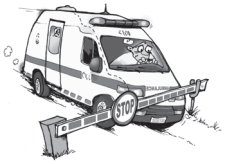

CHAPTER 4

ACCESS TO MEDICINES OF QUALITY

ABBREVIATIONS

ARIPO	African Regional Intellectual Property Organisation for Southern and Eastern Africa
API	Active Pharmaceutical Ingredients
ARV	Antiretroviral medicine to treat HIV/AIDS
CSO	Civil Society Organizations
EMA	European Medicines Agency
EU	European Union
FDA	Food and Medicine Administration Agency (USA)
FTA	Free Trade Agreement
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GNI	Gross National income
HIV	Human Immunodeficiency Virus
IPR	Intellectual Pproperty Rrights
LDC	Least Developed Countries
LP	Local Production
MS	Member States
MOH	Ministry of Health
MSF	Médecins Sans Frontières, Doctors Without Borders
NEML	National Essential Medicines List
NGO	Nongovernmental Organization
OAPI	African Intellectual Property Organisation for Western Africa
PhV	Pharmaco Vigilance
PIM	Product Information Management
R&D	Research and Development
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNCTAD	United Nations Conference for Trade and Development
VL	Voluntary Licence
WHO	World Health Organization
WTO	World Trade Organization

VOCABULARY

Active Substance or Active Ingredient (AI) or active pharmaceutical ingredient is the substance in a medicine that is pharmaceutically active and produces the beneficial or adverse effects on living matter.
Brand name is a name given to a medicine by the manufacturer. The use of the name is reserved exclusively for the owner of the patent.

Branded Medicines are patented medicines that have a brand name.

Bioequivalence is a term used to assess the expected biological equivalence of two different registered preparations of a drug. If two products are bioequivalent it means that they are expected to be, for all intents and purposes, the same.

Compulsory Licence: Mechanism used by public authorities to authorise use of a patent-protected invention by government or third parties without the consent of the patent-holder. Patent-holders are to receive adequate compensation, usually in the form of a royalty. Governments may issue a licence to allow the import, production and use of a patented medicine without the consent of the patent holder on grounds of public interest. The generic copy is for the domestic market and cannot be sold for profit. TRIPS allows for compulsory licensing on grounds of public interest. The Doha Declaration extended compulsory licensing to imports.

Counterfeit (fake) medicines are deliberately and fraudulently mislabelled giving false information about their identity or source. They may or may not have the active pharmaceutical ingredient mentioned. Both branded and generic products can be counterfeited. The ingredients in counterfeit products may be wrong in quality and quantity and may be harmful.

Data Exclusivity: a legal provision that prevents, for a specified period, data collected from clinical trials being used for the creation of a generic product.

Differential Pricing: the practice of setting different prices according to the market, typically higher prices in richer markets and lower prices in poorer markets.

Doha Declaration on TRIPS allows a country to import or produce a patented medicine provided that the owner of a patent or copyright licenses the use of their rights. The patent owner receives a payment either set down by law or determined by arbitration.

Essential Medicines are the medicines that satisfy the health care needs of the majority of the population. They are selected for their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. It is the country's responsibility to decide which medicines are essential. Essential medicines are supposed to be available within the health systems at all times in adequate amounts and appropriate dosages, with assured quality and adequate information, and at affordable prices.

Essential Medicines List (EML) is a list, published by WHO and updated regularly, of medicines that provide safe and effective treatment for the infectious and chronic diseases that widely affect the world's population.

Evergreening: a word popularly used to describe strategies that extend the life of a patent on a compound.

First-line Drugs: the medicines used as a first resort to treat a disease.

Generic Medicines (drugs) are pharmaceutical products intended to be interchangeable with the originator product and which are usually manufactured without a licence (patent) from the originator company. They have the same active ingredients as that the brand-medicine but are marketed under the name of their active ingredient (molecule). Generic medicines are legitimate, as effective as the brand-name medicine, but much cheaper.

Intellectual Property Rights (IPRs) are the rights given to people over their inventions. They give the inventor an exclusive right for a certain period of time over the use of the concept. IPR include copyrights, trademarks or patents, geographical indications, etc. Interpol - International Criminal Police is the world's largest international police organization, with 190 member countries that provide finance of around €59 million through annual contributions. Interpol enables police around the world to work together to fight crime by sharing objectives, data and access to tools and services wherever necessary. Its headquarters are in Lyon, France.

