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UNITAID-FUNDED SUPPLY PROGRAMMES FOR PRIORITY DISEASES CONTROL

PROPOSAL FOR AN OPERATIONAL ACTION PLAN

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1. INTRODUCTION : CURRENT SITUATION

1.1. Massive support of ACAME for UNITAID funding principles

The Association of African Essential Drugs Purchasing Centres (in short ACAME) which includes a score of countries, mainly francophone countries, has been steadfastly supporting the establishment of this new concept of innovative funding since the inception of the UNITAID initiative.

This mechanism in which many ACAME member countries participate by introducing taxes on plane tickets, should generate stable, foreseeable and additional resources for former funding such as those provided by the World Fund or the World Bank

Afterwards, ACAME acceded the objectives clearly outlined by UNITAID, aiming at positioning itself as a safety instrument for the production of drugs that are difficult to acquire, including the ARV, combined forms and paediatric forms.

ACAME commends UNITAID for its role in facilitating drug procurements; this facilitation has led, and it is already the case, to the extension of the pool of suppliers, the increase in the available quantities of drugs mentioned above as well as to the interesting prices based on estimated cumulated needs.

1.2. Launching of the « Dakar Declaration » by ACAME

However, from the operational perspective, ACAME has repeatedly expressed regret with regard to the substitution mechanism of most of the African National Purchasing Centres by the Clinton Foundation and UN Agencies such as UNICEF for the supply of UNITAID-funded programmes for priority diseases control.

In this regard, the Directors general of ACAME member Drug Purchasing Centres launched in march 2007 a solemn declaration dubbed as the « Dakar Declaration » to draw the attention of their regulatory institutions and that whole community of partners and donors to this situation.

In this declaration, ACAME wants the substitution decision to be replaced as expeditiously as possible by a strategy for an optimal use of Purchasing Centres in order to build local capacities, to make national procurement systems sustainable and also, for the best interest of our populations, to improve the performance of the distribution channel

1.3. Adjustments made during the « Ouagadougou Conference»

As provided for in the « Dakar Declaration », ACAME invited the community of Partners and Donors to an International Conference on 19th June 2007 in Ouagadougou. The presence of UNITAID's Special Advisor at this conference was much appreciated.

During this meeting which provided for a direct and constructive dialogue, the Directors General of the Purchasing Centres presented the challenges, inadequacies and inconsistencies that they noticed in their respective countries when their Centres were substituted for by other institutions the results of which were more than mixed.

This field analysis, mainly on previous experiences funded by the World Fund, involves in the same way the first activities carried out with UNITAID's funding.

Several highlights are underscored:

1.3.1. Need for improved consultation

Let us recall first and foremost that the implementation of any essential drug procurement programme in Africa should fall in line with a common approach to strengthen and sustain national procurement systems

So, it is of paramount important to involve more beneficiary countries. The different African field actors, and mainly ACAME and member Purchasing Centres should be actually involved in both the definition of strategies and the formulation of operational choices, as well as in the practical implementation of drug supply programmes.

Joint strategic choices should be made all along the logistic cycle, outlined:

- Procurements facilitation

- Supply up to the country
- Storage, distribution and management within this country
- Re-procurement

This calls for conditions to be fulfilled in this country, at the levels of partners and Purchasing Centres, which we will review.

1.3.2. Lack of task definition and recognition of the various management fees

The different field actors, mainly the African essential drugs Purchasing Centres have the feeling that they are insufficiently involved in the definition of UNITAID's strategy.

The signing of a Memorandum of understanding between UNITAID's subcontractor and the government of the beneficiary country is without any doubt compulsory, but there is a general framework within which practical memorandums of operation must be absolutely and jointly signed.

These must rigorously describe:

- The level of involvement and the precise role of the different actors in the distribution chain, i.e. the responsibility of each actor in the global management process
- The programming of procurement activities and the establishment of an implementation schedule of tasks
- The technical and regulatory procedures to comply with, as well links and information exchange among operators
- The product quality insurance procedures and compliance with the pharmaceutical policy of the beneficiary country
- The management rules between financial partners and technical operators, based on real costs related to each component of the distribution chain.

