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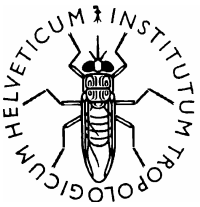

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ACCESS TO MEDICINES

MEDICINE SUPPLY:

LESSONS LEARNT IN TANZANIA AND MOZAMBIQUE

A capitalisation report established in the frame of the SDC Backstopping Mandate 2004 of the Social Development Division's Health Desk

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EXECUTIVE SUMMARY

Access

Millions of people worldwide still do not have access to essential medicines that are affordable and of good quality. Access to medicines means access to treatment. Improving access to quality treatment is currently the most important strategy to reduce disability and death from many diseases. More generally, ensuring access to effective treatment is a high priority issue for international public health. Access to essential medicines is part of the human right to health.

The poor lack access to medicines for many reasons, all of which must be addressed in a comprehensive manner. The most important is poverty, which means that neither the poor nor their governments can afford to purchase essential medicines or ensure their rational use in well-run health systems. Affordability is one core issue at the centre of debates about medicine use in international health.

The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of medicines are a barrier to needed treatments. Prohibitive medicine prices are often the result of strong intellectual property protection. The World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which provides 20 years' patent protection for pharmaceuticals, also includes safeguards such as compulsory licensing, to ensure that countries can override patents whenever they are a barrier to access to medicines. The past years have clearly shown that the Doha Declaration must be actively implemented and defended if it is to have any force.

There are however other major factors which deny access by the populations of low-income countries to effective medicines for the treatment of the diseases to which they are subject. Poor infrastructure and unreliable medicine supply systems, waste and inefficiencies in managing logistics add to low availability of medicines. Most medicine research is carried out by global pharmaceutical companies, which exist to make profits for their shareholders. This means that they focus mainly on the diseases of developed countries, with the result that diseases prevalent in developing countries are largely neglected.

Many of the issues surrounding the accessibility of medicines in low income countries can only be addressed with concerted national and international action. In this paper we consider the issues of accessibility and availability of pharmaceuticals in international health, and describe the initiatives that have been taken by SDC to address them in Tanzania and Mozambique. The situation in Tanzania is described from personal experience over 10 years, the situation in Mozambique is illustrated using information and documentation from SDC, consultants and other sources.

Tanzania

In 1990, when the Dar es Salaam Urban Health Project was launched, the medicine supply situation was inadequate, with chronic shortages, erratic financing, poor management, and irrational medicine use. One objective of the project was to improve resource administration at all tiers, including a reliable, efficient, and sustainable medicine management system that addresses both supply and rational use. Over the 10 project years, the medicine supply system has improved significantly.

Initially, centralized, donor-organized and -funded procurement of medicine kits from overseas was undertaken. Over time, there was a gradual evolution in a stepwise and systemic approach to management. Capacity building and training of pharmacy staff were accomplished. National medicine policy and health sector reform principles were adapted.

A decentralized supply system with medicine requisition at the district level and local procurement from the Medical Stores Department, financed by cost-sharing schemes and government contributions, was established. As a result of the SDC financed activities, essential medicines are now generally available in the public sector of Dar es Salaam.

A sustainable medicine supply system depends on a variety of internal and external components and actors and is part of a health system context. The main pillars for a sustainable medicine supply system are involved and motivated **pharmacy staff**, an efficient **medicine procurement agency**, and an existing **national medicine policy**.

Mozambique

At Independence in 1975, Mozambique inherited a health system that was severely biased towards urban and curative services. Health status was extremely poor in rural and isolated areas. Despite improving health outcome indicators, Mozambicans' health remains among the poorest in the world.

The pharmaceutical area in Mozambique has been going through profound changes, imposed by the evolving political and economic environment, by the post-war reconstruction and by the following expansion of health services to cover previously unserved areas. Due to the critical role played by medicines in health service delivery and to a progressive National Medicine Policy, the pharmaceutical area has received significant support from many donors.

In 1999 a common fund to collect resources from donors including SDC was established to guarantee regular supply of medicines for health facilities. The Common Fund for Medicines and Medical Supplies (FCM) finances both medicine procurement and institutional support to the pharmaceutical sub-sector.

