Warehousing and delivery. The limited number of stakeholders in these two rarely dissociated activities, respectively : (1.15 : 1-2) and (1,40 : 1-3), illustrates the fact that these logistical activities are systematically conducted by government central stores, to the exception of DRC for the UNITAID supply chain for which they are entrusted to a private firm. It should be underlined that, when these activities are conducted by governmental central stores, it is most often without any legitimate financial reward and that corresponding internal expenses must then, in fine, either reduce their margins, or be transferred on other products they deliver.

- Quality control. The number of stakeholders engaged in this activity is the lowest (0,50 : 0-2). Indeed, this activity which is yet mandatory as regards drugs is systematically conducted only in Cameroon. In three countries (Benin, the Republic of Central Africa and the DRC) quality control does not seem to be conducted and in the other countries, they are only carried out as

[36] The word cluster is used to designate the procurement cycle of each funding source.

regards some clusters: the Global Fund and the Government in Burkina Faso, and the Government in Côte d'Ivoire.

That situation calls for two remarks: (i) absence of quality control in the UNICEF cluster seems to be justified by the fact that it is assumed that these operations are conducted upstream by the organization's Supply Division in Copenhagen, but then, it would be necessary to have a copy of the quality control slip forwarded with the drugs as required by national regulations, that remark is also valid for the PEPFAR cluster, for which quality control is entrusted to SCMS, (ii) in the other clusters, absence of quality control could be understood in cases whereby purchases are made from WHO or FDA pre-qualified firms, or still EMEA, but this does not however prevent the manufacturer from issuing, for each batch delivered, a certified copy of the corresponding quality control slip.

This global analysis of PSM cycle, calls for two general comments :

- For the same purpose (ensure procurement and distribution of medicines and diagnostic means), several PSM systems have been put in place. For instance up to 20[37] different systems have been numbered in the 8 sample countries visited even though 5 of them (Benin, Burkina Faso, Cameroun, Cote d'Ivoire and Ghana) do have a well functioning national system. If one admits that having several PSM systems in a country will result in dilution of responsibilities and ineffectiveness, one could imagine the level of efforts required to integrate those systems in order to improve the efficiency of the procurement and distribution chain.
- The reasons why partners favour the multiplication of PSM systems include : the lack of reliability of national PSM systems and weak management of funds disbursed[38]. However, partners do refer to national structures for storage and distribution of almost 80% of their imported medicines and diagnostic means.

It does not make sense to have several PSM systems in a country for many reasons : (i) it is in contradiction with technical and financial assistance provided for decades by development partners to national PSM systems in West and Central Africa[39], (ii) it creates an over cost not offset by additional logistic or technical assistance[40], (iii) increasing the number of actors makes the system more complicated and thereby preclude for assessing the national situation, (iv) those PSM systems actors do no always abide by the rules in at least in 3 areas: importation, registration of products and quality control

[37] Only main supply cycles were considered. This number will be higher if we include secondary supply cycles.

[38] Indeed, all partners are responsible of the funds engaged. It seems then easier to engage external or internal organizations to control the use of the funds, than to take the risk to give this responsibility to national counterparts. In these situations, risk is avoid, but it will create frustration and not involvement of national counterparts.

[39] Since the end of the 90, and even more after the franc CFA devaluation in January 1994, several partners working in the development (European Union, WHO, France and The Netherlands) bring to West and Central Africa, important Technical Assistance, firs to the Central Medical stores, then to the Pharmacy department. The objective of this support was to reach access to essential medicines in health facilities, and to adapt the regulation framework and legislature, to control medicines in the private and public sector.

[40] The realization of the same function (Procurement of medicines) by several structures, each which it own functional cost, is much more expensive than to realize this activity by only one structure.

and, (v) this more complex situations will impede the scaling up of programmes.

c. Field visits

Investigations conducted solely at central level are not enough to offer a global vision of the PSM problematic. Thus, to have an assessment of the situation at the far end of the healthcare chain, consultants were asked to visit each country and to visit three health facilities, and report on the situation on site.