1.3.3. Fragmentation of the supply logistic cycle and dilution of responsibilities

Supply for HIV /AIDS control programmes depends not only on estimated needs, based on delicate estimates, but also on the monitoring of activities and stocks, allowing for continued readjustments

All gaps in field needs result in an inventory shortage, which is dramatic for the health of People living with HIV/AIDS, product expiry, particularly as ARVs are short time products

This means that the current drug supply, particularly ARV supply, should be considered as a whole and that multiplicity of actors entails difficulties with regard to needs

estimation, as well as the dilution of the responsibilities of each actor

As a matter of fact, in this case where the institution in charge of procurements and supplies up to the country is different from the one in charge of control, storage, distribution and management in the beneficiary country, experience shows that it is very challenging to ensure consistency and re-adjustment of all necessary quantities.

It is particularly difficult to always succeed in the delicate re-procurement task, combining the quantification of needs based on proximity work and the programming of orders.

The current challenges regarding the reaction of the different actors to adapt stocks to the needs of health centres, stem from this separation of the purchase cycle from that of distribution.

And this lack of the current supply flexibility is regretted in the field.

1.3.4. underestimation of tasks to accomplish in the country

Experience equally shows that to ensure an adequate drug supply, and particularly a correct supply in due time, in terms of product quality, quantities and delivery frequency, there is need for putting in place a rigorous organisation, involving the various institutions that we describe in our strategy.

The establishment in this country of a small bureau, managed by a Western NGO inadequately prepared, or the use of a non specialized purchasing bureau, and dependent on the United Nations, cannot constitute an adequate or sustainable mechanism, considering the scope of the technical tasks required.

This underestimation of the logistic tasks often leads to the use, after the fact, of Purchasing Centres' service for product storage and distribution, but this logistic work was done without per contra fees.

1.3.5. Multiplicity of programmes and procedures

It would be equally advisable that the different partners involved, undertake to harmonise their administrative procedures, and this would facilitate the operational implementation of their programmes et could result in the grouping of orders.

1.4. Need for a joint strategy

At the end of the Ouagadougou conference, Prefect DUSSOURD, Special Advisor to UNITAID, justified the globalization principle of purchases for better prices and the launching of specific productions with manufacturers.

In a gratifying manner, he recognized that after the starting phase conducted in a certain emergency, during which consultation was undoubtedly short of time, the issue was to define mechanisms for collaboration with Purchasing Centres.

The current sustainability of funding sources, even though it is still relative, allows both UNITAID and beneficiary countries to develop a medium or long term common vision, which leads to improving the drug supply system

Presently, ACAME is proposing a strategic paper highlighting the basic principles to comply with, the organisation to put in place for a good operational implementation of supply programmes, as well as the stumbling blocks to avoid.

2. STRATEGY RECOMMENDED BY ACAME FOR THE OVERALL MANAGEMENT OF UNITAID-FUNDED PROGRAMME FOR PRIORITY DISEASES CONTROL

2.1. Maintain procurements facilitation and price negotiation centralized:

2.1.1. Secure production sources and encourage price negotiation

The role of procurements facilitation played by UNITAID lies upon the availability of sustainable and foreseeable resources, allowing to secure the production of drugs that are difficult to acquire, such as second line ARV, both the combined forms and the paediatric forms

On the other hand, it lies upon the grouping of order quantities in a way to apply the principle of economies of scale, which results, as it is already noticed during the first operations conducted, in interesting prices

Even though some Purchasing Centres were able to secure better direct prices than those negotiated with the Clinton Foundation (with the same manufacturers), ACAME broadly appreciates the true worth of the Clinton Foundation's know-how and the advantages granted to beneficiary countries through this facilitation mechanism (see UNITAID's reports on price drop).

Each beneficiary country, whatever their needs may be, should be regularly supplied, at an interesting pre-determined price.

2.1.2. Ensure drug quality through WHO pre-qualification system

As far as pharmaceutical products quality insurance is concerned, ACAME wants the supplier of UNITAID, such as the Clinton Foundation, to select only products which have met the WHO pre-qualification system.

In this respect, ACAME entreats WHO with support from its partners to reinforce its team in order to develop this important activity, which ensures the quality of products that are distributed

ACAME wishes to thank manufacturers who accepted to engage in this bold activity, and WHO for its essential role played in product quality insurance.

2.1.3. Group order quantities based on country estimations

Given the performances of the Clinton Foundation with regard to price negotiation and securing production, ACAME recommends that this facilitation and needs centralization mechanism be developed.

Drug quantities which should be used as the basis for price negotiation should be provided by the different beneficiary countries, on an annual basis, within a certain range allowing for future possible re-adjustments of these estimates and due dates jointly established with partners.

Thus, each country benefits from purchasing rights pursuant to pre-established conditions.

