

**A STUDY OF
PROCUREMENT POLICIES AND PRACTICES
FOR DRUGS
IN SUB-SAHARAN AFRICA**

**Performed for the European Commission
By Gruppo Soges Spa**

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ABBREVIATIONS AND ACRONYMS

ACAME	Association africaine des Centrales d'Achats de Médicaments essentiels génériques (African Association of Generic Essential Drugs Purchasing Centres).
ACP	African_Caribbean_Pacific (countries).
ACTs	Artemisinin_based combination therapies.
AIDS	Acquired Immunodeficiency Syndrome.
ARV	Antiretroviral .
Asbl	Association sans but lucratif (not_for_profit association).
BTC	Belgium Technical Cooperation.
CAME	Centrale d'Achat des Médicaments essentiels et Consommables médicaux Purchasing Centre of Essential Medicines and Medical Consumables, Benin).
CAMEG	Centrale d'Achat des Médicaments essentiels génériques et des Consommables médicaux (Purchasing Centre of Generic Essential Medicines and Medical Consumables, Burkina_Faso and Togo).
CECOME	Central de Compra de Medicamentos Essenciais. (Purchasing Centre of Essential Medicines, Guinea_Bissau).
CDR	Congo Democratic Republic.
CEDEAO	Communauté économique des Etats de l'Afrique de l'Ouest.
CEMAC	Communauté économique et monétaire en Afrique centrale (Economic and Monetary Community of Central Africa).
CF	Coopération française (French Cooperation).
CHMP	Centrale humanitaire medico_pharmaceutique.
CMS	Central Medical Store.
CNOP	Conseil national de l'Ordre des Pharmaciens (National Council of the Pharmaceutical Board ; France)
CPP	Common Pharmaceutical Policy.
CSO	Civil Society Organisations.
DPED	Direction des Pharmacies et des Explorations Diagnostiques (Directorate of Pharmacies and Diagnostic Examinations. Benin).
DPM	Direction de la Pharmacie et du Médicament (Directorate of Pharmacy and Medicines, Burkina Faso and Mali).
DRA	Drug Regulatory Authority.
EAC	East African Community.
EC	European Commission.
ECOWAS	Economic Community of West African States.
EDF	European Development Fund.
EGM	Essential Generic Medicine.
EML	Essential Medicines List.
EPIC	Etablissement public de caractère industriel et commercial (Industrial and Commercial Public Establishment).
EU	European Union.
FMS	Federal Medical Store
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPSHP	Good Pharmaceutical Storage and Handling Practices.
GRH	General Reference Hospital.
HIV	Human Immunodeficiency Virus.
HNPP	Harmonisation of National Pharmaceutical Policies.
HZ	Health Zone.
IDA	International Dispensary Association. (Amsterdam)
INPN	International Non_Proprietary Name.
IOC	Indian Ocean Commission
ISO	International Organisation of Standardisation.
LEEM	Les Entreprises du Médicament (The Pharmaceutical Companies ; France).
MDGs	Millennium Development Goals.

MoH	Ministry of Health.
MSF	Médecins Sans Frontières.
NGOs	Non_governmental organisations.
NMF	National Medicines Formulary.
NMP	National Medicines Policy.
NPGP	National Pharmaceutical Guiding Plans.
NPP	National Pharmaceutical Policy.
NQCL	National Quality Control Laboratory.
OCEAC	Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale (Organisation for Coordination of the fight against endemic diseases in Central Africa).
PPM	Pharmacie populaire du Mali (Popular Pharmacy of Mali, Mali).
PRSAO	Programme régional de Santé en Afrique de l'Ouest (Regional Health Programme in West Africa).
RDC	Regional Distribution Centre.
ReMeD	Réseau Médicaments et Développement
RG	Reference Group.
SADC	Southern Africa Development Community.
SIAMED	WHO Model System for Computer_assisted Drug Registration.
SIGMED	Système intégré de Gestion de Médicaments (Integrated System of Drug Management).
SR	Sub_region.
SSA	Sub-Saharan Africa
STG	Standard Treatment Guidelines
TB	Tuberculosis
ToR	Terms of Reference
UEMOA	Union économique et monétaire Ouest africaine (West African Economic and Monetary Union).
UN	United Nations.
UNDP	United Nations Development Programme.
UNICEF	United Nations Children's Fund.
UNITAID	International Drug Purchase Facility.
WHO	World Health Organization.
WHO_AFRO	World Health Organisation_Regional Office for Africa.
XAF	CFA Francs (Central Africa).
XOF	CFA Francs (West Africa).

EXECUTIVE SUMMARY

During the first quarter of 2008, a study was carried out in a sample of six countries in Sub-Saharan Africa to identify the principal determinants of success or failure in public drug procurement programmes. Attention was also devoted to closely associated issues, notably quality assurance and control. Following a study of the existing literature, short visits were paid to Benin, Burkina Faso, Mali, Mozambique, Tanzania and Uganda in order to obtain current data and seek authoritative views.

While the principles underlying public drug procurement and the maintenance of quality standards are well-recognized, they are not always optimally applied. The contribution that these activities can make to public health is also heavily dependent on complementary activities within countries, ranging from storage and transportation to the manner in which medicines¹ are used in the periphery. Unobtrusive support from donor partners in identifying and overcoming obstacles or exploiting opportunities in these directions can be no less fruitful than the provision of financial support to procurement and may indeed need to be continued after monetary support of drug supply has ceased to be the first priority. Areas demanding particular attention include:

- The need for more extensive training in public drug procurement
- The importance of maintaining acceptable working conditions and career prospects for drug procurement staff
- The adoption in each country of need assessment techniques that are sufficiently reliable and are also feasible under existing conditions
- The solution of existing logistical problems in the areas of secure storage and dependable transport
- The provision of medicines in presentations sufficiently well adapted to the conditions under which they will be stored, distributed and used
- The identification of tools to counter leakage and corruption
- The development of closer working links between public drug supply and other providers, especially the faith-based organizations
- The advantage of creating a central management structure covering the entire drug sector and capable of ensuring smooth overall operation as well as adequate financing and a sufficient degree of autonomy in law and practice.

Because of historical and developmental differences between countries the priorities accorded to such matters must vary, and the patterns of donor partnerships must be flexible in terms of time and place. A measure of coordination between donor partnerships is vital, but here again the form that this takes must depend on the national situation and current practices.

Account must also be taken of the progressive and encouraging development since 1990 of sub-regional collaboration, especially in Francophone Africa.. The inter-country structures

¹ The terms “drugs” and “medicines” will here be used as equivalents, as is customary in the countries considered here, although in order to avoid confusion the latter is today in fact more correct.

that are emerging will in many cases supplement and in certain cases supplant purely national activities, but only to the extent that trust between nations in these matters grows and bureaucratic obstacles to interchange (e.g customs duties imposed on samples for analysis) are surmounted.. Work-sharing between the agencies of various countries seems more likely to prove acceptable than any imposition of supranational services or structures.

It is to be hoped that comparative studies such as the present one, and the debate that must follow around them will, by throwing light on the similarities and contrasts between national experiences provide useful pointers for the further development of drug procurement and quality assurance in the future.

1. INTRODUCTION

In July 2007, the European Commission took the first steps to initiate a study of procurement policies and practices for pharmaceuticals, including quality assurance mechanisms, in Sub-Saharan Africa.

It has long been recognized that access to essential medicines and assurance of their quality and rational use, vital as these things are to the attainment and maintenance of health, remain unequal in many parts of the world. Sub-Saharan Africa, with its high burden of poverty-related diseases and its often all too weak health systems, is particularly vulnerable to shortcomings in the supply of quality medicines. Over the years, many different global, regional and bilateral initiatives have been developed to support partner countries in that part of the world and elsewhere in developing and maintaining systems for the procurement of medicines for the public sector; these have commonly extended to closely associated issues, in particular means to assure and maintain the quality of medicines. The World Health Organization has played a vital role, both in developing standards and methods and in providing practical help through its staff and consultants. At the European level, the recently introduced European Programme for Action to confront HIV/AIDS, Malaria and Tuberculosis is intended to tackle procurement and related matters where these epidemic diseases are concerned. In a range of countries, the EC-WHO Partnership on Pharmaceuticals approaches these issues for pharmaceuticals as a whole. There are many more such programmes and projects specific to the countries of Sub-Saharan Africa, often maintained in part with the support of European donors..

Questions repeatedly arise as to the design and the efficiency of these programmes and partnerships and their ability to bring about sustainable development of a healthy drug sector for the future. Partners on all sides have reported both routinely and in retrospective studies on what has been and is being achieved, while international agencies, particularly the World Health Organization, have from time to time investigated the issues. That work forms an invaluable starting point in whatever further studies are undertaken at the present day.

The question might well be asked – and indeed it has been asked of those of who examined the situation in the present connection - whether yet another report is needed. Have there not already been sufficient in the way of consultancies, enough evaluation to satisfy all, and a more than adequate volume of reports on the matter? The best and truest answer is surely that, when one sits down with the existing material in the hope of forming a reasoned view on these matters one tends to be faced with too much paper rather than too little. So many aspects of procurement and associated issues have been looked at from so many angles that one inevitably faces a mass of detail, sometimes coloured by conflicting points of view. One encounters some sound generalizations but also some dangerous ones. What one can do with that material is to distil from it some of the essential matters on which in this field the partners need to take clear decisions, and to formulate, working alongside experienced people working in the field, some of the principles that should underlie those decisions. Above all, one can hope to learn from experience, good or bad, and thereby enable one country to benefit from what has happened in another.

It is against that background that the European Commission decided in 2007 that it would be helpful for all concerned to perform a comparative further study of procurement and associated issues in a series of countries in Sub-Saharan Africa in order to complement the work already carried out by others, without duplicating it unnecessarily. The purpose would be to examine and compare experiences in these countries with particular attention to clear successes and failures and to factors either furthering or impeding progress. Such an analysis would serve “*to provide the Commission as well as Member States with insights into needs for support and potentially relevant actions in the fields of pharmaceutical procurement to help ensure access to quality pharmaceuticals in Sub-Saharan Africa.*”

Examination of a series of situations would enable each individual country to benefit from experience elsewhere, since neither problems nor opportunities in this area are entirely specific to a particular country or sub-region, though within national frontiers one often encounters historical, development, economic or other factors which are to some extent determinant for what can be achieved and what types of effort are most likely to bear fruit.

One would stress that it was emphatically not the intention to develop comprehensive guidelines, let alone rules, for successful drug procurement in this part of the world. The World Health Organization, through its consultations and publications, has over the years laid a well-defined basis for procurement practice and drug quality control, laying down standards and proposing modes of operation; its development of the Essential Drugs Principle and its particular attention to achieving what is most necessary when resources are limited have been and remain of immense value to all workers and institutions in this field. Specialized agencies such as UNICEF and the Global Fund have also created guidelines for their own procurement activities. Building on that firm foundation, the present study has sought to profile a series of specific practical issues that come to the fore when procurement programmes are established, issues that need to be anticipated and dealt with. Various of those factors do not relate to the methodology of procurement itself, but to external influences that inevitably bear on the process, ranging from administrative structures, work ethics and training to transport, literacy and topography.

It is to be hoped that this limited but specific study and the Workshop that (in collaboration with the World Health Organization) is to be devoted to it in May 2008 will contribute to the further development of drug procurement and related activities in a part of the world where much has been achieved but a great deal remains to be done if public health is to benefit to the full.

Editorial Note

As noted in Section 2, Dr Juarez Hygino served as Deputy Team Leader of this study and in addition conducted the three country studies in Central and Western Africa; he also collected and examined material relating to a number of other countries in the Sub-Saharan area. He thereby laid a solid basis for the compilation of this report. Unfortunately, Dr Hygino was taken ill before editorial discussions could take place and the report could be drawn up. The editing of this report has therefore been undertaken by Dr M.N.G.Dukes alone, but making use for certain sections of materials gathered by Dr Hygino.

Tehran, May 7th 2008

M.N.G.D

2. METHODOLOGY

For a limited study such as the present one it seemed necessary to concentrate on the situation in a small number of sample countries. In consultation with the European Commission, six countries were selected for study. Central and Western Africa would be represented by Benin, Burkina Faso and Mali. Eastern and Southern Africa would be represented by Mozambique, Tanzania and Uganda. The countries were considered to provide a reasonably representative picture of the situations pertaining in the French, English and Portuguese-speaking parts of Sub-Saharan Africa.

During an initial period, readily available data from these six countries were examined and collated. Much published material is readily available in specialized libraries and on the internet. Additional material was supplied by the World Health Organization, and during a visit to the Organization in Geneva its staff generously provided much further information on its experience in this matter, as well as proposing a number of issues meriting for study.