The outcome of those visits globally shows quite poor situations : storage conditions are not satisfactory, stock managers are not sufficiently trained, management stock tools; even basic ones stock cards) are not systematically used, availability rates are not satisfactory, all centres report inventory shortages and are not systematically supervised (Table 8 appended)

Sampling

The 24 care facilities visited are essentially located in urban areas (67%). Stock control administrators are mainly nurses (38%) and pharmacists (33%) but also health technicians (17%) and medical doctors or pharmaceutical assistants (12%).

Storage conditions

Hardly half of the centres (54%) have enough storage space .Conditions are not satisfactory in half of them (42%) and are poor in 1 centre out of 4. However, the cold chain is operational in 90% of the centres.

The presence of management tools is not systematic: 20% of the centres do not have the national list of essential drugs and only a third of them use either stock management software, or stock cards.

Stock management

83% of health facilities are autonomous as regards stock management and 79% in matters of procurement decision-making.

Only 13% of stock managers benefited from training in the last six months before the survey, and for three quarters among them, training was received more than six months before. 13% of these managers did not receive any training.

All care centres regularly perform stock inventories, most often on a monthly (58%), weekly (25%), or quarterly (13%) basis.

Procurement operations are mostly on a monthly (46%) or quarterly (38%) basis.

All health facilities experienced stockouts. The causes of which are numerous : delivered quantities were less than expressed needs (58%), needs were underestimated when order was placed (33%) delivery delays (25%) non compliance with therapeutic protocols (25%) and drug expiry (38%).

They were requested to compute average availability rates for 4 tracer drugs : first line adult (AZT/3TC 300/150) and (D4T/3TC 150/30), second line adult (IDV+r 400/100) and first line paediatric (NVP 200). Considering that not all centers systematically provide second line or paediatric treatment, only results obtained for first line treatment are presented.

In most countries, the availability rate for such medicines is excellent (100%).The absence of one of them was however noted in Cameroon: 83% (100% - 50% - 100%) and in the Democratic Republic of Congo : 67% (100% - 50% - 50%).

Supervision

All centres produce activity reports mostly on a monthly basis (50%) and nearly 1 centre out of 5 reports it has no supervision (3 centres in the CAR and Cameroon).

3.5 Recurrent difficulties

In addition to the quantitative analyses which show often contrasted situations from one country to the other, consolidation of the qualitative analyses conducted during field surveys shows recurrent disturbing elements, often interacting with each other which are at the origin of major dysfunctions in the procurement chain. These elements result from the combination of many factors : lack of reliability in the forecasting, fragmentation of the PSM cycle which stems from insufficient taking into account by donors of the existing national health systems when setting up organisational schema and operating procedures, lack of flexibility of these operating procedures which make them incompatible with the demand for drugs sometimes erratically expressed and lack of adequate response to stock outs.

a. Lack of flexibility in forecasting

This is the major problem of the procurement chain and the first cause of stockouts or drug expiry. It has several cumulative origins : the difficulties encountered by the staff of the health facilities in correctly counting the number of patients per protocol or molecule, omissions in those centres to report of patients loss to follow-up or newly enrolled, reports of new patients done on the basis of the percentage of care provision objectives and not actual reality, and the technique of needs estimation on the basis of the epidemiological profile and not on the basis of consumption analysis.

Depending on approaches adopted, the estimate forecasts differ radically : the calculation based on the epidemiological[41] profile provides a theoretical estimate, whereas the one based on observation of the volumes supplied by central medical stores reflects the demand, and thus, the actual need consequently, the actual need, which it is however necessary to adjust depending on the residual stocks, stockouts and orders being processed at suppliers' premises. The results of the forecasts provided by the two methods are necessary if we want to establish a realistic procurement plan. For example, ESTHER had been requested for help in a country for a period of three months for 3000 patients and face a situation all too frequent : the needs expressed by the NACP, based on the epidemiological profile, were three times as high as the ones expressed by the medical store, which took into account, on the one hand, the consumption pattern, and on the other hand, the level of the stocks available and the orders under processing at suppliers premises, giving a result much closer to reality. In that same country, the main beneficiary estimated the second line drugs purchase quantities on the basis of the NACP which, depending on the adopted method of computation, was much higher than the ones estimated by the purchase agency, based on procurement[42] flows.