Legislation, financing and procurement of medicines stand out as the fields where the most solid achievements have been documented. There have been significant improvements in the adequacy and predictability of medical supplies in the country.

Much of progress is related to the central level, with emphasis on the financing and procurement of medicines, neglecting the peripheral system and capacity. Regulation, medicine registration and quality control, capacity building, training as well as rational medicine prescribing and use by the patient are areas where much remains to be done.

The creation of the centralized medicine pool (FCM) has proven to be very effective in providing relatively consistent medicine supply to the country. The case of Mozambique again demonstrates the importance of a solid and efficient **medicine procurement structure**. On the other hand, the efficiency gains and economies of scale of this common medicine pool need to consolidated and complemented by improving the **supply chain management** down to the peripheral level. **Quality control and a functional regulatory system** are essential for enforcement of standards and legislation. Management of pharmaceuticals needs to be done by qualified staff and capacity needs to be built by investing in **human resources.**

BACKGROUND / CONTEXT

Access to essential medicines

The enjoyment of health is one of the fundamental rights of every human being. The right to health is recognized in the International Covenant on Economics, Social and Cultural Rights. The right to health facilities, goods and services includes appropriate treatment of prevalent diseases and the provision of essential medicines as defined by the WHO Action Programme on Essential Medicines.

Four criteria by which to evaluate the right to health have been proposed:

1. **Availability** of sufficient and functioning public health-care facilities, goods and services.
2. **Accessibility** of health facilities, goods and services to everyone including non-discrimination, physical, economic and information accessibility.
3. **Acceptability** of all health facilities, goods and services, respecting medical ethics and confidentiality and being culturally appropriate, sensitive to gender and life-cycle requirements
4. **Quality** of health facilities, goods and services

Medicines are a significant part of health care: they can save lives and improve health. They promote trust, participation and utilisation of health services. Medicines are a key component for a well functioning health care system. In fact, medicines are one of the most cost-effective elements of modern health care. However, not all medicines represent value for money and often medicines are marketed with little concern for the real needs and priorities of the people, particularly in developing countries.

Availability of medicines at facility level is often considered a major factor influencing health seeking behaviour. Patients tend to equate medicine availability with quality of care leading to satisfaction with the health system. A well functioning medicine supply system is a major contribution for making a health system operational and improves the responsiveness of the health system to the health care needs of the population. Medicines are thus a very important component of healthcare but need to be used rationally in order to be cost-effective.

Lack of access to medicines has been described as the **Global Medicine Gap.** This description states that global inequities in access to medicines exist between rich and poor countries because of market and government failures as well as huge income differences. Multiple policies are required to address this global medicine gap.

Inequities in medicine accessibility

Illness is a major reason why poor populations remain trapped in poverty. Yet cost-effective tools for treatment of most diseases exist. Medicines can only improve health and secure development gains if they are available and affordable for all people. There is a high degree of inequity in medicine accessibility. Up to 30 per cent of the world's population lacks regular access to medicines.

The Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement by WTO provides 20 years of patent protection, with the goal of promoting innovation by providing incentives to invest in research and development. From a public health point of view, however, one consequence of this is that the introduction of affordable generics is delayed. This is a major hindrance to medicine accessibility, and has been of particular concern in relation to the availability of medicines to offer treatment for the pandemic of HIV/Aids.

Many medicines on the world market are of poor quality, and are also unaffordable to the vast majority of a country's population. Medicine use is often irrational all over the world. Global spending on health research by both the public and private sectors amounts to about $70 billion annually (1998). Global medicine spending as a percentage of total public and private health expenditure varies between less than 20 per cent in industrialized countries and up to 60 per cent in developing countries. In developing countries up to 90 per cent of medicine expenditure is paid for out of the pockets of the patients themselves.

There is a huge gap between the significant health impact of medicines and the reality for millions of people. For them, medicines remain unavailable, unaffordable and unsafe, and even when available they are often used irrationally.
It is important that we quantify these problems. Yet numbers alone conceal much of the real tragedies that occur daily for millions of people who suffer enormously. No more is this better illustrated than in relation to AIDS medicines.