2.2. Separate negotiation and supply functions

The price negotiation function, if cumulated with the supply function, including the determination of order quantities, can result in a conflict of interest.

ACAME feels that UNITAID, and its current subcontractor represented by the Clinton Foundation, should only keep to the fundamental task of purchase facilitation

2.3. Favour a country approach for supply

2.3.1. Define a coherent organisation in each country

Once the supply sources are defined, and suppliers identified, the product quality insured, estimate quantities scheduled, ACAME proposes to favour a country approach, on a case by case basis.

Based on the organisation put in place by the country for priority diseases control programmes, many a solution are envisioned, as a result of consultation.

The management of a priority diseases control programme does not boil down to making a first order and to its delivery in the country

The most important work which should be done in each country to ensure regular supply corresponding to the needs of the population, should not be underestimated, while complying with good stock management rules, resulting in lack of stock shortages and expiries.

Experience shows that expected results are difficult to obtain by simply establishing a small purchasing bureau within an international organisation or an NGO

On the other hand, ACAME recommends the establishment of a coherent organisation, materialized by umbrella agreements as well as memorandum of operation, through assignment of responsibilities at each level of the distribution chain, the establishment of operational links among the different actors, joint procedures to control stocks estimates and management.

2.3.2. Use the potentials of Essential Drug Purchasing Centres

This country approach should notably define, following a constructive evaluation of the whole distribution chain in this country, the institution which will be in charge of supplies and/or distribution in the country.

L'ACAME recommends that all evaluation be carried out in accordance with objective criteria, within a framework of constructive exchanges, which further takes into accounts the global nature of drug issue and the environment in which African Essential Drug Purchasing Centres operate.

In the quest for performance, we feel that it is not justified that each evaluation is not sanctioned by detailed report

2.3.3. Provide for mitigating measures

L'ACAME makes it a point of duty to recall that each member Purchasing Centre has developed a Strategic Development Plan, presenting its strengths, weaknesses and priority activities to carry out. This plan is available for any partner wishing to support a supply programme in one of the member countries.

The strategy put in place by UNITAID has not yet envisioned to vest Purchasing Centres with the responsibility to supply programmes funded by this Initiative.

ACAME is surprised to notice that before defining this strategy, no national competences validation mechanism is envisioned. And yet, ACAME is convinced of the usefulness of conducting constructive evaluations within a joint framework and sanctioned by a detailed report.

ACAME particularly requires that all evaluation systematically provides for mitigating measures in case of possible inadequacies.

In this way, the Purchasing Centre will be able, through technical support, targeted trainings, to provide for the inadequacies identified or through the development of infrastructures, to take back its rightful place within the national supply system.

3. PILOT PROJECT ACAME / UNITAID

3.1. Launch a pilot project in 4 ACAME member countries

ACAME advocates for the principle of the optimal use of national Essential Drugs Purchasing Centres for the supply of UNITAID-funded programmes.

This strategy in line with the sustainability of national procurement system seems to be vital as the results of the different substitution experiences presented during the Ouagadougou conference, have proved to be more than mixed results.

However, as a different strategy was put in place from the beginning of UNITAID activities aiming at assuring some dubitative observers, ACAME proposed on Monday 12th November 2007 to put a pilot project in place in order to test the efficiency of the use of Purchasing Centres in 4 ACAME member countries.

3.2. Put in place a national coordination in the country

Each country selected must comply with the following essential principles, the implementation of which can be noted during a preliminary evaluation of the whole forward management of the programme prior to the launching of operations:

First and foremost, a Coordinating Unit manages the UNITAID-funded supply programmes. This body includes technicians who are available and well conversant with field requirements.

A management guide is developed, outlining the following key elements:

- ARV list, norms and updated protocols in force in the countries
- Procurement, storage, distribution channel and exemption of products, clearly stating the attributions of the different actors involved
- Inventory management procedures at each level of the distribution chain as well as the information chain.

The Coordinating Unit put in place within a joint framework with supply body and all the management bodies.

3.3. Entrust supply to essential drugs Purchasing Centres

3.3.1. Ensure continued procurement cycle and distribution cycle

ACAME recommends not to separate the procurement cycle and the distribution cycle, but to favour the continuity of both cycles instead, and by entrusting them to the national supply body, which is the Essential Drugs Purchasing Centre.

This allows for better adaptation and for good responsiveness to management contingencies, with direct consequences for ARV good management, including

compliance with established therapeutic protocols, decrease in expiries, as well as stock shortages.