Meetings were also held in Geneva with the UN Aids Programme and the Global Fund. Individual consultants thereafter visited the International Dispensary Association (IDA) in Amsterdam, the Centrale humanitaire medico-pharmaceutique (CHMP) in Paris and UNICEF/UNIPAC in Copenhagen. IDA and UNICEF/UNIPAC are both major non-profit suppliers of medicines and medical supplies to public health programmes in Sub-Saharan Africa. A further visit was to Euro Health Group, a Foundation-owned consultancy group in Denmark with extensive experience in Sub-Saharan Africa and in the area of drug policies and procurement programmes.

After this preliminary work, each of the six sample countries was visited by one of the consultants in order to obtain first-hand impressions, to update material on existing reports and to seek the views of national experts and institutions.

Bearing in mind the Terms of Reference, particular attention was devoted to:

a. *The practice of drug procurement*: As noted in the Introduction, the basic principles of drug procurement itself have been very well formulated (and where necessary reformulated and further developed) by the World Health Organization in its publications and teaching. No-one today is likely to doubt the fact that International Competitive Bidding is often the soundest of all practices, nor that well-recognized exceptions to that rule exist. Such exceptions may apply where time is short, or where there is a well-developed national private market, perhaps backed by creditable local manufacturing.

b. *Quality control* On quality control in procurement one encounters a range of mechanisms in use, often with a series of procedures complementing one another. A national drug regulatory system, backed by an adequate laboratory is obviously called for, but what degree of investment in that direction is justified, especially when drugs come from a creditable source? And to what extent will the inspection of foreign manufacturing plants prove trustworthy and cost-effective? These and related issues were examined in the light of each country's experience.

c. Form of supply It proved necessary to examine several more detailed issues relating to procurement policy and donor assistance. As regards the pharmaceutical products themselves, in what form should they be supplied? Is the kit system of supply of Essential Drugs only justified where nothing better is currently feasible , or should one conclude, as do some countries, that it should be accorded a long-term role for primary health care facilities? And does the fact that, according to the MSH Drug Price Indicator Guide, a particular product can be obtained at a bargain price in large plastic bags or bottles justify procuring it in all cases in that economical form?

d. Donor coordination: Failure to coordinate donor-supported programmes is a common point of criticism in this field, and it was necessary to consider how adequate but not oppressive coordination can be ensured. One does still encounter some situations in which donors and their programmes essentially compete, sometimes duplicating one another's work yet on other occasions neglecting essential but perhaps unattractive areas.

During the course of the study it became clear that a number of other aspects deserved attention, and these are considered when the findings of the work are reported (Sections 3 and 6 of this report).

3. SIX SAMPLE COUNTRIES

3.1. BENIN

For statistical and background data see end of this section

Country Review

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Introductory note

Benin has at the national level both a comprehensive Medicines Law (extending beyond drug regulation to cover the licensing and practice of prescribers and pharmacists). It also possesses an official National Medicines Policy that was last updated in 2007. At the regional level Benin is a member of regional bodies (UEMOA, CEDEAO/ECOWAS) but it is notable that the National Medicines Policy has not yet been harmonized with that existing in other member states.

Guidance on prescribing is provided by a National Medicines Formulary, which was last revised in 2006.

Drug regulation

Drug regulation is entrusted to the Directorate of Pharmacies and Diagnostic Examinations (DPED) the scope of which includes the assessment and approval of herbal products.. When granting approval, the Directorate relies heavily on documents received under the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. Licensing of local products is also dependent on the satisfactory outcome of site inspection. . There are about 4,500 licensed products on the national market

Essential medicines

Benin has a national Essential Medicines List , last revised in 2003, covering the different levels of utilisation. This list is used both for public sector procurement and as a basis for the private insurance reimbursement system, and covers all levels of health care.

Public Pharmaceutical procurement and supply system

Since 1989, the Centrale d'Achat des Médicaments essentiels et Consommables Médicaux (CAME) has been the public supply system of Benin.. It handles selection, quantification, procurement, quality control (through the National Quality Control Laboratory, see below), storage, distribution (using both push and pull systems) and some quality assurance in the field. .Products handled by CAME include branded and generic medicines the active substances of which are on the national essential medicines list, as well as medical supplies, laboratory reagents and nutritional products.

As noted above, the public sector procures only those medicines that are to be found on the national Essential Medicines List. . CAME suppliers are companies based in Africa (Benin itself, Ghana, Ivory Coast, Morocco, Tanzania, Togo), Asia (India) and Europe (Belgium, Denmark, France).

Procurement procedures include:

- (i) *Estimation of needs* , carried out by a committee in workshops and based on the critical reassessment of requests/orders received, inventory/controls/stockouts/general overview of adequacy of supply, data on unused supplies, use of epidemiological data, levels of supply (primary, secondary, etc., by percentage), A VEN classification (of Vital, Essential and Non-essential items) is used to set priorities, and to obtain an insight into the supply activities of other agencies.
- (ii) *Prequalification of suppliers*, which may include pre-qualifying tenders (open and restricted), competitive negotiations, special terms for local manufacturers, use of international commercial intermediaries, use of international not-for-profit intermediaries and special terms for individual fields and epidemics). Tenders are bi-annual, with staged deliveries. Documents used are based on those selected by the *Third Meeting of the Ministers of Health of the African countries of the CFA Franc zone, and associated countries, on the Pharmaceutical policy*" held at Libreville, Gabon, on March 23rd – 26th, 1998,.

Quality control and assurance

The Laboratoire National de Contrôle de Qualité des Médicaments et Consommables médicaux (NQCL) is supervised by the Ministry of Health and examines primarily samples from the field. In 2007, this laboratory controlled a total of 1,540 samples; 1,494 (97.01%) complied with the pertinent requirements; 46 (2.99%) did not.. The Laboratory is a member of the Franco-African Network of National Quality Control Laboratories of Medicines. Staff is adequate, properly qualified and trained. Equipment is appropriate and in good conditions. However, the main handicaps are:

- Inadequate premises: The available space is limited and the laboratories are housed in a former office building.
- Limited financial resources: The funds available are insufficient for an efficient and sufficiently extensive control of the medicines on both the authorised and the parallel markets. According to the most recent figures, annual income is only some Euros 86,000, largely paid by the State, which also pays staff costs.

In quality matters relating to procurement , the, CAME also relies on the assessment of suppliers/sources, advance samples and bids, the WHO Certification Scheme (see above), the WHO Inspection Checklist for Drug Receipts, and interchange of information with the

Directorate of Pharmacies and Diagnostic Examinations.

Storage Facilities and stock control

The stores present a number of problems, in particular::

- The facilities are too limited for optimal organization and function
- Too many old (expired?) products are in stock
- Reception and delivery areas are inadequate
- Too few storage racks are available
- Stock control cards provide too little information on the products to which they relate (expiry dates, batch numbers).

On the other hand:

- there is a computer system that does take account of expiry dates and batch numbers – and is used for inventory control.
- Heat-sensitive products are stored in controlled cold rooms or refrigerated areas, as appropriate,
- A procedures manual is available (see reference list).

Pharmaceutical inspection

Pharmaceutical inspection in Benin covers: local manufacturers, importers/wholesalers, retail distributors/pharmacies and the parallel “pharmaceutical” market. Products confiscated from the “official” market because of illegality are burned without being previously analysed..

Regional responsibilities

It may be noted that Benin hosts the Regional Health Programme in West Africa for the 15 member states of UEMOA countries and Mauritania.. This programme seeks to reinforce regional integration between the 16 countries .as regards health policies; it specifically includes issues of pharmaceutical policy. The Programme provides, for instance, financial and technical support to the African Association of Generic Essential Drugs Purchasing Centres (ACAME)) and now plans to undertake a study of the socio-economic determinants of the illicit sale of health products in the 16 countries. Initiation of the Programme was significantly delayed but it is now in progress.

CLOSING REMARKS

Benin has a well-organized pharmaceutical sector where all the necessary legal and administrative elements are in place. Procurement systems are competently operated in accordance with assessment of national needs and with international norms.

It is anticipated that contributors to the Brussels Workshop on May 29th and 30th will be able to provide an assessment of the extent to which Benin has benefited from international support. in the area of pharmaceutical procurement, and the overall adequacy of drug supply.

Current operational problems that require a solution relate principally to:

- the inadequacy of the facilities for drug storage and management as outlined above.

- The very limited facilities for quality control, relating principally to the checking of medicines from the field, including the private market.

It seems clear that future developments in pharmaceutical field in Benin will be related to the increasing integration of policies between countries in the sub-region.

STATISTICAL OVERVIEW BENIN

Population:	6.7 millions
GNI per capita	US\$ 450
Life expectancy at birth:	53 years (2003)
Infant Mortality per 1000	154
HIV prevalence adults	1.9 % (2003)
Adult literacy	46%
Govt. health expenditure;	US\$ 9 per capita (2005) (at average exchange rate)

3.2 BURKINA FASO

For statistical and background data see the end of this section

Country Study

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Introductory and Historical

For a long time, Burkina-Faso retained the French “Public Health Code”, of 1953, as the basis for its medicines law. In 1996, the provisions were updated and adapted to the needs of the country. There are a large number of relevant regulatory texts which have been conveniently summarized in a WHO report (Gamatie et al., 2006). They cover the entire field of dug regulation and also extend into the licensing and duties of prescribers and dispensers.

Burkina Faso has also an official National Medicines Policy, last revised in 2001, and comprising part of the National Plan for Health Development. The document is however not yet harmonised regionally at either the UEMOA or the CEDEAO/ECOWAS levels.

The national Essential Medicines List was last revised in 2005 and as of May 2007 a further revision is pending.. The list covers all levels of healthcare and is the basis for public sector procurement. The latest revision includes herbal medicines, too.

A National Medicines Formulary is expected to be available soon.

Institutional structure and drug regulation

When the General Directorate of Health was established in 1996, one of its divisions was a Directorate of Pharmaceutical Services. In 2002, this latter Directorate was reorganized as a General Directorate of Pharmacy, Medicines and Laboratories. It now has three sections, dealing respectively with medicines issues (registration, regulation and quality control), laboratory services and traditional medicines.

Drug regulation is entrusted to a Commission (Commission technique d'Enregistrement du Médicament et des autres Produits pharmaceutiques) created in 2003, who takes care of all requests and proceed to the pertinent evaluations. SIAMED is available and operational. As in neighbouring countries, regulatory requirements are generally in line with the "*Reference for the harmonisation of the homologation procedures for generics in the CFA Franc zone*

and associated countries” (see references), and WHO recommendations in this area. The Commission also relies on materials available under the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce”
There are currently 3,193 licensed products on the national market.

Public Pharmaceutical supply system

The Centrale d'Achat des Médicaments essentiels génériques et des Consommables médicaux (CAMEG), established in 1992 following the WHO/UNICEF-sponsored Bamako Initiative to improve drug availability,, is responsible for drug supply to the public sector. Its main warehouse, in Ouagadougou, is modern and was inaugurated in 2004.; there is also a secondary store in the capital. CAMEG carries out the entire train of activities relating to procurement and supply from quantification of needs through to storage and supply (push and pull). Quality Control of incoming drugs is subcontracted to the , National Laboratory of Public Health. While quality assurance is handled by the General Directorate of Pharmacy. Products handled include generic medicines (whether listed on the Essential Medicines List or not) as well as medical supplies, laboratory reagents and nutrition products.

Procurement procedures include:

- (i) Estimation of needs (quantification), carried out by a Department of Purchases and Logistics, and based on the critical reassessment of the requests received, data on past purchasing and on actual use available, inventory controls/stockouts/general overview of adequacy of supply, data on unused supply, levels of supply (primary, secondary tertiary, by percentage); a variety of VEN classification is used to set priorities. Epidemiological data are not directly handled by the Department but by a cluster of specific programmes attached to the structure.
- (ii) Prequalification of suppliers, which may include pre-qualifying tenders (open and restricted), use of international commercial intermediaries and the use of international not-for-profit intermediaries. Formally speaking, tenders are biannual, with phased deliveries. However on some occasions it may be necessary to issue several invitations to tender in a year. As in neighbouring countries, the documents used are based on, or variations of, those produced by the *Third Meeting of the Ministers of Health of the African countries of the CFA Franc zone, and associated countries, on the Pharmaceutical policy*”, in 1998, referred to in this document

CAMEG-Burkina Faso suppliers are companies based in Africa, Asia and Europe.

Quality assurance and control

CAMEG- also adopts routine procedures to ensure quality, involving assessment of suppliers, examination of advance samples and evaluation of bids. Use is also made of the WHO Certification Scheme ,WHO prequalification and the WHO Inspection Checklist for Drug Receipts, and there is an ,interchange of information with the regulatory body.

CAMEG maintains its own Quality Assurance and Logistics Service to deal with quality issues inside its premises (including the regional stores. . A procedures manual was published in 2006. .