Defining the problem
Access to medicines is a multidimensional concept. An analytical perspective reveals not only the complexity of the issue but also the multi-faceted definitions and approaches used to investigate it, and the diversity of solutions recommended to overcome lack of access. What is needed is a broad framework that integrates perspectives from various disciplines. Access to essential medicines correlates closely with other measures of health system performance such as access to health care, health outcomes, health systems responsiveness, fairness in health financing and income level.
Causes of medicine deficiencies can be summarized as poverty and resource constraints, unaffordable medicine costs, lack of human resources, TRIPS and patent laws, constraints of infrastructure, poor logistics systems, poor regulatory capacity and leadership.

An important question on access is whether people get the care they need. Although treatment is the final goal of seeking care, it is only one aspect. Care also involves other aspects ranging from communication, empathy to diagnosis and medicine quality.

Both access and care are affected by health policy and broader social, economic and political forces. The interaction between them can be studied by examining four distinct but related dimensions of access. These are:

Determinants and indicators of access

Dimension	Definition	Indicators	Determinants
Geographic accessibility	Location of the medicine/service and location of the patient.	Distance to health facility* Operating hours of health facility	Health facility and patient location Transport Human resources
Availability	Type and quantity of the medicine/service needed and the type and quantity of the medicine/service provided	Per cent of key medicines available Type and quantity of medicines	Medicine demand and supply Medicine supply management Staff capacity and performance
Affordability	Cost of the medicine/service provided and the patients ability to pay for the medicine/service	Number of work days to pay full treatment	Income, ability to pay Direct and indirect costs
Acceptability	Attitude and expectations about the medicine/service and the actual characteristics of the medicine/service Quality of care provided Attitude, respect, confidentiality and compassion of the health staff	Patient satisfaction Health outcome Attendance of vulnerable groups	Cultural and psychosocial attitudes and beliefs Trust in technology and competence of providers Training, motivation, enabling environment Gender sensitivity, stigmatisation and discrimination

* Access has been defined as a 2 hour walk or 10 km distance to a health facility that stocks 25 essential medicines.

An important factor affecting access is the social dimension including for instance the effect of gender and vulnerability on accessibility of care or medicines which is also determined for instance by income, ability to pay and cultural attitudes as well as mobility and stigma.

But access alone is not enough. We also need to ask whether the care people get is **effective and of good quality:** are health care services and interventions actually being delivered according to defined standards?

The provision of medicines takes place within a much broader system of health care service delivery. Medicines therefore need to be considered alongside service delivery as part of a comprehensive concept. Service delivery includes information, advice, instructions, precautions but also interpersonal attitudes as politeness and friendliness. Indicators have been developed to measure and monitor these dimensions of medicine access.

To investigate whether people have access to the quality care they need we have to consider the interaction between two sets of characteristics:

1) Individual and household factors: A review of available data and experience indicates that management of diseases is often highly situational, dynamic and complex. Personal, cultural, social, economic and situational factors combine to influence access to effective care. Of particular importance is the interplay of acceptability and availability.

2) Health system factors: In many developing countries, weak health care infrastructures and inadequately trained staff often lead to incorrect diagnosis and treatment. Inadequate logistics and difficulties of physical access further compound the problem.

Strategies to improve access to medicines

Effective disease treatment relies on a long chain of factors, including R&D of appropriate medicines; production; quality control; adequate distribution networks; good medicine supply management; reliable information for, and adequate training of, healthcare professionals; financial accessibility; and good patient compliance.
Each of these stages is vulnerable to competing interests that can compromise effective treatment — and the poorest are the first to suffer.

Disease prevention is an important intervention that will reduce the need for access to medicines. But, as HIV has shown, prevention alone is not enough: 42 million people are already infected with HIV, and there are 6 million people living in less developed countries who need antiretroviral therapy today. While everything must be done to prevent disease in the future, the provision of effective treatment for those who suffer from treatable diseases today is also a medical and ethical priority.

Enhancing access to medicines needs concerted action and can only be tackled with the commitment of all actors involved. WHO has proposed a framework of complementary approaches for collective action. The four components of this framework are:

- **rational selection,**
- **affordable prices,**
- **sustainable financing, and**
- **reliable health and supply systems.**

Other strategies needed to support these components include **National Medicine Policies, Public Private Partnerships, strengthening of human resources** and **reorientation of the research agenda**.