3.3.2. Technically adapt the Purchasing Centre to this new challenge

In each country that is part of the pilot project, the Purchasing Centre adapts its organisation to take up the challenge related to the supply of UNITAID-funded programmes for diseases control.

The Purchasing Centre puts in place a special department in charge of UNITAID-funded products supply, as well as field distribution monitoring.

This department draws on specialized and specifically trained human resources, mainly through the training programme on supplies management and more specifically on the management of ARVs provided for by ACAME, and including three modules (procedures, quality insurance, and forward management).

3.3.3. Establish a controlling body within the Purchasing Centre

During the 10th General Assembly of ACAME from 6th to 8th November 2007 in Libreville, a resolution was taken to establish within each of the member Purchasing Centres, a surveillance Committee open to partners.

This controlling body will allow them to have information about the management of programmes and follow-up of the performance of the Centre..

Purchasing Centres participating in the pilot project should then comply with this resolution to assure UNITAID with regard to each Purchasing Centre' readiness for transparency and openness.

3.3.4. Evaluate the Purchasing Centre

In each « pilot » country, the Essential Drugs Purchasing Centre, after clearly expressing its will to fully involve in the process of UNITAID-funded ARV supply, is ready for a transparent evaluation

This evaluation is carried out within a joint and constructive framework, including the whole pharmaceutical environment in the country, using objective criteria and formulates recommendations if need be.

The Purchasing Centre should prove that it has an organisation that is adapted to ARVs supplies management (transparency in the management and operational self-sufficiency, compliance with procurements procedures allowing for quality products by ensuring competitive bidding rules, compliance with good distribution practices, provision of adequate infrastructures and logistics adapted to products conservation requirements.

Should the Centre be validated, it will be then clearly identified as the sole and unique national body for the supply of products funded by UNITAID.

3.4. Estimate annual quantities and submit them to UNITAID / Clinton Foundation

A national supply plan is developed, including:

- Field qualitative and quantitative needs, always jointly estimated with users.
- Inventory levels at each stage of the distribution chain,
- Re-procurement frequency and deadline

In this respect, the Purchasing Centre is involved in the planning process of activities impacting on the supply processes, and is part and parcel of the committee in charge of the management and follow-up of inventory; this committee is composed of different technicians involved in the national management.

These estimate annual needs are forwarded to UNITAID / Clinton Foundation within a deadline previously established (for instance 6 months before). Thus, UNITAID can successfully conduct its facilitation and negotiation activities with suppliers

3.5. Exercise «purchasing right»

Once supply sources are defined by UNITAID /Clinton Foundation, suppliers clearly identified, product quality insured and prices negotiated on the basis of scheduled estimate quantities, each pilot country benefits from a «purchasing right».

Order quantities could vary from estimates forwarded by the country, within an agreed range (minus 30% to plus 30% for instance). This arrangement will allow updating needs according to field reality, reducing risks of stock shortage and product expiries.

This re-adjustment of needs will be facilitated by putting in place an inventory management and control follow-up system at each level of the distribution chain.

3.6. Develop a subcontract between UNITAID and the Purchasing Centre

Prices and products being defined, the Purchasing Centre will conduct procurements through mutual agreement with pre-qualified suppliers.

It will be necessary to institutionalize in each country this procedure of exceptional flexibility, given the upstream short-listing work carried out by UNITAID.

Each « pilot » Purchasing Centre will be considered as UNITAID's subcontractor, which will be remunerated as such based on the percentage of the amounts of drugs distributed.

The subcontract should provide for the conduct of an audit each year, as a condition for the

renewal of the contract.

Conclusion

ACAME, with a view to making national supply systems sustainable, to building local capacities and to making countries accountable, feels that the use of drugs Purchasing Centres will significantly improve on the impact of funding provided by UNITAID in Africa.

Pursuant to commitments by the Permanent Secretary of ACAME on the 12th December 2007 in Paris during a meeting with MR. Philippe DOUSTE BLAZY, Chairman of the Board of Directors of UNITAID, and its team, ACAME is offering to show the interest of the strategy to involve Purchasing Centres through the implementation of a pilot project in four member countries.

ACAME is ready to make substantial efforts to adapt the organisation of Purchasing Centres to the requirement of UNITAID-funded supply programmes.

Moreover, ACAME insures that this pilot project is monitored by UNITAID in greater transparency.

The Permanent Secretariat of ACAME remains at the disposal of UNITAID's Board of Directors to discuss this strategy or to provide any further information

Lazare BANSSE
Permanent Secretary