However CAMEG also has a formal agreement with the National Laboratory of Public

Health, to carry out all necessary drug controls at the Directorate of Control of Medicines and Non-foodstuffs Products. The latter is directly linked to the Secretary-General of the Ministry of Health and plays a major role. In 2007, this laboratory controlled a total of 456 products; 437 (95.83%) complied with the pertinent requirements; 19 (4.17%) did not.. Burkina Faso' NQCL is a member of the Franco-African Network of National Quality Control Laboratories of Medicines. It is also on the way to become a WHO pre-qualified institution. Staff is adequate, properly qualified and trained. Equipment is appropriate and globally in good conditions. However, significant problems comprise::

- A deficient supply of reference substances and reagents.
- Long waiting times (06 – 12 months) for spare parts for the equipment.

It is difficult to identify a budget which is specific to the Quality Control Laboratory, as the State budget for the pertinent activities is not separated from that accorded to the National Laboratory of Public Health as a whole; the latter comprised some 789,686.00 Euros annually in 2007. Nevertheless, its turnover is known: and would seem to comprise some 9% of the total.

Storage and supply

Although the main store at Ougadougou is so modern, some of the procedures in use are less than ideal, e.g.:

- Actually, storage racks and products are not adequately identified
- The stock control cards in use do not indicate products expiry dates or batch numbers

However, heat-sensitive products are stored in controlled cold rooms or refrigerated areas. There is also a “SAGE Gestion commerciale 500” stock control programme in use that does indicate expiry dates and batch numbers – and is used for inventory control.

Inspection

The pharmaceutical inspection system covers: importers/wholesalers, retail distributors/pharmacies and the “parallel” pharmaceutical market that in fact represents an “underground” activity with sales of unapproved products. The risk of the latter to public health is evident and both professional and consumer organizations are strongly opposed to its continued existence. In May 2005, the Government, through the Ministry of Justice, instructed all prosecutors to apply the entire set of legislative means and regulations to combat this illegal drug trade and internationally there was support from the Order of African pharmacists. Other measures have included consumer information and political pressure. It would appear that these various reactions have at least prevented further growth of the “underground” drug market.

Regional involvement and the work of ACAME

Burkina Faso hosts the “Association africaine des Centrales d’achats de Médicaments essentiels génériques” (ACAME), created in 1996 following devaluation of the CFA Franc, to promote the joint interests of public drug procurement agencies in the region. The Association is based primarily in 19 western African countries. Its principal objectives, which could have significant influence in Sub-Saharan Africa as a whole, are:, among others:

- To contribute to the regular supply of quality and affordable essential drugs to African countries.

- To adopt gradually a common policy for quality generic essential drugs supply.
- To help to create Generic Essential Drugs Purchasing Centres in African countries or regions where such centres do not yet exist ;
- To promote the prescription, the delivery and the use of generic essential drugs;

More controversial was an effort by ACAME to transfer primary responsibility for the purchase of certain high priority items from national purchasing agencies to international bodies. The fields involved were those of antiretroviral agents antitubercular drugs and antimalarials. The international bodies that ACAME had in mind include UNICEF and UNDP but also UNITAID, the Clinton Foundation and some western non-governmental bodies. While these latter bodies already play a significant role in ensuring the supply of drugs in these priority areas, any transfer of responsibility to them is opposed to the basic principle of development of national capacity and the evident need to rationalize existing supply systems.

Following further consultation with the Global Fund, UNITAID and others, which led to the Dakar Declaration of December 2006 and an International Conference at Ouagadougou (June 2007) alternative approaches were developed. These were directed primarily to work-sharing between agencies and to better staff training. As regards the procurement cycle and quality assurance systems.. Results are starting to become evident. Currently, three drug supply agencies (those of Benin, Burkina Faso and Mali), are now fully taking care of the provision of medicines used for the treatment of priority diseases, as per their original mission. ACAME is in the meantime supporting the development of uniform procedures amongst its member agencies. A Charter of 107 articles covering institutional and pharmaceutical supply management issues has recently been drawn up.

CLOSING REMARKS

The data on ACAME obtained as a result of the study in Burkina Faso, where it is based, provides an encouraging example of the best type of regional initiative relating to this area of work in Africa, progressively moving towards meaningful work-sharing between countries.

In Burkina Faso itself, one again sees how specific weaknesses in the overall medicinal supply system can undermine the work performed to develop sound procurement. Even such specific matters as a shortage of suitable storage racks or difficulty in obtaining spare parts for laboratory equipment can weaken the overall operation.

STATISTICAL OVERVIEW BUKINA FASO

Population:	13 millions
GNI per capita	US\$ 350
Life expectancy at birth:	48 years (2004)
Infant Mortality per 1000	97
HIV prevalence adults	1.8 % (2003)
Adult literacy	46%
Govt. health expenditure;	US\$ 5 per capita (2002) (at average exchange rate)

3.3. MALI

For statistical and background data see end of this section

Country review

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Introduction and general

Since 1991, Mali has consolidated and extended its pharmaceutical legislation to include all essential areas of drug regulation, inspection and supply, as well as dealing with prescribing and dispensing practice. The system includes the regulation of herbal medicines.

Mali has also an official National Medicines Policy which was adopted in 1998.

Mali also has a national List of Essential Medicines EML, last revised in 2006. The list is covers all levels all levels of health care and includes herbal medicines.. It is used in the public sector procurement and in the private insurance reimbursement system.

Standard Treatment Guidelines (STG) have been available since 2000, while a National Formulary that was updated in 2006 is about to be published.

Drug regulation

In 2000 the Pharmacy and Medicines Directorate (DPM) was created to serve as the national drug regulatory authority. The Directorate has two Divisions, the one dealing both with quality assurance and pharmaceutical economics, and the other with regulatory issues.

Note: A recent WHO evaluation (Trapsida, 2007) concluded that the number of people working at the DPM is inadequate, there is no lawyer attached to it, and the staff in charge of the regulatory affairs is not suited to performance of the tasks allocated to the Directorate in law.. Furthermore, the personnel are not bound by the general code of conduct applicable to government servants, which deals with such issues as confidentiality and conflict of interest.

Regulatory requirements are broadly in line with those set for countries in the CFA Franc area and with WHO recommendations. The system makes use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.. Licensing is a requirement for local suppliers and is based on site inspection.

There are currently 3,012 licensed products in the national market, including 10 herbal medicinal products.

Public Pharmaceutical supply system

The historically famous PPM (Pharmacie populaire du Mali) was created as a State corporation as long ago as 1960-. Since 1993 it has been reorganized under the same name as an “Industrial and Commercial Public Establishment” (EPIC) and has responsibility for all public drug supplies and for distribution. ... The Company has 7 stores and one retail pharmacy in Bamako, as well as 8 regional stores.

The PPM engages in: drug selection, quantification, procurement, reception, quality control of receipts (delegated to the Drug Quality Control Service of the National Health Laboratory), storage, distribution (both push and pull systems) and field quality assurance. Products handed by the PPM include generic medicines (including some items not on the Essential Medicines List) as well as medical supplies and laboratory reagents.

PPM suppliers are companies based in Africa (Benin, Egypt, Ghana, Ivory Coast, Mauritius, Niger, Senegal), Asia (China, India), Europe (Austria, Belgium, Denmark, France, Germany, Holland, Italy, United Kingdom) and North America (Canada, United States of America).

Procurement procedures include::

- (i) Estimation of needs (quantification), this work is carried out by a quantification committee, and based on the critical reassessment of the requests received as well as data on past purchases and on actual use (where available), inventory controls/ and stockouts, general overviews on the adequacy of supply, data on unused supplies, use of epidemiological data, levels of supply (primary, secondary tertiary, by percentage); a VEN classification is used to set priorities.
- (ii) Prequalification of suppliers, which may include pre-qualifying tenders (open and restricted), competitive negotiations, special terms for local manufacturers, use of international commercial intermediaries, use of international not-for-profit intermediaries and special terms for individual fields and epidemics). Tenders are bi-annual, with phased deliveries. Documents used are based on, or variations of, these produced in the sequence of *“Third Meeting of the Ministers of Health of the African countries of the CFA Franc zone, and associated countries (1998)*.

Quality Assurance and Control

PPM has a special Quality Control Service, both centralized and regional, as part of its Supply Department which handles all aspects regarding quality assurance and control, during the prequalification and tendering processes. A procedures manual is available, covering all aspects concerning the Company activities

In addition, PPM has a formal agreement with the National Health Laboratory, to carry out all necessary drug controls in its Drug Quality Control Department. (see below)

PPM routinely assesses suppliers, advance samples and tender materials as well as relying on Certificates supplied under the WHO Certification Scheme. and on the WHO prequalification procedures. Information is exchanged with the regulatory authorities, and the procedures specified in the WHO Inspection Checklist for Drug Receipts are followed.

The National Health Laboratory, through its Service of Drug Quality Control, is the principal centre for quality control of medicines.. In 2007, this laboratory controlled a total of 919 samples of different products: 907 (about 98%) samples complied with the pertinent requirements; 17 (about 2%) did not. The laboratory is situated in new premises and newly equipped, with EDF support. Staff is adequate, properly qualified and trained.

Storage, stock control and distribution facilities

Stock control cards, which indicate expiry dates and batch numbers, are supported by a computer programme; the latter is a locally developed and upgraded version of “SIGMED – Système intégré de Gestion de Médicaments (Integrated System of Drug Management)”, for inventory control.

The main PPM stores, located in the centre of Bamako, are old but well maintained and organised., though it should be noted that there is a severe important lack of storage racks. Heat-sensitive products are stored in controlled cold rooms or refrigerated areas, as appropriate.

Inspection

The Mali Health Inspection Authority was created in 2000. It is placed under the direct control of the Minister of Health and comprises two Departments: Pharmacy and Medicines, and Medicine and Hygiene. Pharmaceutical inspection covers: importers/wholesalers, retail distributors/pharmacies and the parallel but illegal “pharmaceutical” market (locally identified as “*Pharmacie par terre*” (“*On the ground pharmacy*”). In this connection it is important to point out that a national commission has been specially created to deal with the problems posed by this “unofficial” market, but that the Health Inspection Authority does not have the necessary financial, human and logistic resources to enable an important work in this area.

CLOSING REMARKS

The system in Mali has much in common with that in other francophone countries in the region, and cooperation is generally developing well.

The generally well-organized system for the control and supply of medicines is impeded on a few points of detail such as the lack of storage racks in otherwise exemplary storage facilities; relatively trifling expenditure in these areas would result in considerable improvement in overall operation..

Mali is one of the countries where an “unofficial” market in pharmaceuticals exists alongside the formal system. Commendably, an official body has been created to study this issue but manpower is likely to be insufficient to deal with it. It is to be hoped that the Brussels Workshop will succeed in throwing more light on this area in which obvious risks for public health exist.

STATISTICAL OVERVIEW MALI

Population:	13 millions
GNI per capita	US\$ 4,835 m
Life expectancy at birth:	48 years (2004)
Infant Mortality per 1000	121
HIV prevalence adults	1.9 % (2003)
Adult literacy	46%
Govt. health expenditure:	US\$ 6 per capita (at average exchange rate)

3.4. MOZAMBIQUE

For statistical and background data see annex

Country review

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Embassy of Norway	Clarissa Barbosa-Fernando, donor coordinator, drug aid
DFID (U.K., Maputo)	Marie Castelo-Branco, Policy & Programme manager
US AID	Polly Dunford, Country Director Benedito Chaque, Logistics Activity Manager, Marilyn Noguera, Country Director, John Snow Inc.
Swiss Development Corp.	Fatima Aly, Administrator of Common Fund
WHO Consultant:	Paul Spivey

Introductory note

The drug sector in Mozambique has been the subject of a series of evaluation reports, notably from a number of missions sponsored by DFID (UK) between 2001 and 2007 and an extensive programme of evaluation by WHO/HQ (2005-2007), while one still awaits release of a further WHO report on improving prequalification methods, compiled after a mission in March 2008.

The procurement and quality control arrangements have in some respects been unusually complex, while political decisions on the sector (some of which are not yet fully executed) have affected structure and procedures; while further changes recommended by WHO are only now being implemented. The present short report draws in part on the WHO evaluation, updating the facts as necessary. The situation is still transitional and some speculation is unavoidable.

Procurement and supply management: organizational principles

Officially, the purchase and supply of medicines for use in the National Health Service is planned and managed by the Ministry of Health. In fact it has over a long period delegated this task to the CMAM (Central de Medicamentos o Artigos Médicos). In turn, there was a complex arrangement by which CMAM theoretically delegated many of its tasks in procurement, warehousing and distribution to the MEDIMOC firm, a former state enterprise that was later privatised. In reality, however, CMAM retained a firm grip on much of what MEDIMOC did, notably as far as procurement was concerned; this resulted in a complex (and apparently labour-intensive) interaction between the two bodies. The arrangement was

much criticized and when problems arose in public drug supply there was a tendency to blame MEDIMOC . Within the last eighteen months, however this entire situation has been subject to change at the instigation of the present Minister of Health.

While for a number of years the thinking moved in the direction of improving the efficiency of MEDIMOC by putting it into competition with other privately-owned wholesalers to handle public procurement and supply, the current Minister decided, apparently in consultation with WHO, that the entire operation should be taken away from MEDIMOC and handled instead by CMAM itself. This process is now (as of April 2008) largely complete.. .