Patents and access to medicines

For the destitute sick in the developing world, the price of medicines can determine whether they will be treated. Patents drive medicine prices up which can be the predominant factor limiting access to medicines, because medicines account for up to 60 per cent of health expenditure in some developing countries.

For the individual, inability to pay for full treatment can result in sub-optimal treatment, debt or even no treatment at all. At the country level, health budgets spent on expensive medicines means money diverted from other essential areas like training of health workers and improving health infrastructure. Indeed, the price of medicines can determine whether or not a government is able to treat a particular disease. The most striking example is Aids, which, despite the development of almost 20 approved medicines in the past 15 years, is still not widely treated in a number of high-prevalence countries because of the cost of medicines.

The World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) sets out the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. WTO has come under fierce criticism because of the effects that increased levels of patent protection will have on medicine prices. While TRIPS does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

The Fourth WTO Ministerial Conference, held in 2001 in Doha, Qatar, adopted a Declaration on TRIPS and Public Health ("Doha Declaration") which affirmed the sovereign right of governments to take measures to protect public health. Public health advocates welcomed the Doha Declaration as an important achievement because it gave primacy to public health over private intellectual property, and clarified WTO Members' rights to use TRIPS safeguards. These measures include compulsory licensing to allow the production or importation of generic medicines without the consent of the patent holder, and parallel importation to allow governments to seek the cheapest available brand-name medicine on the global market. Although the Doha Declaration broke new ground in guaranteeing Members' access to medical products, it did not solve all of the problems associated with intellectual property protection and public health.

Intense lobbying from the multinational pharmaceutical industry and some Western governments, for instance, has frustrated the use of these safeguards. Experience from South Africa, Thailand, Kenya and Guatemala shows the enormous pressures countries face in implementing the TRIPS Agreement in a manner that protects public health and underscores the vital role played by civil society in defending the right to access affordable medicines.

The ability to access quality generic medicines has proven to be crucial to a number of health programmes across the developing world. In Brazil, antiretroviral medicines have been distributed freely across the public health system since 1997. This successful programme, which has halved Aids mortality, is based on a political commitment to generic medicine production.

The reduction in costs of hospital admissions and treatment of opportunistic infections has also been significant.

Prices for antiretroviral therapy fell from $5,000 to $365 per patient per year and less for some initiatives.

Campaigns and Initiatives

Access to medicines in developing countries is a highly political issue, and as such it is subject to intense lobbying by all the principal actors. Leading non-governmental organizations (NGOs) such as *Oxfam* and *Médecins sans Frontières* have run vigorous campaigns advocating that all people should have access to essential medicines, especially for the treatment of the main killer diseases: malaria, HIV/AIDS and TB. Many organizations and institutions working in poor countries have put 'treatment access' at the top of their agenda. But 'access for all' remains a challenge that is difficult to achieve.

Access initiatives run by the NGOs, other advocacy groups and UN organisations have had a significant impact on public opinion, media reporting, international organisations and the pharmaceutical industry. These campaigns have also raised important questions on social responsibility and ethical dimensions. Because most medicine research and development is carried out by a for-profit pharmaceutical industry, a central issue is whether, or at least to what extent, private shareholders should benefit financially from the ill-health of others, particularly those who cannot afford it and who may well die in the absence of such medicines. The fundamental question of 'corporate profit or public health?' has opened up an important and critical debate on corporate social responsibility, and on the interrelation of all the actors involved in health systems in a globalized yet pluralistic world.

Public-private partnerships

It is notable that the most important funding over the past few years has come not from private industry or the public sector, but from increased interest and commitment from philanthropic individuals and foundations. For example, The Bill and Melinda Gates Foundation, in addition to providing substantial funding for vaccines, has become a major force in neglected disease medicine development. However, whilst additional support from foundations is welcome, foundations cannot and should not take the place of public sector responsibility.

Another type of policy initiative that has become of increasing importance is the public-private partnership (PPP). PPPs attempt to approach diseases of poverty and access to medicines by mobilizing expertise, capacity, and funding from both the public and private sectors. The objective is to develop synergies among public and private stakeholders of pluralistic health systems. Typically, the PPP plays a coordinating and management role around a disease-specific R&D and access agenda, and seeks a combination of public funding, philanthropic donations and in kind donations from industry.