Low Standard Medicines are brand-named or generic medicines whose ingredients correspond to those mentioned on the package but where the percentage or quality of the active molecule does not reach the standards mentioned or expected.

Patent: a set of exclusive rights granted by a state to an inventor for a period of time in exchange for the public disclosure of the invention. In the case of medicines, the patent grants the Pharmaceutical Company that develops a medicine a monopoly of that drug for 20 years. This means complete control over the production, distribution and price of the drug.

A Patent Pool for medicines is a structure where patent-holders share their patents and receive royalties in return. It has the potential to increase access to patented medicines for people living with HIV in the developing world. Medicine companies can access these patents to produce cheaper versions of the patented medicines. The companies are financially rewarded and patients benefit from access to more affordable medicines. A Medicines Patent Pool for HIV was formally established in July 2010.

Parallel Import is a product imported from another country without the permission of the intellectual property owner.

Pharmacopoeia Monographs is a compilation of data about Active Pharmaceutical Ingredients (API) or Products with their identification tests, impurity profile, assay method, solubility etc. It ensures that the product meets the standards. Many countries have developed their own pharmacopoeia. Four have become international benchmarks, those from Europe (EP), the USA (USP) and the United Kingdom (BP) and the international one defined by WHO.

Pooled Procurement is the joint purchasing of medicines from different countries in order to resolve challenges of price, quality and other difficulties associated with the procurement and supply chains of essential medicines.

Prequalification is the evaluation and assessment of quality, safety and efficacy of medicinal products. It is based on information submitted by the manufacturers and inspection of the manufacturing and clinical sites. When the evaluation results are positive, the site or medicine receives a certificate of prequalification.

Qualification System is a pool of processes used to select the sources of medicine supplies so as to ensure that they conform to the ethical principles of the Charter.

Quality Assurance is a set of measures implemented to ensure the quality of the sources of medicines. Two concepts are important: homogeneity of the lots produced by the producer and the concept of risk/benefit ratio.

Quality Control involves occasional analysis of the drug. As often it is only the active ingredient that is checked, it cannot ensure by itself that the medicine is of good quality. Other ingredients which could include impurities, effects of deterioration, toxic contamination, etc. may not be tested. So patients can still be at risk. No rigorous authority (such as the European Medicines Agency) relies purely on quality control. Quality control is part of quality assurance but is useful only in conjunction with other checks. It is only meaningful if it is independent.

Tentative FDA Approval: is awarded by the US Food and Medicine Administration Agency (FDA) to a medicine product that has met all required quality, safety and efficacy standards, but is not eligible for marketing in the US because of existing patent protection. Tentative approval does give a guarantee of quality to the product and makes it eligible for purchase outside the US.

TRIPS (Trade-Related Aspects of Intellectual Property Rights) is an agreement of the World Trade Organization (WTO) that sets standards and conditions for the protection of intellectual property. TRIPS requires that patents are granted in member states.

World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

WHO Prequalification assesses and assures acceptable standards of quality, safety and efficacy in a medical product.

WHO's Prequalification Programme provides guidance to purchasers on the quality of medicines. It is a standard for the identification of quality of essential medicines and has significantly improved access to quality medicines over the past years.


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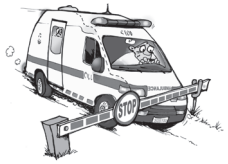


CHAPTER 4

ACCESS TO MEDICINES OF QUALITY IN AFRICA

1. INTRODUCTION

Access to medicines is a human right and the cornerstone of an effective primary health care system. Therefore good quality essential drugs for the prevention and treatment of prevalent diseases should be available at all times, in adequate amounts, in appropriate dosages and at a price the community can afford. Yet 270 million people in Africa lack access to the medicines they need and this contributes to millions of deaths and untold suffering from easily treatable diseases.

Malaria, HIV/AIDS, TB and other infectious diseases are the main causes of mortality in Africa although there are medicines to cure these illnesses or improve patients' lives.

The lack of access to medicines also has serious social and economic consequences. More than 100 million people fall into poverty annually to pay health care expenses for sick family members. In Africa, patients have to pay out of their own pocket for 50 to 90 % of essential medicines.