This most certainly simplified the situation, but it would be fair to say that for several reasons it created something of a crisis in the short term:

- In 2007 the Minister also relieved some senior experts in the drug field, including CMAM staff, of their positions; they included both expatriates and certain Mozambique nationals who had been paid largely by donors; they were replaced by young but well-qualified and academically trained Mozambique nationals, essentially on government salaries. CMAM was thus obliged to take over the work of MEDIMOC at a time of internal staff shortage, training and readjustment.
- The MEDIMOC operation itself had been very far from perfect. Quite apart from suggestions of corruption, its network of nine warehouses was generally in poor condition and poorly staffed. In some instances it was not even clear where ownership of a particular warehouse lay.
- At the express wish of the Ministry, no MEDIMOC staff members were offered positions with CMAM.
- To complicate matters further, the construction of a modern and urgently needed central drug warehouse at Zimpeto, outside Maputo, was rudely interrupted in March 2007 when a nearby ammunition depot exploded.

It is very much to the credit of the new management of CMAM that its assimilation of the entire process of procurement and supply has proceeded so far within a limited time, but much remains to be done.

Financing of drug supply

The procurement of drugs and medical devices for the public sector is in principle financed by the Government, but with an important degree of support from a series of donors.² The bulk of the latter support was from 1999 onwards provided through the so-called Common Fund or “Medicines Pool” (FCM, Fundo Comun de Medicamentos), administered by the Swiss Development Corporation and having a bank account in Switzerland.. Contributions to the fund attained US\$ 28.9 million in 2006 and annual disbursements have been at a similar level. The UK and Norway have over the years been the major contributors.

Four other sources of funding have however become of increasing importance in recent years:

- a. An increase in direct state funding to the drug sector, attaining 20% of total drug funding in 2007

² Currently supported by the European Community, Denmark, Finland, France, Ireland, The Netherlands, Norway, Switzerland and the United Kingdom.

- b. The creation by the Government of a health sector wide common fund (PROSAUDE) which can also contribute to the drug sector, and which covered 9% of drug costs in 2007.
- c. An increase of “in-kind” donations (attaining 10% of aid in 2007)
- d. Contributions from other sources (PEPFAR, USAID, GAVI., World Bank) attaining 13% in 2007.

In all, therefore, these contributions amount to some 52% , now slightly exceeding the 48% contributed by the Common Fund .

It may be noted that a small part of the national contribution is based on “user fees” but that in 2007 the present Government declared its intention of abolishing these fees and henceforth supplying drugs free of charge to the entire population (see later);

Procurement methods

In line with national legal provisions on procurement, competitive bidding is required except in emergencies. The bulk of procurement (including that of complete drug kits) is through *Limited Competitive Bidding* (LCB) using a list of prequalified international wholesalers which was drawn up some years ago by MEDIMOC and CMAM with the aid of an international consultant. According to CMAM, the process takes some 4 months from planning to the signing of contracts and a further 4 months until goods are received.

International Competitive Bidding (ICB) is used only where a financing partner (notably the World Bank) insists upon it, and is considerably slower (12-24 months from planning to receipt of goods)

Kits, essentially comprising a “push” system of supply, are the basic units of supply for primary health care, three types of kit being provided depending on the staffing and expertise of the units concerned. The kits are packaged overseas; their composition has not always kept up to date with changes in therapeutic policy (e.g.chloroquine continued to be supplied for malaria long after it had been superseded in the national malaria programme.)

Quality control

It is clear that an assurance of quality is to a large extent sought by using the *prequalification of suppliers*. The list of prequalified foreign suppliers³ needs revising, and WHO is now (2008) assisting in this process. There has also for a number of years been *external supervision* of quality by SGS⁴ and by Intertec. SGS assists in tender evaluation on behalf of donors (it is not involved in tenders for state-funded supplies; Intertec acts on behalf of the customs authorities, checking goods at foreign sources of supply prior to shipment).

At any stage of procurement the procuring agency can however send samples for testing to the national *Quality Control Laboratory* (LNCQM). With its staff of 28 (including five with university qualifications) the Laboratory has the capacity to examine some 600 samples yearly; this is considered entirely inadequate, especially since the Laboratory is also supposed to examine samples submitted from the field. The Laboratory does not have a true budget of its own but is heavily dependent on the fees earned by examining samples from

³ There is until now no local pharmaceutical manufacturing

⁴ Société General de Surveillance, Geneva, Switzerland

CMAM or others and apparently also on the financing of reagents by CMAM, with funds taken from the drug budget.

A consultancy report in 2003 noted considerable shortcomings in the laboratory facilities, and it is disappointing to note that, despite the call for improvement at that time which was discussed with the then Minister, the very thorough WHO study in 2007 still noted similar failings and was forced to make a long series of recommendations for expansion and upgrading. Broadly speaking these relate to: Improved and enlarged accommodation ; the current housing is shared with the laboratory of Food and Water hygiene. WHO called for:

- Improved training of staff in analytical techniques; improved motivation of staff
- Qualification of equipment and improved maintenance
- Acquisition of a broader range of equipment; currently only a proportion. of the drug items on the market can be analysed with the methods available and functional in the laboratory.

The WHO report indeed considered this issue sufficiently pressing to urge that, as a temporary measure, some of the work that needs to be done should be subcontracted to another (WHO-approved) laboratory. Funding for the above changes is still being sought. As regards external facilities: it is at the present moment uncertain to what extent CMAM, once it is fully operational in its new role, will continue to make use of these; the SGS role will presumably continue so long as donors are directly involved; since Intertec is primarily operating for the Customs authorities it will no doubt continue to do so.

Despite the use of prequalification there is a clear need for the creation and maintenance of a competent Quality Control Laboratory for the drugs sector, as recommended by WHO. It seems unlikely that use will ever be made of the regional laboratory network established by the Organization many years ago; no samples ever seem to have been sent to the WHO-designated Laboratory in Nairobi and the current staff attribute this to slow postal connections and the liability to customs duty of samples sent for analysis.⁵

Adequacy of public drug supply

At the time when Mozambique recovered from its long period of civil unrest (\pm 1992) supplies of drugs were grossly inadequate. The massive donor support of the ensuing decade greatly improved the situation, but as late as 2003 both internal and external evaluations still considered that supplies in the public sector were “at a bare minimum level”. Improvement was however still continuing, and when in May 2006, WHO examined the mean availability of 15 key medicines in five sample regions it found this to be 86.7% at the warehouse level and 86.7 in public health facilities. Apparently there are however variations from region to region; in 2003 a study found that in more than half the districts examined there were stockouts of one or more essential drugs, sometimes lasting for many weeks.

The private sector

During the WHO study, figures for a market share of 30-40% were quoted for the private market. It is however only significant in the cities and larger towns.

⁵ This is an issue on which WHO may wish to comment

Counterfeits

The main WHO study recommended coordinated action to combat counterfeit supplies, but no estimates of the extent of this practice, that varies widely from one sub-Saharan country to another, appear to be available for Mozambique.

Corruption and theft

Although various statements have been made as to the extent to which corruption exists (or occurred when MEDIMOC was in control of supply and delivery) it does not seem possible to quantify the problem. Theft certainly occurs, probably most markedly at the lowest level of the system.

Law and regulation

A fairly comprehensive draft Pharmaceuticals Law was prepared as early as 2003 with consultant assistance, but for a long period it did not progress through the legislature. Passage now (April 2008) appears imminent, and although it is not known whether the draft has been substantially changed its enactment is likely for the first time to provide a proper legal basis for the drug regulatory system and other relevant institutions. A number of senior appointment to the new drug regulatory system have been made. With the very limited regulatory system existing until now there has been no significant collaboration with the regulatory authorities of neighbouring countries but in principle approval will be more readily given to products already approved by the FDA or within Europe; it would seem reasonable to extend this practice to South Africa, since that country is likely to be involved in training Mozambican regulators and in practice trades with many of the same foreign producers as does Mozambique.

Positive achievements

Mozambique has been going through a long period of recovery, and it is clear that in the drugs field massive donor input has *contributed greatly* to improvement in the supply and health situation over a period of some sixteen years. Ensuring reasonably adequate drug supply over a long period also had less direct but nevertheless evident and highly beneficial effects. It would be fair to say, for example, that one of the essential reasons why over a decade CMAM was enabled to build up a competent staff was the long-term assurance of donor funding for medicines, providing the prospect of meaningful employment for the foreseeable future.

- During much of that period, there has also been *positive political support and understanding*.
- It is encouraging, too, to observe the progressive increase in the contribution made from *national funds*, to which may be added the increasing ability of part of the population to secure drugs from the private sector when necessary.
- Structurally, a positive aspect of the donor scene has been the functioning of the *Common Fund* financed by as many as nine donors, with its policy of critical disbursement from a fund still maintained in a third country, until such time as full responsibility can be transferred to the national authorities.

The prolonged maintenance of a *kit system* in a country such as Mozambique is generally adjudged defensible. Although such a system is based on a very rough-and-ready estimate of

average district needs in primary health care, it has to be said that, having set its objectives the system has succeeded in meeting them completely (100% supplied), whereas in the “pull” system of specific ordering (“Via Classica”) there are clearly unsatisfied needs, with only some 60-80% of orders being met. As a “rough and ready” system operating on a “push” basis rather than on specific evidence of needs, the use of kits does involve a degree of wastage, but it simplifies procedures and probably reduces the risk of loss and theft. That said, however, the composition of the kits needs to be reviewed periodically. . One problem that now needs to be solved concerns the inclusion in kits of a multicomponent artemesin preparation from Novartis; although the recommended WHO prices have been secured for the product, its inclusion has massively raised the cost of kits, most other components of which are simple generics.⁶

Finally, as noted by WHO, the *low prices* that have characterized the drug sector in Mozambique have been important factor in promoting access.

Past and present problems and sources of concern

During a sixteen-year period of donor assistance in the pharmaceuticals field, Mozambique has experienced a series of vicissitudes, and various of the difficulties and doubts arising during that time are instructive for future planning. In arbitrary order they may be summarized as follows:

1. Inefficient internal structures

- For a long period, the Quality Control Laboratory has reported to the National Health Directorate, having no links in authority or organization to the drug regulatory sector. (This is now being corrected)..
- The Laboratory has shared facilities with another state laboratory having different tasks (Food and Water).
- The complex interrelationship between MEDIMOC and CMAM, with the latter controlling and checking at every stage of the procurement process has led to much bureaucracy, expense and delay. This again is essentially corrected by transferring MEDIMOC’s tasks to CMAM, but for the reasons noted above it is happening at a singularly difficult moment.

2. Unexpected political measures While as noted above the donor effort has generally been complemented by strong political support within Mozambique, there have been problems, some attributable to a certain reluctance to benefit from foreign experience . In particular:

- A longstanding consensus between the Government and drug donors on the creation of an effective drug regulatory system, by enacting a law that was already drafted, was for several years not put into effect, weakening the entire drug situation
- A number of experienced senior staff who had come to play a vital role in the drug procurement and management process were in 2007 discharged and replaced by inexperienced newcomers. Bearing in mind the severe shortage of

⁶ During the discussion of this paper, the comments of WHO participants on this point will be appreciated

- such experience in Sub-Saharan Africa as a whole these measures have unavoidably weakened CMAM for a time
- A reasonable recommendation that, in view of the rapid growth of a competitive wholesale drug market in Mozambique, Medimoc be put into competition with other firms capable of procurement, while apparently accepted by an earlier Government, was not put into effect. Instead, in a later phase, the Government decided to transfer its functions to the by now weakened and overburdened CMAM.
- At a crucial moment, with the system already under strain, the Government announced its intention of providing free medicinal care to the entire population. While idealistic and politically attractive this would remove a source of income (user fees). It might also increase demand unreasonably, although in fact some of the users fees are extremely low (5 Meticals).
- Up to the present CMAM has been bound largely by governmental salary guidelines and has been less able than a firm like MEDICON to raise incomes to a level that would attract and retain staff in this problematical field where expertise is in such short supply. CMAM is however now entitled to provide a modest ““top-up” on governmental salary levels, that may be sufficient to assist it in this respect.

3. Uncertain basis for needs assessment As the various consultancies have made clear, needs assessment has been based very largely on past usage and requisitions thus perpetuating whatever patterns of over- or under-use or inappropriate distribution may exist. WHO has made concrete recommendations on the need for a proper system for assessing drug needs and these need to be instituted if funding is to be optimally used. As the WHO has emphasized, however, there are a large number of simple everyday drugs for which demand is relatively constant and for these there is no need to engage in complex needs assessment.

In 2007 the Health Minister stressed the need for practising physicians to be involved in needs assessment. The WHO report of 2007 expressed qualified agreement with this view insofar as physicians were expressing the needs of their own specialities.