Major examples of this approach are the **Medicines for Malaria Venture** (MMV), the **Global Alliance for TB Medicine Development** (GATB), and **International AIDS Vaccine Initiative** (IAVI). These have been established to ensure the availability of medicines for these specific diseases to affected populations. However, the need for a more integrated approach in tackling these major diseases has been recognised by more recent global partnership initiatives such as **The Global Fund.** This has focused on stimulating further interest in financing the provision of medicines for the world's top three killer infectious diseases: AIDS/HIV, malaria, and tuberculosis.

SDC APPROACH

SDC recognizes the important role and impact that access to medicines has for a pro poor health system of good quality. SDC has, for example, invested significantly in the health and pharmaceutical sector in Tanzania and Mozambique. As an initial focus, improving availability has been at the core of activities entailing strategies to improve the medicine supply system. Complementary activities to promote rational medicine use in the case of Tanzania and improving medicine regulation in Mozambique have been undertaken. Furthermore, focus on the support of health systems, efforts to reduce the 90/10 research gap, community empowerment strategies, mainstreaming HIV/AIDS and advocacy for developing countries in the ART debate add to the SDC commitment to improve the access to medicines of the poor.

Tanzania

The Swiss Agency for Development and Cooperation (SDC) has supported the Dar es Salaam Urban Health Project (DUHP) in Tanzania from 1990 to 2002. Objectives concerning medicine supply envisioned improved resource administration at all tiers including a reliable, efficient and sustainable medicine management system, addressing both supply and rational use and covering the three urban districts.

In 1990 the inadequacy of the pharmaceutical supply system in Dar es Salaam, commercial capital of the United Republic of Tanzania, was evident. There was chronic shortage of medicines at health facilities, supply was erratic as was Government funding, medicine supply management was poor and use of medicines irrational. Despite a national policy to provide medicines free of charge, unofficially patients often had to pay for them. Medicines were purchased from the national Central Medical Stores, which were seen as inefficient, unreliable and poorly stocked. Medicine quality was questionable and pharmacy premises were often unsuitable – hot, humid and cluttered with piles of medicines, some of them expired. Pharmacists tended to have low professional visibility and not to be involved in hospital committees. At a time when studies showed that patients equated availability of medicines with good quality of care, a survey of user patterns in Dar es Salaam in 1990 reported that "the majority of patients complained that usually health facilities do not have medicines at all".
Over the years, the DUHP medicine supply system has improved significantly. Ten years on and the picture is very different. Dar es Salaam has a decentralised supply system with medicine requisition at district level and local procurement from a restructured Medical Stores Department, financed by cost-sharing schemes and Government contributions, and based on the National Medicine Policy.

How was this achieved?
Initially the project provided an injection of funds and materials with centralised, donor organised and funded procurement of medicine kits from overseas. The supply system gradually evolved with a stepwise and systemic approach to management. Procurement was delegated to the restructured Medical Stores Department and quantification by indent system was introduced in hospitals. With decentralisation of municipalities, pharmacy storage premises were reorganized and a medicine supply monitoring and documentation system was introduced.
Capacity building and training of pharmacy staff was organised. Pharmacists were involved and empowered to contribute to better medicine supply and use. Principles of the National Medicine Policy and Health Sector Reform were adopted and integrated. Rational medicine use was promoted with the development of Standard Treatment Guidelines and training of health providers. Considering study results that at least 20% of the Dar es Salaam population are absolutely poor, an exemption policy for poor households was implemented in the framework of cost-recovery.

The DUHP objective concerning medicine availability in the three municipalities of Dar es Salaam has been achieved and is one of the recognised accomplishments of the project, appreciated by patients and health workers. It has contributed greatly to the credibility of the Dar es Salaam health care delivery system and the willingness of patients to share the cost of services.
Long-term sustainability is now likely but contingent on further improvement of medicine supply management, strengthening of pharmacy staff, ongoing promotion of rational medicine use and continuing government funding. Medicine quality has improved due to good procurement practice of the Medical Stores Department. Cost-sharing is well established and generally accepted with exemption policies for certain groups and has had little impact of attendance rates.