[41] The epidemiologic profile enables obtaining order by size only because the data on which it is based are not reliable and prescriptions are not rational.

[42] The NPAC estimated at 39 % the number of PLWAs under second line treatment, whereas the government procurement agency estimated it at 10%.

As regards cost, this translated into a purchase value much higher than what was necessary which generated significant foreseeable losses.

The solution to that situation would be, on the one hand, making forecasts from effective monitoring of consumption at central level, i.e., at the level of procurement agencies where the drugs are delivered before being despatched to treatment centres, and on the other hand, from monitoring of consumption trends using simple and proven trends like linear regression and finally, smoothing procurement peaks by setting in place a stock management system based on annual , or multi-annual supplier markets, executed according to fragmented delivery schedule and sufficiently flexible to take into account the supply chance factors and the erratic characteristic of the demand expressed by care centres.

b. Fractioning of the supply chain

The multiplicity of stakeholders in the procurement chain (ref. supra chapter 4) and fragmenting of its essential functions (forecasting, market contracting and monitoring, management of orders placed with suppliers and drugs warehousing) among all these stakeholders, sometimes grouped in commissions[43] are factors of loss of efficiency as regards the global function. In another respect, this organisational pattern dilutes responsibilities in the occurrence of mistakes which tend to blamed in a cascade movement on the final operator, at the down stream end of the chain, i.e., the central Medical store.

Under such schemes, depending on the donors' requirements, information flows are most often unidirectional, going bottom up : thus procurement agencies give regular reports of the activity[44] (which, in another respect, if judgement is made on the basis of the preceding paragraph on forecast reliability, do not seem to be taken into account), but are not, in turn, sufficiently informed about the programming of the orders placed with suppliers, or the dates at which those orders will be delivered, or the corresponding quantities, which greatly disturbs the functioning and constitutes a de-motivation factor.

c. Lack of flexibility in operating modes

Many difficulties identified during the assessment result from incompatibility between, on the one hand, inadequately expressed demand owing to its dynamic nature (for several reasons, the number of patients vary upward, or downward[45]), non compliance with therapeutic protocols and lack of forecast reliability, and on the other hand, enforcement of procurement techniques poorly adapted to demand specificities : sometimes insufficiently informed operators with poor knowledge of both the issues related to HIV/AIDS and procurement, too lengthy procurement procedures (time lapses between bid tenders and deliveries take sometimes more than 12 months to cover a consumption period of 12 months) and not flexible (contracts with suppliers do not include adaptation clauses of delivered quantities to face, should the case occur, a quantitative or qualitative variation of demand) with suppliers who, sometimes

[43] Quantification Commission

[44] State of stocks and deliveries provided to health facilities.

[45] Deceased, loss to follow-up patients, or new patients on ARV treatment, adaptation of treatments to the patients' immunological status, patients progressively placed on treatment, incompatibility of some medicines for TB patients, etc.

are not very reactive (reaction time for some supplier recommended by the Global Fund are sometimes much too long).

Thus, while the specificity of this situation necessitates strong operator reactivity to hammer out difficulties, no adapted mechanism was enforced to ensure regular drugs procurement and means of diagnosis.

d. Lack of satisfactory response to stockouts

To frequent stockouts sometimes generated at central level by lack of flexibility of implemented procurement procedures (ref. supra) and in health facilities due to disruptions in supply channels, delayed and under-estimated orders as well as various management constraints, no satisfactory response has yet been brought forward in a sustainable way. The emergency stock set in place by ESTHER and stored in the CHMP warehouses in Kenya has little been used, and when such was the case, it was not possible for beneficiary countries to use available donor funds to reimburse ESTHER, amount corresponding to that emergency assistance.