The HIV/AIDS field is one in which it may be noted that drug supplies are now very closely attuned to feedback from the field on the numbers of patients having need of them; this situation is exceptional. USAID has assisted in this area and is now helping in the expansion of the method to a number of other priority areas of treatment.

4. Incomplete coordination of donor efforts In view of the success of the Common Fund with 8-9 participants it might have been helpful to invite new donors and vertical programmes, including agencies providing in-kind support to join the Fund or at least to engage in closer consultation on drug needs and experiences. Informal consultation does however now take place (there was a very useful round-table discussion during the present field trip) though there have in the past been instances of a new donor taking ill-advised steps that could have been avoided through contacts with those more experienced in the field. Perhaps the best guarantee for donor coordination lies with the recipient partner ; in the case of Mozambique it has been observed that CMAM, handling supplies and finances from various sources, has on many occasions astutely welded them into a logical entity, doing much to avoid duplication or gaps between complementary inputs. .

5. Hesitation in full attainment of SWAP It appears to be agreed that donor aid must move progressively towards a Sector-Wide Approach (SWAP) but in some quarters it is felt that for a considerable period a degree of control will need to be retained by the donor community. One cannot avoid the impression, repeatedly encountered, that the health management system as a whole (and this can be seen in many countries) tends to underestimate the role of medicines in health care, particularly where other means of care and treatment are in short supply. The pressures to use available funds for purposes other than drug supply can be extreme. In Mozambique the Department of Finance appears on occasion to have diverted PROSUAD funds intended for the drug sub-sector and employed them for other purposes (e.g. purchase of bed nets). Such concerns seem to underlie the hesitation that one encounters about entering into complete SWAP commitment with the risk that drug expenditure may suffer at the expense of other pressing priorities. In such matters, as will be considered below, it could be that strong and specific central management of the pharmaceuticals sub-sector as a whole is called for if priorities are to be handled properly.

CLOSING REMARKS

1. As noted at the outset, Mozambique now finds itself in the *transitional situation* that is likely to occur in any country as the phase of massive donor support to the drug sector is rounded off. National development has reached the point where the donor community has to abandon any paternalistic pretence of knowing what is best for the country concerned. In Mozambique, one example of the pain that may be involved in transition is likely to concern the move from the successful Common Fund to a SWAP situation. Another concerns the fairly abrupt introduction of “Mozambification” with the departure of experienced managers; it was perhaps wise to insist that a young generation of professionals take control. It was also certainly defensible to insist that the awkward operational arrangement between CMAM and MEDIMOC be abolished, despite the transitional problems that ensued. Even if there may have been controversy as to how to handle the MEDIMOC situation, some sort of drastic change was needed.

It is however clear that in all these respects the new system now coming into being will presently have to prove itself to the population; it will no longer be possible to blame expatriates, an older generation of managers or the creaking MEDIMOC for the shortcomings of the drug system.

2. Surveying the overall scene one senses the *need for firm and balanced management of the pharmaceutical scene* in all its aspects. Overall drug policy is now widely accepted as a necessary entity in many countries both to optimize operation of the drug sub-sector and to ensure that it achieves and retains a proper place in health care. The need seems particularly acute in Mozambique when one takes into account such factors as:

- the progressive expansion of the National Formulary to list more than 800 drugs, apparently under pressure of physicians. It seems very doubtful indeed whether a public sector list of this breadth can be justified so long as basic needs for essential drugs (e.g. 300) have not been fully met across the country, and bearing in mind the complementary role of a growing private sector.
- known instances in which political pressure by the medical profession or individual specialists has distorted priorities in drug supply, inevitably at the risk of depriving less privileged parties.

- The manner in which, following massive accidental damage to the ambitious new central medicines warehouse there was a period of what one might call stunned inaction for many months before policy was adapted to meet this setback

The fact that the Minister of Health has in the recent past intervened personally and decisively in various matters specific to the drug sub-sector (even to the point of examining all individual tenders and issuing detailed issuing instructions on other matters may have raised some controversy but it was surely necessary in the absence of a strong manager for the drug sector as a whole. In the long run, however, it is not reasonable to expect a Minister, who has so many other duties, to deal with all this.

Perhaps one of the most important legacies that a donor programme might hope to leave behind, apart from an adequate supply of medicines and vaccines, is a comprehensive and strong management of the entire drug sub-sector as a whole.

STATISTICAL OVERVIEW MOZAMBIQUE

Population:	19 millions
GNI per capita	US\$ 270
Life expectancy at birth:	42 years (2004)
Infant Mortality per 1000	104
HIV prevalence adults	12.2% (2003)
Adult literacy	46%
Govt. health expenditure;	US\$ 8 per capita (2005) (at average exchange rate)

3.5. TANZANIA

For statistical and background data see annex

Country review

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Introductory note

The drug field in Tanzania has been examined in several recent consultant missions having a heavy emphasis on procurement and associated issues. A limited study for WHO was carried out in 2006 and much more extensive study, jointly commissioned by the Ministry of Health and Social Welfare and the donors (Health Development Partners) was conducted over a period of some months in 2007. There have been no significant changes since the teams reported on their findings, though some of the findings are being actively implemented. The present overview therefore relies heavily on this previous work, the value of which is amply confirmed by interviews.

Outline of history

Unlike some of the other countries examined in the present study, Tanzania has experienced a relatively long period of smooth development, and the various institutions involved in drug procurement and supply have generally functioned well. Criticisms and recent proposals for change relate not so much to fundamental issues as to matters of detail on which there is room for improvement in performance or capacity.

Tanzania has a well-organized system of health care providing some 80% of the population with access to health services, while more than 90% of the population live within 10 km. of a health facility. Some two-thirds of these facilities are supported by government or parastatal organizations, while 15% are operated by religious or other non-governmental bodies.

A series of reforms have been ongoing since 1994 , aimed particularly at improving service to the rural poor. Much donor help has moved from specific assistance to a Sector-Wide Approach (SWAP); while national financing mechanisms now include a national insurance scheme, community health funds and a degree of cost sharing.⁷ There has been considerable decentralization of health delivery; while the Ministry of Health and Social Welfare retains overall responsibility for the performance of the services, it allocates available funding to the 113 local authorities and to hospitals as well as providing subsidies to voluntary agencies in the field.

⁷¹ User charges in fact contribute less than 2% of costs.

A National Drug Policy has existed since 1991, while a Pharmaceutical Master Plan was put in place during the decade from 1992 to 2002, though both have been found by recent studies to be in need of some updating. The Tanzanian Food and Drugs Authority (TFDA) handles regulation and inspection and is well-reputed while the Medical Supplies Department (MSD) is responsible for procuring drugs and supplying them to hospitals and to primary health care facilities. The entire drug sector is supervised by the Ministry's Pharmaceutical Supplies Unit (PSU; see later).

Financing of public drug supply

As of 2007, the national programme (that naturally includes donor contributions through SWAP) provided some 53% of the financing for drugs in the public sector, while 47% was provided by the vertical programmes; the latter proportion has continued to increase and as of 2008 considerably exceeds national finance.

a. National Programme: The Ministry of Finance, that accords a high priority to drug supply, has a specific budget for drugs and disburses this on a quarterly basis to the Ministry of Health and Social Welfare, where it is held by the Ministry's Pharmaceutical Supplies Unit. Release from the Ministry of Finance is conditional upon the Ministry of Health's having submitted at the beginning of each financial year both a cash-flow plan and a procurement plan. It is up to the Ministry of Health to decide how the funds shall be divided between the various types of facility and the various regions of the country. Once received from Finance, the funds are then allocated to the Medical Supplies Department so that it can engage in procurement and supply.

One might add that PSU is well aware that the present allocation of funds to regions relies too heavily on population figures; a revised formula is being devised to take account of regional variations in poverty and morbidity.

b. Vertical Programmes: The largest vertical programmes are those dealing with vaccines (Extended Programme of Immunization= EPI), HIV/AIDS (National Aids Control Programme = NACP), Tuberculosis and Malaria. The supplies procured within these programmes are all stored and distributed by the Medical Supplies Department.

The Medical Supplies Department

The Department is essentially a government-owned wholesaler with several interrelated tasks: procurement, storage and supply of essential drugs to units of the public health service at all levels. It does not have a monopoly in this, since it competes with some 200 private drug wholesalers who also sell to public sector units, while at the same time serving private pharmacies. The Department also engages in:

- Similarly, procurement and supply of essential drugs to mission-based and other NGO units
- Procurement and supply of indent-packaged drugs (see below)
- Procurement of certain of the drugs required by the various vertical programmes (others are procured by these programmes themselves through Crown Agents. UNICEF etc.) and storage and supply of all these drugs for the various vertical programmes.

The Medical Supplies Department should in principle be capable of operating without loss, since it normally only procures drugs when it had received the necessary funding from the Ministry, and in any case it is able to charge a handling fee of 17.4% for its work.. At one

stage in the past, MSD actually had built up a financial reserve that served as a buffer. This reserve was exhausted, apparently primarily because of delayed payments by the Ministry for kits, which the Department was obliged to provide to the periphery even where payment had not been received. Another factor is however the loss incurred on handling items for certain vertical programmes (see later).

Per capital expenditure on drugs (public sector)

This is somewhat difficult to estimate, since existing figures may or may not include the contribution of the vertical programmes. The best figures appear to be those for 2006 from the Drug Tracking Study of 2007:

Essential Drugs	US\$ 0.70
Vaccines (EPI)	0.14
Vertical Programmes	0.77

Essential drug expenditure constitutes about 11% of total public health expenditure. In 2005 it was estimated that the government contribution to the total costs of drugs and supplies in the public sector was some 75%, with the remainder coming from donors, but the 75% in fact includes certain donations as well as funding from GAVI and the Global Fund.

It is also notable that in fact the total volume of funding allocated by the government to drugs was in 2005/6 not fully utilized, only some 88% being spent. There appear to be several possible reasons for this, notably:

- a. Failure to fill orders where drugs were out of stock
- b. Delay in payments by the Ministry to MSD, especially at the beginning of the financial year when negotiations are conducted between the Ministries of Health and Finance.

Donors

Most of the donors active in the health sector have entered into a SWAP agreement and do not specifically earmark funds for the drug sector; the proportion actually spent on drugs therefore depends on the contacts between the Ministry of Finance and the Ministry of Health, as explained above.

Danida (Denmark) by contrast does specifically support the drug sector, and does so in three ways:

- Support to the Medical Stores Department in replacing the kit system with an “indent system” involving specific ordering
- In the framework of Health Sector Programme support Phase III, helping to improve drug supply management and rational use
- Financing a pilot project through the “Mission for Essential Medical Supplies” to improve drug utilization in rural hospitals

The kit system

The National Drug Policy of 1991 laid down the principle that the kit system of drug supply was purely an emergency measure that in due course must be phased out. As in a number of other countries, the kit system has therefore indeed been progressively eliminated because of its inflexibility. The “indent system” that replaced it was something less than a pure “pull” system. Health centres and dispensaries could indeed place specific orders with MSD for

the drugs in its catalogue that they needed, but this was subject to a quarterly maximum sum allocated to each centre when the budget was established. If an order exceeded the unit's budget, MSD was authorized to reduce the quantities or the range of items supplied. The so-called ILS (information logistics system) is a recent modification of the indent system to include STI and reproductive health products as well as general drugs.

As of April 2008, the original kit system is still operating in two districts where the staff have not yet been fully trained in stock control and ordering; the Pharmaceutical Supply Unit, with assistance from the consultants JSI,⁸ are providing the necessary teaching

Procurement methods

MSD is obliged to follow the provisions of the Public Procurement Act of 2004,⁹ which requires it to use the tender method, employing International Competitive Bidding (ICB) and Limited Invitation to bid (LIB). Local tendering is also used, only Tanzanian firms being eligible to participate.

Prices obtained are generally very favourable. The 2006 study found the average lead time for ICB to be 9-12 months. Where necessary to maintain supplies, existing tenders can be extended. Direct or negotiated procurement is permitted in emergencies or where there is no reasonable alternative. A relatively high proportion of items are procured from local manufacturers and local importers where lead times are shorter.

Estimates of procurement levels needed to maintain adequate stocks

In theory, MSD operated for a long time on a formula for drug procurement that was based on estimates of "Average Monthly Consumption" (AMC); a so-called "3+6+9" rule was applied:

- a. Safety stock to be kept centrally at MSD: 3 x AMC
- b. Additional quantity to be in stock at MSD: 6 x AMC
- c. Stock currently on order by MSD: 9 x AMC

Because of problems experienced with cash flow, the level of procurement had to be reduced for some months in 2005/6 and a "3+3+6" rule was applied instead.

Stock levels and stockouts

The operation of the system as described above was subject to particularly critical scrutiny in the 2007 study in view of reports that stockouts were relatively common. Though the seriousness of the situation varied, one may note that an internal MSD report in August 2006 found that 144 out of 202 "vital" items were out of stock as were 212 out of 301 "essential" items.¹⁰ Both that work and the more limited study by WHO in 2006 confirmed a series of more or less serious shortcomings in the actual operation. Looking at the same issue at another level: when 187 consumers seeking drugs were interviewed in 2007 it was found that only 58% obtained *all* the medicines that had been prescribed for them, the most usual problem being non-availability of the remaining items in the health facility; as a rule, the

⁸ John Snow International

⁹ It may be noted that the entire Public Procurement System, affecting all sectors; is currently under review.