Shortcomings

- Management capacity is still insufficient (storage, inventory management, documentation, monitoring of medicine flow) particularly at district hospital level. Supervision needs to be strengthened and accountability reinforced.
- The human resource potential of pharmacy staff should be strengthened further (knowledge, skills, motivation and involvement).
- Quality of care in terms of attitude and patient care needs improvement.
- Rational medicine use needs further promotion to improve prescribing behaviour (continuing training and supervision).
- There is a great need to better educate patients about medicine use.

Lessons learnt

An efficient, reliable and sustainable medicine supply system depends on a variety of internal and external factors and its success is determined by many components and actors

➢ **Involved and motivated pharmacy staff** proficient in medicine supply management would have been most important from the very beginning for better allegiance and cooperation including early capacity building and training. The emphasis needs to be placed on improving skills, increasing motivation and changing attitude. Supportive supervision and monitoring, incentives as well as continued education are important tools.

➢ An efficient national **Medical Stores Department** has proven to be one of the main pillars for the medicines supply system, providing medicines of good quality at affordable prices. Thus externally organised tendering and import from overseas could be replaced by local and professional bulk purchasing, clearing, distribution and storage of essential medicines.

➢ The Tanzanian **National Medicine Policy** has been an important tool and framework for the development of a more efficient, equitable and sustainable medicine supply system for the DUHP.

Mozambique

Mozambique is recovering from thirty years of turmoil. The country has moved from colonial rule and protected economy to an ambitious development experiment. Various natural disasters have also taken its toll on a disrupted society with minimal coping capacity such as famine, drought, floods and epidemics. The transition from war to peace focussed on reconstruction. The health sector, supported by many donor agencies, has been particularly active in this ongoing process. At Independence in 1975, Mozambique inherited a health system that was severely biased towards urban and curative services. Health status was extremely poor in rural and isolated areas.

The new government launched an ambitious programme in the health sector based on primary health care, the National Health Service NHS. The Mozambican health policy was based on principles of broad and equitable access to health services with an emphasis on preventive and basic curative services. The coverage of comprehensive integrated basic services increased with a rapid expansion of the network of primary health care facilities. Despite successes however the health system also showed serious drawbacks. The health system was fragmented and large gaps in service provision between urban and rural areas remained. The referral and support system remained weak. Training was neglected resulting in low quality care. Inadequate management capacity hampered many initiatives. There was a spectacular increase in external financing to the health sector and by the mid 80's the NHS had become entirely de-

pendent on external aid. An innovative and highly successful medicine policy was introduced in 1975, at a time when WHO began to promote the essential medicine concept.
After the peace agreement in the early 90's, displaced populations returned to devastated rural areas and limited access to health services. After the transitional phase, service coverage and consumption increased significantly. Due to the lead donor agency in the health sector, Switzerland, donor coordination was initiated.
Although health outcomes indicators have been gradually improving since the end of the civil war in 1992, Mozambicans' health remains among the poorest in the world. At the same time Mozambique is also one of the poorest countries in SSA and belongs to the group of states that is highly dependent on external aid (i.e. up to 25% of GNP).

Pharmaceutical sector
The pharmaceutical area in Mozambique has been going through profound changes, imposed by the evolving political and economic environment, by the post-war reconstruction and by the following steady expansion of health services to cover previously unserved areas. Due to the critical role played by medicines in health service delivery and to a long-established, progressive National Medicine Policy, the pharmaceutical area has received support from many donors, with an annual financing of US$15-20 million. The reform process is guided by a strategic plan, formulated in 1995 and under implementation since 1997, which aims at strengthening the pharmaceutical sub-sector.
In 2000, 22% of recurrent health expenditure was allocated to pharmaceuticals and 40% to health staff costs. The rapid expansion of health services with doubling of outpatient consultations between 1993 and 2000 has been progressively followed by an increase of medicine supply. The National Health System NHS has remained fairly well supplied with medicines even through difficult years.
There is evidence of irrational medicine use, in particular overprescribing of antibiotics. In terms of quality of care it was noted that consultation time with patients is very limited, medicine labelling is poor and many patients do not know how to correctly take their medicines.

Since its creation in 1977, the NHS has seen health service delivery as a responsibility of the State, to which the patient is supposed to contribute at nominal charges. Charged fees were to pay for medicines by outpatients, at low prices. The charging of user fees proved most problematic and resulted in minimal revenue and a widespread, chaotic and tolerated system of under-the-desk paying as compensating strategy of low paid health workers. It is estimated that cost-sharing revenues are in the order of only 3%.