Such stockouts may have serious implications as they force health facilities staff to not respect protocols; this was noted during field visits. This process is as follows : when a first line molecule is not available, treatment is adapted based on the availability of other molecules the effect of which is considered as equivalent. Most often, such adaptation consists in choosing a second line molecule. New protocols thus appear, carrying two negative impacts : their number makes the estimation of needs more complex and such modifications may lead to drug-resistance if initial treatments are not strictly adhered to. It appears necessary, to find a solution to these unavoidable stockouts, as they result from lack of simultaneity between supply and demand at a given moment, or more simply delivery delays from suppliers, or too cumbersome and tedious procurement procedures, interruption of funding flows between two phases of a donor' process, waiting time for non objection of a given administrative decision, or yet still, customs or bureaucratic red tape, etc. in setting in place a mechanism enabling with deadlines compatible with the emergency required by situations, procurement continuity in a way that ensures uninterrupted and adequate treatment of patients. This mechanism or facility, regional by nature, should respond to the two types of difficulties commonly encountered : immediate emergency assistance, in cases of proven stock outs and anticipated drug exchanges before expiry date and analysis of causes of stock outs so that they would not happen again.

e. Absence of a formal consultation framework between national AIDS Programmes and central medical stores

In many countries, the forecasting, ordering and receiving ARVs, OI drugs and diagnosis tests are conducted by national AIDS programmes without the involvement of Central medical stores or authorized operators. They latter know of the existence of drugs and materials only when they are already warehoused, without any prior consultation.

Even though ARVs, OI drugs and diagnostic tests are free of charge or heavily subsidized, it is recommended that Central stores managing other essential drugs be involved in the smooth operation of the care system (essential medicines, minor medical surgical equipment, radio

products etc.) during the various phases of the cycle of these products : Forecasting, Procurement, Monitoring of orders, conformity control, warehousing, quality control and distribution).

This will only be possible through a formal collaboration framework between HIV/AIDS programme managers and Central medical stores and other entities involved (National drugs control laboratories, the Pharmacy and Drugs Department). Involving staff in these structures in the development of proposal to be submitted to the next rounds of the Global Fund should contribute to improve the global efficiency of supplies and, therefore, "*to make better use of money available*", as recommended by UNAIDS.

4 CONCLUSION

The general lesson to be drawn from this evaluation exercise is that, in view of the complexity of the PSM issue within developing countries facing difficulties of all kinds, which therefore requires appropriate and flexible responses, systems designed to ensure procurement of ARVs and diagnostic tests lack of transparency, are hierarchical, too rigid and not efficient, which negatively impacts on the efficiency of funds committed.

In addition, they are not backed by transfer of competences, yet necessary for participating countries to develop ownership vis-à vis such systems.

Finally, the Global Fund offers to finance medical equipment procurement, services (quality control, forwarding agents…) and non-medical equipment (vehicles, rehabilitation work, new constructions…) but countries do not seem to resort as much as needed to this facility.

Whereas patients should be at the centre of donors and operators concerns, administrative and accounting aspects seem in many respects to prevail.