¹⁰ The terms "vital" and "essential" are as used in the so-called "VED" classification of medical needs for drugs which classifies items as vital, essential or desirable.

individuals concerned then turned to the private sector to obtain the items in question. The average availability of individual drugs in health centres was found to be less than 50% and it was only a little higher in the public sector dispensaries (58%). Very low availability of essential drugs was found in some district hospitals (as little as 51.3%) and it is striking that in all parts of the country mission hospitals had a higher level of availability.

Multiple causes of this situation were detected:

- a. The Ministry of Health commonly released quarterly funds too late. Particularly at the beginning of a financial year, as noted above, this was due to the negotiations between the Ministries of Health and Finance to establish the budget on the basis of the proposed cash flow plan and procurement plan.
- b. Suppliers delivered goods later than intended. It would appear that because of the tendering procedure suppliers tend to accord MSD a lower priority than other clients which are able to negotiate longer-term contracts. The 2007 study showed that less than 50% of procured items arrive on time.
- c. Estimates of “average monthly consumption” had been too low, since they were based on past performance, including “rationing” and failure to supply some orders at all, because of stockouts.
- d. The ORION computerized administration of stocks and orders at the centre was in need of further development, e.g. in order to automate allocation of batches leaving the stores according to the “FEFO principle (“First expiry, first out”). The system was also clogged with less useful reports and on occasion collapsed completely. In the periphery, stock administration was not computerized at all. USAID is providing assistance with updating the system and ensuring smooth online links with the regional warehouses, but ORION may need replacing entirely.
- e. Staff were in various respects insufficiently trained, e.g. to identify opportunities to fill an order for an “out of stock” drug by supplying an acceptable equivalent (e.g. a different packaging size or strength), or in checking for and disposing of expired drugs.
- f. The rigid “3+6+9” principle for ordering could better be modified to take account of the “vital” or “essential” nature of certain items and those items of this type which are in frequent demand; for these, a larger reserve of stocks would be desirable

Quality Control

While in the past quality was a recurrent problem, this now seems to be well in hand. The principal assurance of quality is that provided by the provision and examination of samples by the supplier submitting a tender, complemented by the inspection of samples taken both at the port of entry and from the field and examined by the Food and Drug Administration. In addition the Medical Services Department maintains its own quality control laboratory to examine samples when there is any reason to doubt their quality; difficult analyses are delegated to an academic laboratory. There are however some risks to quality as a result of the unsatisfactory state of the storage facilities in a number of the provincial medical stores, including poor hygiene, inexpert supervision and the common absence of air conditioning; the Director General himself is of the opinion that quality controls at that level need to be intensified.. Expiry at the various levels of supply does not appear to be a major problem, particularly since stocks move so rapidly and are soon exhausted, but the 2007 study recommended more extensive stock feedback and controls

throughout the system to counter possible problems on this score. In principle MSD does not issue products with a remaining shelf life of less than three months, but it seems doubtful whether its stock administration is yet sufficiently strong to ensure that this criterion is consistently met.

Performance of Vertical Programmes

The vertical programmes mostly operate on a “pull” system, though some supplies go through a carefully monitored “push” mechanism.

As noted above, the vertical programmes route all their supplies through MDS. Bearing in mind that at one stage there were some 30 vertical programmes operating independently this is a considerable achievement. In principle each vertical programme could use commercial wholesalers but preference is given to MDS because of its countrywide distribution and because, whatever the current deficiencies of its computerized stock management system, the organization can supply the donor/partners with information on the stock situation, distribution figures and current batch expiry dates.

Each programme negotiates the form of payment to MDS for its services. However, the payment levels for two of these programmes (NACP and the Global Fund) were found to be unrealistically low, even taking into account that the Ministry pays a proportion of the distribution costs; the result has been a net loss to MDS on the operation.

That said, the vertical programmes have exercised more complete control over the stock situation than has the programme of essential drug supply, so that stock-outs are much less common. This in part reflects the greater staff capacity (an higher standard of supervision) in the vertical programmes, and the insistence placed by these programmes on regular and precise feedback from, MDS.

Corruption

Although the issue of corruption is widely discussed in the media and elsewhere as comprising a national crisis (“....It is now our way of life..”¹¹) one has assurances from various sides that it is not a serious problem in the drug supply sector.

Performance of PSU

As noted above, the Ministry of Health’s Pharmaceutical Supplies Unit (PSU) is among other things supposed to monitor the performance of MSD, but it has in fact a very broad responsibility that extends through to all aspects of drug policy from procurement to rational use. In fact, PSU is only minimally staffed and not yet sufficiently well equipped to perform this task fully. This surely explains why MSD performs better (e.g. in stock control and reporting) where the vertical programmes are concerned, since in that situation it is working under the watchful and critical eyes of experts employed by the development partners concerned and Ministry staff who have been well-trained by the partners to fill this role. . PSU has with its limited capacity already done much to lubricate the functioning of the sector and ensure contacts between the various national institutions and with the international donor community on the other. It has also coordinated consultations on priorities, resulting in the

¹¹ Chachage C. (2008): What if corruption is within you? *The Citizen* (newspaper) Dar es Salaam, 18 april, p.8.

reduction of the Essential Drug List from 700 to less than 500 items and revision of the VED classification, and it is providing training for hospital staff on drug quantification. The notion of strengthening PSU is vigorously supported by the Unit itself, provided confines of funding and space (in the Ministry of Health) can be overcome.

CLOSING REMARKS

1. Tanzania is one of the countries where all the structural elements needed to maintain an effective drug policy are in place and it is notable that the major drug tracking study conducted in 2007 did not propose any structural changes or additions, though numerous suggestions were made as to how various of the institutions could be strengthened. With that strengthening even better use will be made of the input from donor partners.

It is particularly good to find here a central drug policy unit (i.e. the Pharmaceutical Supplies Unit) in the Ministry of Health that has the broad task of dealing with all aspects of drug policy including not only finance and supply but also drug information and rational prescribing. It is precisely this unit that in many countries is lacking, a situation in which the various elements of medicines policy are fragmented or in imbalance, sometimes even rendering it necessary for a Minister of Health to manage the drug sub-sector himself. As the 2007 study concluded, PSU needs to be strengthened but not essentially changed.

2. The *integration of much donor support to the drug sub-sector into a SWAP* for health as a whole can be regarded as successful. The fact that very recently not all the money destined for the drug sector has actually been used is not due to policy failure but to a number of operational problems, pinpointed by the 2007 tracking study, and these can be corrected, especially if there is a strong PSU to ensure that obstacles are circumvented or removed. The vertical programmes too have been in a sense integrated into the overall operation thanks to the good service provided by the Medical Supplies Department, as a result of which they have no reason use separate channels for storage or distribution.

3. Danida has chosen to play its own independent supportive role to the sector, concentrating on a number of issues where it has particular experience in providing support. It does not in any sense compete with other partners – indeed it played a major role in bringing about the conduct of the 2007 tracking study that was to the benefit of all. In the SWAP concept there is nothing wrong in an individual donor developing its own support initiatives in areas in which help is called for, and USAID has in fact also provided specific forms of support, e.g. in training.

4. No negative points need be noted,, but experience in Tanzania does emphasize the fact that technical systems that have been put in place with donor assistance may after some time need to be updated or replaced, especially in the area of information technology where progress is so rapid. The ORION management information system at MSD is an example; a considerable advance when it was introduced, it now needs to be revised or replaced. . In such a field, donor partners may be well placed to provide assistance, to the benefit of the entire drug sector.

STATISTICAL OVERVIEW TANZANIA

Population:	38 millions
GNI per capita	US\$ 320
Life expectancy at birth:	46 years (2004)
Infant Mortality per 1000	97
HIV prevalence adults	7.0% (2003)
Adult literacy	78%
Govt. health expenditure;	US\$ 13 per capita (2002) (at average exchange rate)

3.6. UGANDA

For statistical and background data see the end of this section

Country review

*Principal Informants**

National Medical Stores	Nicholas Kyaterekera, Head of Procurement (nkyate@yahoo.com) Mr Andrew Kaggwa , Procurement Officer Mr Paul Njala, Head of Stores
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**Because of air transport disruption, a number of conversations had to be completed by telephone or e-mail*

Introductory note

The drug scene in Uganda is the subject of some mutually contradictory opinions and even to some extent of contradictory data. The account which follows attempts to present a balanced picture, with the emphasis on issues which call for the serious attention of the donors.

Outline of history

The development of the current drug situation in Uganda can most usefully be traced back to the initiation of redevelopment and recovery aid, which began during the 1980's some time after the end of the Idi Amin regime. Public drug supply had long been in the hands of the governmental *Central Medical Stores (CMS)* in Entebbe, which was physically and financially in poor condition, but supplies of medicines were ensured to some extent by the church-based *Joint Medical Store (JMS)* in Kampala, established at the time to supply the mission hospitals.

At that time, Danida (Denmark) initiated and funded a massive programme of drug supply in kit form. With technical support from Danida . a new *National Drug Authority and Policy* were established by law, and at the same time the new *National Medical Stores (NMS)* were created as an autonomous body to serve the public sector. The former CMS. buildings were

rehabilitated and largely rebuilt for the NMS, and again Danida funded and trained new procurement staff.

During the last decade, Danida aid to the medicines sector has been progressively phased out, though that donor still provides substantial assistance in the field of medical equipment. It is notable however that NMS has chosen to continue to procure and distribute a fair percentage of its total drug turnover in the form of kits in view of their practical advantages. A series of vertical (largely global) programmes (notably the Global Fund and the (U.S.) President's Malaria Initiative have come to play a major role in dealing with the principal epidemics. The National Drug Authority has, after some vicissitudes, developed progressively, and a National Drug Control Laboratory has been created as one of its arms.

The situation as of 2008

a. The National Medical Stores The NMS, though created as an autonomous body, remains in effect the official body handling drug procurement and supply, and it is clearly the government's intention that it remain the principal body for this purpose. External observers note that senior appointments (notably that of the General Manager) have been politically motivated and not always dictated by individual expertise or experience, but within NMS there is certainly a large mass of expertise and skill. .

Estimates of the proportion of the total medicines market served by NMS supplies vary widely, but a figure of 40% appears to be realistic. However, NMS also plays a major role in warehousing stock for the vertical programmes; of the stock held at NMS in its various warehouses, only some 32% represents goods procured by NMS, the rest being stock held for third parties.

While it is clear that the functioning of NMS represents a vast improvement on that of the former CMS, it is not regarded, even by its own management, as entirely efficient. An attempt at restructuring in 2003, based on external consultant advice, did not bring about further improvement, and the recommendations adopted at that time have been reversed. NMS has had a series of General Managers; at the time of our interviews, the post was temporarily held by Mr Apollo Mwesigye but because of very recent problems with theft and corruption at the lower levels (see below) the Minister of Health has insisted on the immediate appointment of a permanent incumbent, and one was due to be in place in early April.

NMS procures using various methods, and purchases both domestically and internationally; the largest geographical source of goods is India, followed by Europe. Although Kampala Pharmaceuticals (KPI) remains the largest domestic manufacturer, others of good standing are emerging. International wholesalers who are involved include IDA (5-7% of orders) and Missionpharm (Denmark). Where stockouts occur, NMS procures supplies from JMS. However, procurement by NMS faces a series of problems. :

- In the view of some spokesmen for NMS the *Public Procurement and Disposal Act (2003)* causes considerable difficulties. This well-intended piece of legislation was designed to cover all forms of public procurement of goods and services, perhaps without a full appreciation of the special circumstances which prevail in the medicines sector. The law requires in principle that for all goods priority be accorded to open domestic bidding, with selection of winning bids in a matter of days; there is provision for

prequalification of suppliers. The emphasis on price is all too central in the procedures prescribed under the Act. The law takes no account of the special situation arising in medical emergencies (e.g. to deal with the risk of Ebola infection during recent floods where extraordinary measures were needed to procure drugs immediately. At the other extreme, the PPD Act requires that for products for which there is a constant demand, advance planning of procurement be limited to one year; this is unrealistic, since where drugs are concerned one may need to plan and order supplies for three years to obtain favourable prices and quality guarantees. The bureaucratic steps involved in conforming with PPDA requirements are complex, with a great deal of form-filling. Finally, some of the quality standards set for procurement (a “merit point system”) are not applicable to drugs where basic quality standards are often absolute.

The NMS is now seeking to obtain a special dispensation (“accreditation”) to procure drugs in a manner appropriate to the sector, but some consider that a special Act will be required.