The Common Fund for Medicines and Medical Supplies (FCM)
A most important strategy was the initiative in 1999 to establish a common fund to collect resources from donors including SDC and to guarantee a steady supply of medicines for the network of health facilities in Mozambique. It was understood however that beyond financing medicine supply, management support is needed for procurement, storage, distribution, quality control and rational medicine use.
Considering this, the FCM finances two major components:

a) medicine procurement and purchase on the international market based on international tendering standards
b) institutional support to the pharmaceutical sub-sector for strengthening of procurement, distribution, management, planning, inspection and regulatory systems.

The Common Fund for Medicines and Medical Supplies (FCM) has been recognized as an effective financing mechanism and as a consequence 9 donors now contribute to the medicine pool (FCM) with an annual volume of approx. 28 mio USD.

Between 1993 and 2000 the number of outpatient consultations has doubled which necessitated a massive increase in the volume of medicines. This tendency will continue with the immense needs for ARV and other medicines related to HIV/Aids.

The support by SDC
Switzerland has been providing health-related assistance to Mozambique for 18 years and is gradually moving towards a budgetary and sector-based support, focusing on primary health-care, pharmaceutical needs and management. Switzerland has joined other countries to establish common procedures, such as the Common Fund for Medicines and Medical Supplies. Since 1998, at the request of the Ministry of Health, Switzerland has assumed responsibility for managing the funds supplied by other external sources for the purpose of importing medicines and medical equipment and financing recurrent expenditure.
SDC currently contributes approximately 20% of its annual budget of 6mio CHF for health in Mozambique to the Common Fund for Medicines and Medical Supplies.

Current situation
An internal evaluation in 2001 and an external evaluation in 2003 provided a comprehensive overview of the current situation in the pharmaceutical sector.
Overall, progress has been registered in relation to many of the goals originally formulated in the strategic plan. Legislation, financing and procurement of medicines stand out as the fields where the most solid achievements have been documented.
Regulation and its components, such as medicine registration and quality control, as well as rational medicine prescribing and use by the patient are areas where less has been achieved and much remains to be done. Further, an important distortion has been recognised, as most resources are allocated to central medicine purchasing and inadequate funding is invested in supply management capacity, warehousing, transports and human resources.
The mounting AIDS toll is expected to heavily affect the pharmaceutical area, imposing a re-adjustment of both volume and type of the medicines needed by the health sector, supply channels, human resources and patient education to promote treatment adherence.

Achievements
Much of the registered achievements are related to the central level, with special emphasis on the financing and procurement of medicines.

- There have been significant improvements in the adequacy and predictability of medical supplies at facility level due to the allocation of a significant share of growing budget to pharmaceuticals, together with good supply procurement procedures
- The medicine procurement system is sound and effective and allows bulk purchasing and economies of scale with competitive prices
- An internal inspection unit was created and is functional, covering peripheral health units
- Legislation of the pharmaceutical department has been strengthened
- A Medicine Information Centre was created, organising training on rational medicine use.

Weaknesses
The focus on central medicine financing and procurement has left the periphery weak due to the limited expertise available proceeding down the system's ladder and due to the multiplication of actors and venues to be covered.

- There is some evidence that the medicines and medical supplies available are not sufficient to cover needs of the programs and the demand of the population
- The central procurement of medicines has induced the widespread perception that supplied goods are cost-free leading to irrational requisitioning practices as well as irrational use of medicines. There is substantial medicine wastage. Quantification of medicine needs has to improve and be harmonized for better forecasting of medicine quantities
- The pharmaceutical sector faces significant difficulties to train, recruit and retain pharmacy staff in the public sector. Private pharmacies, attracting the most skilled cadres, erode the human resources available to the public sector. Undergraduate and in-service training as well as continuing education is needed. General management capacity of pharmacy staff needs strengthening

- A functional medicine regulatory agency needs to be established with medicine regulation and legislation implemented and enforced.
- Quality control of medicines is inadequate and a quality control laboratory is needed
- Rational medicine use needs to be promoted with prescribers, dispensers and patients
- The cost sharing system needs to be improved in view of long term sustainability