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ANNEXE 2 : PSM SYSTEM RELATED TO HIV/AIDS IN IVORY COAST

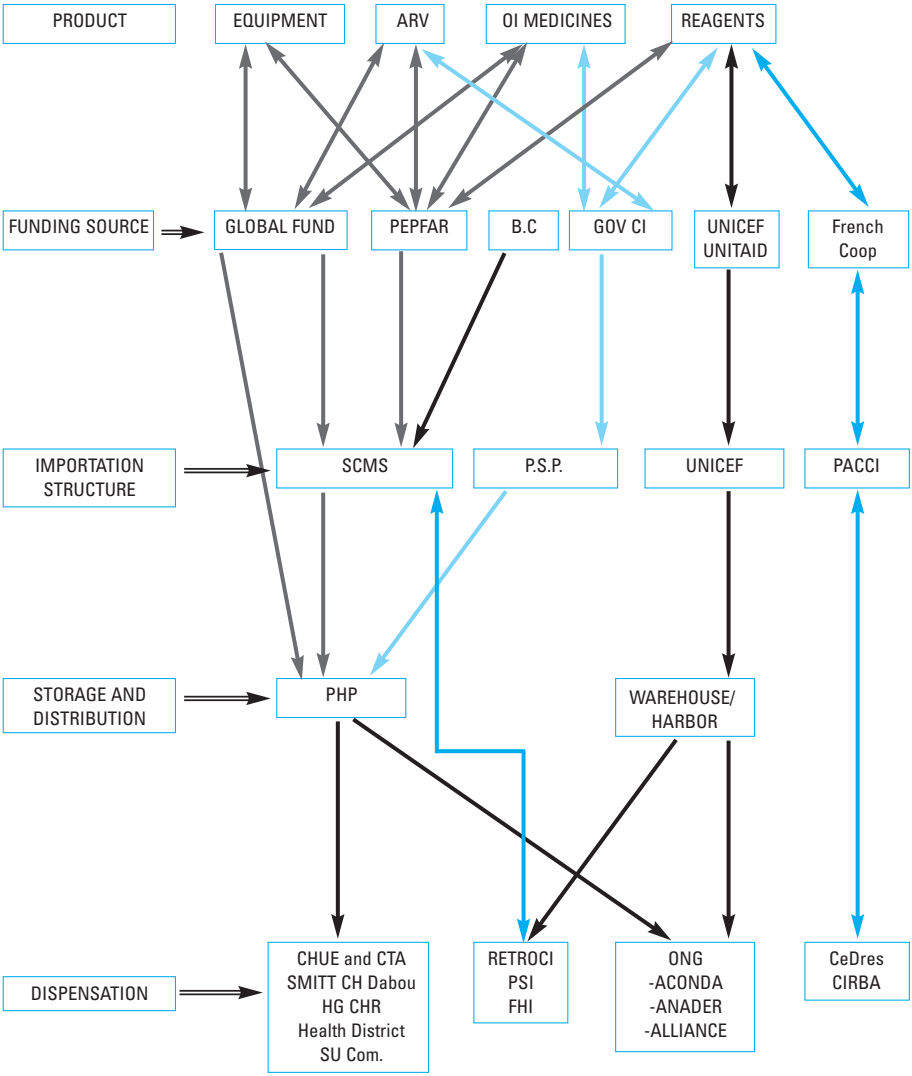

Table 8. Results from Health facilities visits

	Benin			BF			Cameroon			CAR			Congo			RCI			Ghana			RDC		
Hôpital H Centre C Other O	n.a.	C	C	H	C	A	n.a.	n.a.	n.a.	B	B	B	n.a.	n.a.	n.a.	H	H	C	C	H	H	C	H	H
Urban U, Rural R	U	U	U	U	U	U	R	UR	R	U	U	U	R	R	R	U	U	U	U	R	R	U	U	U
Stock Management Officer	I	P	M P	P	P	TS	I	I	M	TS	I	I	I	I	I	P	P	Aux Ph	TS	P	TS	I	P	P
The CTA manages stocks	no	yes	no	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no
The CTA places orders	no	yes	no	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	yes	yes	yes	no
Training of officers	no	> 6	> 6	> 6	> 6	> 6	> 6	> 6	> 6	> 6	< 6	< 6	> 6	> 6	> 6	> 6	> 6	> 6	> 6	> 6	< 6	> 6	> 6	> 6
Storage Conditions A B C	C	B	B	A	A	B	A	A	A	C	B	B	A	B	B	A	C	B	C	A	A	A	C	C
Compliance with cold chain requirements	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes	yes	no	yes
Adéquate surface	no	yes	no	no	yes	no	yes	yes	yes	no	yes	no	yes	no	no	yes	no	yes	no	yes	yes	yes	no	yes
Presence of National List of Essential medicines	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	yes	yes	no	yes	yes	yes	yes	yes	yes	no	no	no
Stock card or software	yes	yes	no	yes	yes	yes	no	no	no	yes	yes	no	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	no	no
W B M T Inventory	M	M	H	M	M	T	M	M	M	H	M	M	n.a.	T	M	H	T	H	M	H	H	M	M	M
H B M T IR Distribution		M	M	T	T	T	T	T	T	M	6 mois	M	T	T	T	M	M	M	M	M	M	M	IR	Stock
Delivery time (days)	1	5	4	7	7	15	1	1	1	7	120	7	2	n.a.	7	15	7	7	7	7	n.a.	7	7	n.a.