(One must add that one encounters outside opinions that it is wrong to regard the PPDA as restrictive, since it provides alternative mechanisms of procurement that are sufficient to cover all the needs of the drug sector, and that the procedures are not grossly different from those of the former Central Tender Board).

- *The rapidity with which Government policies on drug treatment can change;* on one recent occasion, new instructions on the drug treatment of HIV/AIDS were issued with immediate effect, leaving NMS with excessive stocks of one drug and an out-of-stock situation for another.
- *Problems with quantification of needs.* The NMS has still not succeeded in developing an adequate means of estimating drug needs at all the various levels of the health system. Outside observers in particular regard this as a serious failing of the management and planning process.
- *Lack of coordination with procurement through the vertical programmes* (HSSPII, Global Fund, HIV/AIDS, TB etc). Although there are informal meetings of a joint “Working Group” the procurement units of NMS and JMS do not participate in these, and they therefore have too little insight into what these programmes are supplying or planning to supply. This makes it impossible to plan NMS’ own procurement adequately and it can even prove difficult to accommodate “vertical” supplies for which NMS has contracted to provide storage space. The procurement department would like to have a routine monthly contact where information and plans relating to procurement are exchanged and discussed..
- *Rapid turnover of staff.* In Sub-Saharan Africa as a whole there is a shortage of procurement staff and in particular of specialists in drug procurement, and there are virtually no possibilities for specialized training. Too often drug procurement has to be handled by staff who are trained in general procurement

but not in pharmacy or vice-versa. Despite its autonomy, NMS has not succeeded in retaining experienced procurement staff for long periods; they are commonly tempted by other positions in the governmental or private sectors. Salaries have to be approved by the Privatisation Council (a provision dating from an earlier decision to privatize the stores, which has still not been put into effect, though it remains on the books) but the salary levels appear to be reasonably good. The problem of staff turnover is certainly not purely financial; work in NMS drug procurement is said to be stressful, with a constant succession of crises throughout the week.

- *Liquidity problems.* For various reasons NMS negotiates contracts on the basis of a 30 day payment period, but in practice it may be 3-4 months before payment is actually made. This renders it impossible to work with some reputable low-cost suppliers who will only sell on the basis of cash payment. The use of Letters of Credit is proving helpful in alleviating the problem but for some purposes the issuing of Letters takes up to three months. According to its records, NMS seeks to maintain 598 drugs in stock. However, stockouts occur frequently, and NMS attributes these primarily to the PPD legislation and secondarily to incidental problems including the slow Kenyan clearance of imported goods entering via Mombassa Port; a non-NMS commentator indeed noted that at a given moment NMS had only some 35-40% of Essential Drugs in stock.
- The duty imposed on NMS to warehouse stock for third parties has imposed a considerable burden on the organization, probably due to poorly planned contractual agreements. NMS has found itself obliged to rent a large amount of expensive warehousing space for this purpose, and the costs of overstocking, obsolescence and expiry of third-party stocks has fallen on NMS. NMS has recently sought to renegotiate these agreements.

Prices secured on NMS procurement appear to be generally favourable, as is evidenced by the WHO/AFRO Pricing Survey, and NMS is generally capable of paying its way without external support. . The liquidity problem is however severe; according to the Ministry of Health website, the Government's debt to NMS currently (March 2008) stands at some \$3 million, equivalent to about a quarter of the Stores' annual turnover. .

The physical stores are very well managed and administered

Quality assurance is not regarded as a major problem. All; drugs procured domestically or imported must have been approved by the National; Drug Authority which with its laboratory is regarded as capable of ensuring good quality standards, though NDA's countrywide inspection of the situation in the market is described by observers as cursory. . NMS itself does not visit foreign suppliers, but the NDA does undertake such visits periodically. One encounters some scepticism as to their value, since the visits are unavoidably arranged in advance, allowing an unscrupulous supplier an opportunity to make a superficially favourable presentation to the inspection team. NMS does maintain a very small laboratory of its own for spot checks where there is a reason to perform these.

Although there have been (recently much-publicized) incidents of loss of goods from NMS, resulting in some staff suspensions and prosecutions (notably among lorry drivers employed on the NMS countrywide delivery service) it is clear that these problems are of minor degree compared with the “leakage” of stock from government hospitals to the private sector (see below). NMS printed notepaper includes an emphatic statement that “management neither condones nor entertains any form of corruption” and it is probably true that the current senior management group makes a real effort to prevent theft and loss.

b. The Joint Medical Store: Established jointly by the Protestant and Catholic Missions in 1979, and still owned by the two church bureaus, the JMS has long enjoyed a reputation for idealism and efficiency.

While originally created to serve the Missions and their hospitals, JMS now supplies much more widely, and on some estimates the volume of goods supplied from JMS to the public now equals or exceeds that provided by the National Stores. Though government health facilities are formally supposed to purchase their requirements from the National Medical Stores, only turning to JMS where the national system is suffering a stockout, but in practice this requirement is not rigidly enforced. As a rule JMS has some 370 drugs in stock, and availability of Essential Drugs is rarely less than 92-94%, which goes far to explaining the popularity of JMS. Markups are rather less than with NMS and although JMS has never been regarded as “cheap”, its price levels are widely seen as satisfactory.

Procedures are not dissimilar to those at NMS, including the need for all drugs to be registered with the National Drug Authority as a means of ensuring quality. Unlike NMS, the Joint Store does not maintain its own Quality Assurance facility, but where necessary it sends samples for analysis to the (similarly church-based) MEDS organization in Kenya, but this is time-consuming. It does not itself inspect foreign manufacturing facilities but it has sought to identify one or more fully independent laboratories which could undertake this task; this is particularly necessary in India, but no fully satisfactory facility has so far been identified. It was notable that during its early years JMS received substantial donations for its infrastructure, e.g. the EU largely covered the cost of improved buildings. The JMS does not need financial support for its day to day drug operations since it pays its way and has indeed financed the newest generation of buildings (currently being completed) out of its profits. Infrastructure help or provision of training would always be welcome provided it is free of conditions. The World Bank at one stage offered to finance the purchase of additional stock for the store but for the goods in question it imposed certain conditions on procurement which the JMS found unacceptable.

c. The private market: It does not seem possible to provide any reliable estimate of the extent to which drugs are being procured and sold through the private market, but it is a burgeoning sector, often using aggressive commercial techniques to increase its hold on the overall market. The fact that Government hospitals and clinics, while in theory providing free service, refer their out-patients to private pharmacies to obtain their drug supplies means that there is a very considerable demand but also that the private sector is motivated to supply medicines at reasonable prices and indeed often does so. Government Hospitals requiring medicines for their own patients will also frequently obtain these from the private sector, especially when there are stockouts at NMS. Much of the private sector appears to engage in bone-fide procurement, though there is a constant flow of stolen public-sector items into private pharmacies (see below).

d. Corruption Although it was not the intention of this study to examine corruption in the pharmaceutical sector, one was repeatedly confronted by the topic and by opinions concerning its extent and effects. There is no doubt that this is a national problem grossly affecting many sectors and dating back to the early post-Amin years when the currency became virtually worthless, salaries lost their value and many individuals lost their sense of personal integrity. In the medicines sector the most marked phenomenon is the “leakage” of drugs from Government hospitals and clinics to the private sector, either as a result of theft or of illegal sale by staff. Donors, it was pointed out repeatedly, need to be aware of the sometimes considerable extent to which their donated supplies are diverted; though they ultimately reach patients, the entire process undermines the purpose of aid, benefiting the dishonest and penalizing the patient. Hospital patients themselves commonly observe theft and corruption around them but dare not report it for fear of retribution. Regrettably there was in 2006/7 a major corruption scandal at the governmental level, directly relating to misappropriation of grants made by the Global Fund.¹²

The ability of the law to correct the situation as a whole is very limited; legal process is extremely slow, government servants relieved of their positions are rarely dismissed outright but are transferred to other posts, and the judicial service itself is not free of corruption/

e. Counterfeit drugs The view was expressed by several observers that there is a very low incidence of counterfeits among the drugs circulating in Uganda. This may be true, though in view of the high incidence of counterfeits elsewhere in Africa and the porous nature of Uganda’s long frontier it seems surprising.

f. Prospects for joint (regional) procurement Again one encounters differences of view on the proposals that exist for joint procurement of medicines by the member states of the East African Community. The notion of centralized procurement for the region is generally regarded as unrealistic, but there is a view that the countries could well share out the process of drug procurement, with each member state handling procurement of a specified range of drugs for the entire Community.

g. Expiry of Aid Programmes Where aid programmes are due to expire, there must be timely consultation on the ability of national procurement agencies and funding to assume responsibility for the continuation of supplies. This has not always been achieved.

h. Medical Access Uganda In 1998, UNAIDS, in partnership with a number of pharmaceutical companies, established this not-for-profit company to procure and distribute HIV drugs at favourable prices. Considerable price reductions were secured, and the programme later expanded to cover the supplies provided by the Global Fund.

i. The National Drug Authority: This body has, after some earlier lapses developed a good reputation and is widely stated to be responsible for the generally high quality of drugs on sale. It has however experienced some serious financial difficulties, with registration fees at times covering only 50% of its expenses. Financed during the early years of its existence by Danida it has hesitated to raise fees because of the likely effect on drug prices . It is not

¹²¹ In 2006 three former health ministers were dismissed and charged with this offence, the misappropriations being of the order of magnitude of several hundred thousand dollars. (Audit Report, 2006).

impossible that some donor aid could better be redirected from procurement to the solution of the Agency's financial difficulties. The (U.S.) President's Malaria Initiative has provided a contribution, but this relates exclusively to the Authority's work on antimalarial drugs.

CLOSING REMARKS

One's overall impression, in spite of conflicting data and opinions, is that the issues most urgently demanding attention in Uganda are:

1. lack of adequate field data on drug needs and use, as a basis for setting goals and priorities and for planning and tracking of supplies
2. insufficient respect for the principle of autonomy where the National Medical Stores are concerned
3. an inadequate approach to tackling corruption and theft in the drug sector
4. insufficient adequate donor coordination.

These problems are clearly interrelated (e.g. improved tracking will detect and counter theft) and they need to be tackled in parallel. *Where the NMS is concerned, USAID (through the RPM+ and SPS programmes) is already beginning to assist the Stores in improving its operational systems, and if a major European donor could join in this effort it would be very welcome.*

ad. 1: Although the failure to develop adequate tools to identify drug needs and track both supplies and usage could be seen as reflecting incomplete execution of the National Medical Stores Act of 1993, the creation of tools and systems for this purpose would benefit all suppliers and all programmes and not merely the NMS. It would much reduce wastage through over-supply (leading to expiry) and the incidence of stockouts. It is also questionable whether the Davision stock control system funded in the past by Danida is still adequate for its purpose, given the increased size and complexity of the stores.

ad. 2: The 1993 Act clearly established the NMS as an autonomous body. From the start, this was not fully accepted by Government, and there were at first blatant examples of interference by the then Director of Health with day-to-day operations including individual procurement orders. This extreme fault has been eliminated, but appointments to the most senior managerial posts are widely considered to be based on political considerations and not on managerial competence. One encounters outside NMS the view that a thorough process of management reform is needed to ensure the creation of a strong and truly independent and expert management.

ad. 3: Corruption is a major problem in Ugandan society but it can be and has been tackled successfully in individual sectors, e.g. in the Uganda Revenue Authority, the example of which merits study. Some donors to the health sector have chosen to ignore the problems, others have insisted on a sufficient measure of control of their donations to counter it; when for example Saudi Arabia equipped the cardiac clinic in Kampala, the donor's own experts supervised the installation and use of the equipment including the flow of the consumables provided. Various observers believe that donor support to a sector-wide effort to reduce corruption would be welcome.

ad 4: Donor coordination has. been only partially achieved. Some observers observe that donors in a sense compete with one another (when one withdraws aid because of perceived faults in the system, another is usually ready to take its place) and that successive

governments have taken advantage of this to maintain aid levels without the need to remedy system faults. It must be noted however that a National Procurement Plan for medicines and health supplies for a “Uganda National Minimum Health Care Package” (UNMHCP) was adopted in 2006 and experience with its first year of operation has just been reviewed. *The full report on this initiative was unfortunately not yet released at the moment of the present field visit, but it is hoped that the principal findings will be available before the Brussels Workshop on 29 and 30 May 2008. It is likely to be of considerable importance in developing further donor initiatives.*

The problems relating to the storage of third-party stock by NMS appear to have been solved by recent renegotiation of the relevant agreements; it is clearly unrealistic for a vertical programme to escape from (or mask) certain costs associated with its activities by agreements which transfer these costs to another party – the true overall costs of aid need to be acknowledged.

Finally, it would seem likely that when planning ongoing donor assistance in the drugs field, this should where necessary be redirected in part towards solving the financial problems of the National Drug Authority.