Lessons learnt

- The case of Mozambique demonstrates vividly how the general **political and economic situation** affects the needs of a health care system in terms of resources and services.
- The creation of the **centralized medicine pool (FCM)** has proven to be very effective in providing relatively consistent medicine supply to the country showing the importance of a solid and **efficient medicine procurement structure**.
- The efficiency gains and economies of scale of the common medicine pool need to be consolidated and complemented by improving the **supply chain management** down to the **peripheral level.**
- **Quality assurance and a functional regulatory system** are essential for enforcement of standards and legislation.
- Management of pharmaceuticals needs to be done by qualified staff and capacity needs to be built. Investment in **human resources** with training and motivation is essential for a pharmaceutical system.

CONCLUSIONS

The experiences of Tanzania and Mozambique have clearly demonstrated that a medicine supply system cannot be managed in an isolated way but needs to be considered as part of a larger socio-cultural, political and economic context and environment. It is also part of an organisation, the supporting **health care system** from which it can not be isolated. The pharmaceutical sector is as resource for and in interrelation with other sub-sectors which have to be coordinated. For a medicine supply system to be sustainable and in order to solidify achievements, active consolidation is necessary. This involves strengthening with internal and external support and translates into careful monitoring, supportive supervision and continuing education. Assumption is a stable and supportive **political and economic environment** as well as **sustainable financing**. The backbone of a public sector medicine supply system is an efficient, transparent and well performing **medicine procurement structure**. A solid **National Medicine Policy** with legislation and enforceable regulation and quality assurance backed by a functional **Medicine Regulatory Authority** forms the basis of a well functioning pharmaceutical sector. **Human resources** and their skills and motivation are an essential factor and determinant for an effective and sustainable medicine supply system. Finally the **HIV/Aids epidemic** will have an enormous impact on any pharmaceutical sector both by a growing inflow of ARV and other related medicines, needed infrastructure and logistics systems and an increased need of additional human resources at all stages of the medicine supply cycle, from international procurement to monitoring of patient adherence.

Medicine availability however is only one component leading to equitable access of medicines and treatment to all. Accessibility of medicines will only be achieved when available medicines are of good quality, affordable to patients, culturally acceptable and used rationally by patients. Only then medicine treatment promises to be cost-effective, leading to good clinical outcomes.

FURTHER REFERENCES

Dar es Salaam Urban Health Project DUHP, Project Brochure and CDRom , 2004
Available at STI Basel and City Council Dar es Salaam

How to Investigate Medicine Use in Health Facilities, Selected Medicine Use Indicators, INRUD/WHO, 1993

International Covenant on Economics, Social and Cultural Rights; Article 12.1 and 12.2 and The Committee on Economic, Social and Cultural Rights, General Comment nr.14 (May 2000)

Managing Medicine Supply, Management Sciences for Health, Kumarian Press, 1997

Reich M, The global medicine gap, Science Vol 287, March 2000, 1979

Sachs J et al, Macroeconomics and Health: Investing in health for economic development, WHO, Geneva 2001

Wiedenmayer K, Mtasiwa D, Transforming Medicine Supply in Dar es Salaam, Essential Drug Monitor, 28&29, WHO, 2000

World Health Organization, Policy Perspectives, Equitable access to essential medicines: a framework for collective action, 2004

Worldbank, Better Health in Africa. Experiences and Lessons learnt, World Bank, Washington DC, 1994

www.who.int/medicines/

www.msh.org

www.inrud.org

LIST OF PICTURES AND LEGENDS

Figure 1: DUHP: Kits distribution to a semi-urban dispensary in Dar es Salaam

Figure 2: DUHP: Training of rational medicine use based on standard treatment guidelines

Figure 3: DUHP: Storage of medicines at municipal hospital pharmacy

Figure 4: DUHP: A dispensing window

Figure 5: DUHP: A poster warning from buying medicines in the marketplace and a medicine ledger

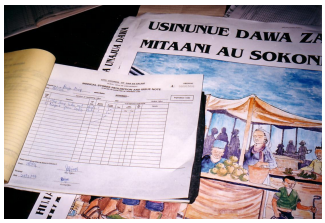

Figure 6: Mozambique: Patients waiting in front of a health facility