Another reason for poor access is that research and development are not directed to the medical needs of the people of Africa. Only 1% of newly marketed medicines in the past 30 years were developed for tropical diseases or tuberculosis, yet the existing medicines for these diseases are often toxic and resistance makes them less and less effective. As pharmaceutical companies do not consider the African market to be financially viable they do not invest in those diseases. In Africa, there is very little research and development on traditional medicine, while laboratories elsewhere are already patenting products made from them.

Low quality drugs pose another problem. Medicines can use up a significant proportion of individual or family income, so people look for cheaper medicines on markets or in kiosks, but their quality is questionable.

Medicines of poor quality can be the cause of treatment failure or even death. Low-quality versions of a medicine increase resistance because they do not kill all the parasites. The quality of essential medicines is a key issue for public health.
In Africa high prices, low quality, inappropriate prescriptions, improper use of medicines and the proliferation of counterfeit (fake) medicines are all taking their toll on the health of the people who are often not getting value for their money.

2. ACCESS TO ESSENTIAL MEDICINES

Many factors define the level of access to medicines: selection of medicines, affordable prices, sustainable financing and reliable health and supply systems. We are looking mainly at affordability.

One of the main reasons for the lack of access to essential medicines is the high cost of medicines produced in the West, chiefly Europe and the USA. The patent system, used and promoted by pharmaceutical companies, raises the prices of medicines because there is little competition. This system is not working for the poor countries.

2.1. Trade and Access to Medicines

International trade regulation is becoming increasingly significant for health services. Trade policies, with their emphasis on the removal of import and export duties, mean that the health sector and trade in health-related services are open to foreign investors. This affects not only the availability and price of medicines (therefore people's right to health) but also the tax revenue available to governments to fund health and other public services. The liberalization of health services forces the public sector to compete with the private sector (that already attracts the best qualified health personnel). National health systems will grow weaker and, once again, it will be the poorest who suffer most.

Moreover, when Intellectual Property Rights, such as patents and data exclusivity, are included in Trade Agreements, access to cheaper generics is not easy and poor countries find it hard to access essential medicines.

Please see TRADE section 2.2.4 on Trade in Services.

2.2. Strengthening of Intellectual Property Rights

Today 'knowledge' is an asset. Enterprises and individuals that possess 'knowledge' (technical, scientific, intellectual, etc.) protect it by holding rights. In exchange for sharing their knowledge, the owner of the knowledge is granted a monopoly on the income generated by the invention. Others have to pay to use or reproduce the invention. This knowledge protection is called 'Intellectual Property Rights (IPRs).' It can be in the form of copyrights, trademarks or patents, as in the case of medicines. IPRs are a powerful tool for pharmaceutical companies to increase their profits, so they lobby their governments hard to strengthen IPRs.

The Intellectual Property Rights are a barrier to access to medicines. Strengthening of IP protection makes access to cheap generics difficult and increases the cost of medicines in Africa. Furthermore, increased IP protection hinders developing countries from establishing their own pharmaceutical industry.

The TRIPs (Trade Related Intellectual Property) Agreement of the World Trade Organisation (WTO) protects Intellectual Property Rights (IPRs). Patents, a part of IPRs, grant exclusivity of production, sale or import of medicines for a minimum of 20 years.

Before TRIPS, most developing countries did not recognise patents for pharmaceuticals. This allowed copies of new medicines (generics) to be made. TRIPS obliges WTO member states (all African countries except Ethiopia) to provide patents. Least Developed Countries have to implement patents for pharmaceutical products before January 2016.

TRIPS is supposed to keep a balance between the interest of health-care product developers (IPRs protection), public health and the interests of users. For this reason, some 'flexibilities' and safeguards were retained or added to allow developing countries in certain circumstances to override patents and facilitate their access to generic medicines. For example 'parallel imports' where governments can shop around for cheaper sources of a patented medicine on sale abroad. In 2001 the WTO Doha Declaration allowed governments to issue 'compulsory licences for reasons of public health.' A government may grant permission to produce a patented product without the consent of the patent owner. The country can produce or import the generic medicine even during the validity of the patent. Many Western countries, like the USA, the EU and its member states oppose the right of developing countries to declare 'compulsory licenses.'