STATISTICAL OVERVIEW: UGANDA

Population:	28 millions
GNI per capital	US\$ 250
Life expectancy at birth	49 years (2004)
Infant mortality per 1000	80
HIV prevalence adults	4.1 (2003)
Adult literacy	6.9%
Govt health expenditure	US\$ 8.- per capita (2005) (at average exchange rate)

4. NOTES ON SOME OTHER SUB-SAHARAN COUNTRIES

During the study of the six sample countries it became clear that a number of salient experiences from other Sub-Saharan countries were already well-documented and should be taken into consideration. Some relevant data from a number of these countries relating to procurement and quality control are provided below; it is not claimed that any of the situations noted here have been examined at first hand or that the analysis is in any sense comprehensive.

4.1. Congo Democratic Republic

Congo Democratic Republic is a Member State of the Southern Africa Development Community (SADC). An extensive review of Pharmaceutical legislation and the regulatory system in the country was conducted by WHO early 2008.

Although the legal instruments that govern the sector were established during the colonial period in 1933, the national pharmaceutical programme was revised in 2005. Under the current system, the -Direction de la Pharmacie, du Médicament et des Plantes médicinales (DPMPPM) is the national medicines regulatory authority.

Pharmaceutical supply is assured by a system of central medical stores (FEDECAME) with ten regional distribution centres, by a faith-based sector and by a commercial private sector. Imports represent about 90% of the supply; the local production (by some 20 units) covering the rest of the needs. At the time of independence the state system provided all medicines free of charge, but its role thereafter declined and the private sector developed rapidly.

In line with a decentralization policy adopted following a study by Belgian Technical Cooperation in 2002, no central stocks of medicines are held by the public system, all goods being stored by regional centres. Public sector medicines are sold but at subsidised prices. There is no national pharmaceutical quality control laboratory; activities in the field are carried out by four laboratories (2 public, 1 university-linked, 1 private) contracted by the Ministry of Health. None of these is properly housed or equipped for this task.

The illegal “parallel” market is, as in some other countries, of major concern, but no strategy to overcome the problem has been developed.

According to the recent WHO review, the main problems are:

- (i) *Lack of logistical resources.*
- (ii) *Lack of guidelines and procedures.*
- (iii) *Lack of an adequate quality management system.*
- (iv) *Lack of records.*
- (v) *Lack of reports.*

4.2. Ghana

An overview of the successes and pitfalls of the decentralized procurement and supply system in Ghana was presented to the Brazzaville meeting on Procurement and Supply Management in African countries in June 2006 (see reference list). Successes since the creation of the Central Medical Stores in 1998 included the development of procurement capacity and a procurement manual, as well as direct disbursement of funds to health facilities. Main challenges remaining relate to *poor product specifications, inadequate quantification of*

needs, inadequate numbers and mix of human resources and inadequate funding mechanisms.

4.3. Eastern Cape Province, South Africa

Among the problems noted in a presentation to the Brazzaville meeting of June 2006 were the existence of *poor working conditions* and *low staff morale* in the supply system.

4.4. Senegal

Among the problems impeding public drug supply, as described in 2006, was the *absence of tax exemption* for pharmaceuticals.

4.5. Miscellaneous

Among the various recommendations made by the Brazzaville procurement meeting in 1996 were calls to:

- Pay more attention to *transparency and good governance in procurement*
 - *Harmonize reporting tools* to lessen confusion among and the burden upon health workers.
 - *Recruit sufficient numbers* of pharmacists and lower cadre personnel for PHC levels. In particular the World Bank was specifically requested to reconsider recruitment caps imposed on some countries and to allow recruitment of health personnel.
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5. DISCUSSION AND DRAFT RECOMMENDATIONS

It is anticipated that the EU/WHO Workshop to be held in Brussels on May 29th and 30th will formulate recommendations based on the present study, on earlier work by others, and on presentations made to the participants. The present section provides starting points for the discussion of a number of salient issues.

a. The practice of procurement As noted at the outset of this study report, the basic principles of drug procurement have been extensively studied and laid down by others, and they will not be re-examined here. Where problems with drug procurement arise in Sub-Saharan Africa it is not as a rule because those principles have been insufficiently elucidated or publicized. Two types of impediment are particularly prominent:

(i) Failure to recruit or retain expert procurement staff In this region as a whole there is a shortage of trained procurement personnel. What is more, national agencies encounter great difficulty in attracting and retaining such expert staff as exist. This is commonly a financial problem. National procurement agencies, or the institutions to which they report, are commonly bound by salary rules applicable to government staff as a whole. They often compete for procurement staff with the private sector that is not bound by such restrictions, and experienced staff are often lost to that sector.

Other procurement staff in the public service often find that they have little chance of promotion within their institutions where the higher positions are as a rule concerned with general management; where the opportunity arises they are therefore likely to apply for more senior posts in other branches of the government service.

(ii) Failure of associated processes in drug supply Viewed broadly, procurement begins with reliable estimates of need and is completed only after the goods are received and are delivered to a point in the public service where they will be reliably stored and transmitted further to ensure that the needs are met. Too often, need estimates prove to be unreliable, either nationally or with respect to certain areas of the country; at worst, they are more than an extrapolation of earlier supply figures. The procurement process will also be rendered ineffective if the point at which it has been agreed that the drugs shall be delivered is inefficient at ensuring their ultimate supply through the public system to the patient. There may be leakage or theft either at the central storage point, during transport or in the periphery, reflecting either lack of efficient control or frank corruption.

RECOMMENDATIONS:

Ad (i): Throughout the region there is a need for more facilities for training procurement staff, an area that could well merit additional donor support. In certain countries the conditions currently accorded to such staff will often require careful reevaluation if these experts are to be attracted and retained.

Ad (ii) Partnerships in drug procurement sometimes appear to devote too little attention to adverse factors that may undermine the public health benefits that the partnerships are intended to provide; these relate primarily to the operation of the internal supply system.

b. The role of faith-based organizations In many of the countries in the region, the faith-based drug supply organizations play a vital role in supplementing the public supply systems;

while geared primarily to supply to their own institutions, these organizations commonly supply government facilities as well. They are generally well organized, idealistic, virtually free of corruption and capable of supplying medicines of good quality at competitive prices. Some do however struggle with unreliable funding and with government restrictions on international procurement generally.

RECOMMENDATIONS:

While donor assistance in the medicines field will necessarily always be attuned primarily to the public sector, the example of efficient organization provided by the faith-based organizations often merits study and emulation, particularly because of its sound use of resources. Where feasible there should be more openness and information-sharing between the public and faith-based bodies. In some cases, partner assistance to the latter, for example in developing physical facilities, will prove rewarding in terms of serving the population.

c. Quality assurance and control As is the case with procurement itself, the various approaches to quality assurance and control are well devised and documented but they are not consistently employed. Lack of laboratory capacity, equipment (or availability of spare parts and repair facilities) and inadequate training are among the factors than can undermine the maintenance of quality and the identification of problems.

RECOMMENDATIONS:

There are no absolute rules as to the best manner in which quality assurance and control can be maintained or which institutions should undertake these tasks. However in each country a careful determination must be made of which approaches are most likely to be both feasible and sufficiently effective. It is preferable to choose a limited number of methods and apply these consistently than to rely on multiple but inadequate methods

d. Form of presentation: As noted at the outset (Section 2 of this report), many drugs can be procured most economically when accepting them in bulk, e.g. in large plastic bags or bottles. The question arises whether it is efficient and in the interests of public health to procure them in this form, in the absence of repackaging facilities at the central point of delivery. When one sees drugs like these ultimately reaching the patient wrapped up in scraps of old newspaper, with no identification, no instructions for use, no protection from damage or damp,, one is bound to wonder whether the small additional cost of strip packaging in some well-chosen material should not have been shouldered from the outset.

RECOMMENDATIONS

The optimal form of presentation for each individual drug needs to be selected, bearing in mind the costs on one hand and the health interest on the other.

e. Donor coordination. Particularly where vertical programmes are active one may encounter as many as thirty ventures alongside one another. On the other hand one also espies some excellent examples of joint effort by the partners, as in the case of Mozambique's Common Fund, which operate successfully without depriving any individual donor of the right to engage in complementary supportive activities of his own to the benefit of all.

RECOMMENDATIONS

Donor coordination is especially necessary where there are multiple programmes in operation in order to avoid duplication on the one hand and gaps in supply on the

other. While donor coordination may be undertaken by the recipient country, donors themselves can successfully develop patterns of cooperation that render the overall programme of work more effective without impairing the freedom of action of individual donors to develop their own initiatives.

f. The need for flexibility In a study such as this one is again and again confronted by the need for flexibility in the donor approach. There was a time when support in the donor field simply entailed shipping boxes of pharmaceuticals, while at other times it has developed around the need to fund procurement. Often, however, a donor with sufficient insight into the problems he encounters in the field will realize that some of the real obstacles to drug supply lie in other directions. If he learns that none of the local transport firms guarantee to use trucks that will be firmly locked and guarded on the road, should he not become involved in the delivery process?

To take another example: one reads accounts of how a particular country may at one time have been urged by its partners and the international institutions to privatize the bodies engaged in public drug supply – only to be told a number of years later that it would be most inadvisable to do so. Perhaps a doctrine such as that of privatization in this sector is no more than a political weathercock on which conviction readily shifts as the years go by.

Not dissimilar is the belief that groups of countries in Sub-Saharan Africa should entrust some of their activities in this field to sub-regional bodies acting on their behalf, for example to procure drugs for them all.¹³ Certainly there has been a healthy tendency for certain countries in the region to cooperate on specific issues, such as the mutual recognition of drug regulatory approval. Yet in another direction attempts at regionalization may prove unfruitful; the belief, held a decade ago, that Quality Control could well be handled by a Regional Laboratory for the countries of East Africa does not seem to have been particularly fruitful; even though the facilities were there, it seems to have stumbled on practical difficulties (inefficient postal links, imposition of customs duties on samples) though it is not clear whether it was given a fair trial. In these countries that only gained their independence within the last generation there is also an understandable element of national pride in maintaining one's fully independent system; We in Europe are not the best qualified to insist on the need to create strong regional authorities in Africa: in our own region, after all, it took six centuries after the time of Charles the Great to achieve even the partial unity that we know today.

Again one returns to the need for flexibility on the part of a donor partner. One can cite many examples of the manner in which a donor is today working quietly in the shadows of an African drug supply system to lubricate it - teaching, guiding, and providing advice where it is asked for. It is not the most spectacular way for a donor to operate , but it may be one of the most fruitful and the most beneficial

RECOMMENDATIONS:

In almost every aspect of partnership activity concerned with drug procurement and supply, operations need to be adapted to the conditions pertaining in each individual country, taking full account of physical feasibility, specific needs and problems and national preferences . Regionalization of some forms of activity is to be encouraged,

¹³ The most successful example of joint procurement for several countries is that provided by the Eastern Caribbean Drug Service. This is however a situation in which a number of small and very closely associated countries with a common tradition work together.

but there are also areas in which, under African conditions, it may impede progress rather than promoting it.

f. The culmination of aid Many of the debatable issues around donor support to drug supply come to a head at the time when a particular programme approaches its completion, or is quietly merged into a Sector Wide Approach. It would be dishonest to pretend that at this stage a donor never feels certain dire forebodings as to what may go wrong when he steps aside or essentially puts his funding into other hands. Something similar may happen when a country matures to the point where it senses the need to discard all vestiges of the donor era. In one country that we experienced that step had involved a radical replacement of the persona involved, a generation change, even at the risk of forfeiting experience and old wisdom. As a donor one may consider that this is rash or premature and it indeed may involve some risk, but it is surely the final confirmation that the sector has come of age. At such moments donors may again find themselves moving into the shadows, continuing to provide some form of support, especially in technical matters, but doing so from the sidelines and without any much in the way of public acknowledgement; that may seem thankless, but it is logical and wise.

RECOMMENDATIONS

One is bound to wonder whether, at the time partner support programmes are concluded, sufficient consideration is always given to the manner in which existing achievements can be maintained. On some occasions it would appear that relatively limited forms of unobtrusive structural support and guidance, such as those suggested in the preceding paragraph, will need to be devised and continued for a longer period if the public interest is to be fully served.

CLOSING REMARKS

Such, then are the sort of impressions and questions with which one is left after looking at two decades or more of experience with pharmaceutical support to the countries of Sub-Saharan Africa. There are indeed lessons to be learnt and principles to be distilled from the overall experience. But at least as pressing, when we begin to note down the lessons that we believe we have learnt, is to recognize the exceptions to our hard-won rules. The countries of Sub-Saharan Africa indeed have much in common, but they differ in their aspirations, their stage of development and their older and more recent history. Two countries may require two very different solutions to the same problem. Partners need to recognize that fact, all the time drawing a careful distinction between genuine differences in need and feasibility and those divergences in practice which have a more subjective basis and which in the common interest might better be eliminated.

APPENDICES

APPENDIX A

MAPS OF AFRICA

Figure 1: The countries of Africa



Figure 2: PRSAO Countries (Programme régional de Santé en Afrique de l'Ouest)



APPENDIX B:

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APPENDIX C

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