Causes of stock outs																								
Delivery<Order	yes	yes	yes	yes	yes	yes	yes	yes	n.a.	yes	no	yes	no	yes	yes	yes	no	no	n.a.	no	no	n.a.	yes	yes
Deliveries<needs	no	no	no	no	no	no	no	yes	n.a.	no	yes	yes	yes	no	yes	yes	yes	yes	n.a.	yes	yes	n.a.	no	yes
Delays in deliveries	no	yes	no	no	no	no	no	no	n.a.	yes	yes	no	no	yes	yes	yes	no	yes	n.a.	yes	yes	n.a.	yes	no
Limited financial resources	no	no	no	n.a.	no	no	no	no	n.a.	no	no	no	no	n.a.	yes	yes	no	yes	n.a.	no	no	n.a.	no	yes
Expired products	yes	yes	yes	yes	no	no	no	no	n.a.	yes	yes	no	no	yes	yes	yes	yes	yes	n.a.	no	no	n.a.	yes.	no
Non compliance with protocols	no	yes	no	no	no	no	no	no	yes	no	no	no	no	yes	yes	yes	no	no	n.a.	no	no	n.a.	yes	no
Availability rate	20%	14%	83%	90%	100%	90%	100%	100%	20%	83%	100%	83%	100%	100%	83%	100%	83%	83%	83%	100%	100%	100%	50%	33%
Frequency of submission of W B M T IR progress reports	M	M	M	T	T	T	M	B	n.a.	IR	IR	IR	T	T	T	n.a.	M	M	M	M	M	M	M	M
Structure regularly supervised	yes	yes	yes	yes	yes	yes	yes	yes	no	no	no	no	yes	yes	yes	yes	yes	yes	IR	yes	yes	yes	yes	yes

Sources : PSM survey

Notes : (i) Management staff : I = Nurse, D = Doctor, P = pharmacist, HT = Health technician, (TS) Training of officers in charge : >6 = over 6 months, <below 6 months, (iii) Deadlines for inventories, procurement and frequency of activity report submission : H = Weekly, B = bi-monthly, M = monthly, T = quarterly, IR = irregular

Table 9. Population, socio-economic and epidemological data for the UNICEF West and Central Africa Region

Country	Estimated population	Pop. growth rate	Life expectancy at birth		HDI Rank capita	GNP per HIV (ppp)	adult aged 15-49 prevalence	People living with HIV	Adults aged >15 living with HIV	Women aged >15 living with HIV	Deaths due to AIDS	Children aged <15 on ARV	Orphan aged 0-17 due to AIDS	Pregnant women receiving PMTCT	Men & women receiving ARV	
			F	H												
Benin	8 439 000	3,2%	53	54	162	1 120	1,8%	87 000	77 000	45 000	9 600	9 800	62 000	38,0%	33,0%	25 410
Burkina faso	13 228 000	3,2%	48	47	175	1 220	2,0%	150 000	140 000	80 000	12 000	17 000	120 000	1,1%	24,0%	33 600
Cameroon	16 322 000	1,9%	51	50	148	2 090	5,4%	510 000	470 000	290 000	46 000	43 000	240 000	4,2%	22,0%	103 400
Cap Verde	507 000	2,4%	71	67	105	5 650	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
CAR	4 038 000	1,3%	41	40	171	1 110	10,7%	250 000	230 000	130 000	24 000	24 000	140 000	16,4%	3,0%	6 900
Chad	9 749 000	3,4%	48	45	173	1 420	3,5%	180 000	160 000	90 000	11 000	16 000	57 000	0,2%	17,0%	27 200
Congo Brazzaville	3 999 000	3,0%	55	53	142	750	5,3%	120 000	100 000	61 000	11 000	15 000	110 000	1,0%	17,0%	17 000
Côte d'Ivoire	18 154 000	1,6%	47	41	163	1 390	7,1%	750 000	680 000	400 000	65 000	74 000	450 000	4,3%	17,0%	115 600
Equatorial Guinea	504 000	2,3%	44	42	121	7 400	3,2%	8 900	8 000	4 700	<1000	1 000	4 600	n.a.	0,0%	0
Gabon	1 384 000	1,7%	59	55	123	5 600	7,9%	60 000	56 000	33 000	4 700	3 900	20 000	0,7%	23,0%	12 880
Gambia	1 517 000	2,8%	59	55	155	1 900	2,4%	20 000	19 000	11 000	1 300	1 200	3 800	16,6%	10,0%	1 900
Ghana	22 113 000	2,1%	58	56	138	2 280	2,3%	320 000	300 000	180 000	29 000	25 000	170 000	1,3%	7,0%	21 000
Guinea Bissau	1 586 000	3,0%	48	45	172	690	3,8%	32 000	29 000	17 000	2 700	3 200	11 000	19,5%	1,0%	290
Guinea Conakry	9 402 000	2,2%	55	52	156	2 130	1,5%	85 000	78 000	53 000	7 100	7 000	28 000	0,4%	9,0%	7 020
Liberia	3 283 000	1,4%	44	39	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	7 200	n.a.	n.a.	n.a.	n.a.	n.a.
Mali	13 518 000	3,0%	47	44	174	980	1,7%	130 000	110 000	66 000	11 000	16 000	9 400	0,8%	32,0%	35 200
Mauritania	3 069 000	3,0%	60	55	152	2 050	0,7%	12 000	11 000	6 300	<1000	1 100	6 900	n.a.	4,6%	550
Niger	13 957 000	3,4%	41	42	177	830	1,1%	79 000	71 000	42 000	7 600	8 900	46 000	n.a.	5,0%	3 550
Nigeria	131 530 000	2,2%	46	45	158	930	3,9%	2 900 000	2 600 000	1 600 000	220 000	240 000	930 000	0,2%	7,0%	182 000
RDC	57 549 000	2,8%	47	42	167	680	3,2%	1 000 000	890 000	520 000	90 000	120 000	680 000	n.a.	4,0%	35 600
Sao Tome	157 000	2,3%	60	57	126	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Senegal	11 658 000	2,4%	57	54	157	1 720	0,9%	61 000	56 000	33 000	5 200	5 000	25 000	1,4%	47,0%	26 320
Sierra Leone	5 525 000	4,1%	40	37	176	790	1,6%	48 000	43 000	26 000	4 600	5 200	31 000	n.a.	3,0%	1 290
Togo	6 145 000	2,7%	56	52	143	1 690	3,2%	110 000	100 000	61 000	9 100	9 700	88 000	1,8%	27,0%	27 000
Total	357 333 000							6 912 900	6 228 000	3 749 000	578 100	646 000	3 232 700			683 710
Weighted mean		2,5%	48	46		1 182	3,4%							3,1%	11,7%	

Source : 2006 Report on the global AIDS epidemic - a UNAIDS 10th anniversary special edition

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