For the TRIPS flexibilities to be valid, countries need to incorporate TRIPS flexibilities into their domestic legislation and use them where necessary and feasible.

In recent years a number of countries, among them the European Union (EU), have been reinforcing IPRs. In their bilateral agreements they introduce TRIPS-Plus, clauses that enforce IP protection beyond the requirement of TRIPS. This has severe consequences for public health. A measure being introduced is the increase of 'data exclusivity' protection to up to 12 years. This means that for 12 years generic companies cannot use the existing clinical data on a medicine to register it, regardless of whether a patent exists or not. Data exclusivity is another way of extending the monopoly of the patent protection and blocking off generic competition. This undermines the balance between safeguarding access to medicines on one hand and stimulating innovation and business on the other.

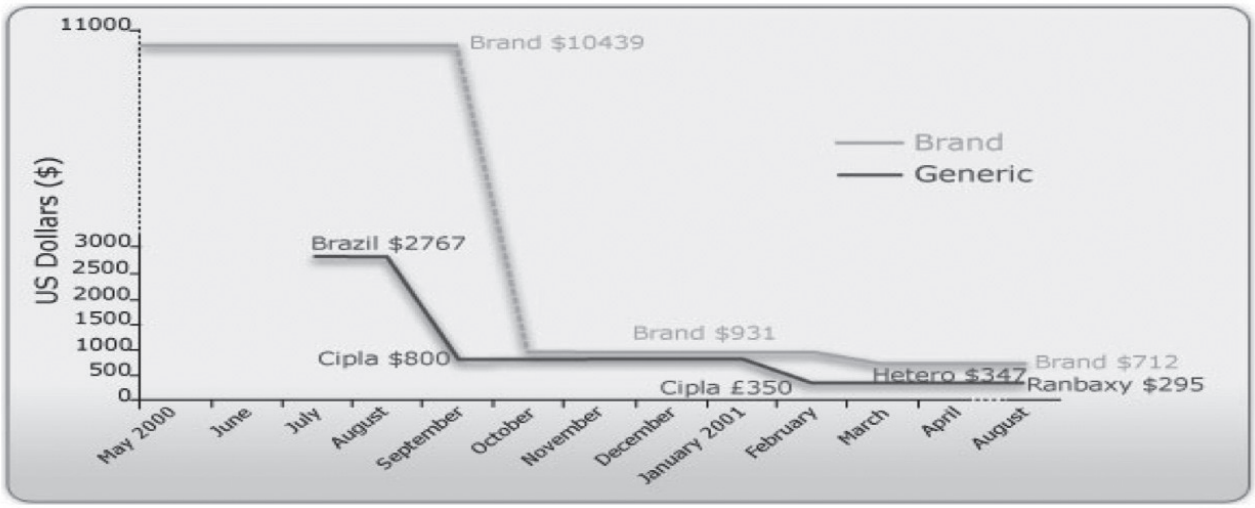
2.3. Price and Patents

The price of medicines is determined by the company that produces them. When a company or an individual has a new medicine approved, it gets a PATENT to compensate for the expenses of developing the new medicine. The patent grants the company exclusive rights (monopoly) of production, distribution, terms of sale and pricing of the medicine for 20 years. During this time other companies cannot produce or sell cheaper generic versions of the patented medicine. The absence of competition prompts the manufacturer to set high prices in order to increase profits. As a result, medicines are expensive and people in developing countries cannot afford the treatments they need.

In order not to lose the 'exclusivity' to produce and sell the medicine pharmaceutical companies often use strategies to extend the patent term (life) on the same compound. This is called evergreening. Some of those strategies include giving new uses to the same medicine or putting two medicines into one.

Patent protection has increased over the past few decades from just a few years to the 20-year monopoly of today. Studies indicate that TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition. The current system gives priority to the profit of pharmaceutical companies at the expense of the public health of developing countries and this is costing millions of lives.

As soon as a generic comes onto the market the price of the medicine drops by an average of 40-80%. Reducing the patent life facilitates the possibility of producing generics, creates competition and consequently lowers the price of the medicine for both the original brand product and the generic forms.



Graph: **Médecins sans frontières**. It shows the lowest world price per patient per year of triple combination therapy made up of d4T (stavudine) + 3TC (lamivudine) + nevirapine.

2.4. Generic Medicines

When a patent expires other laboratories can produce the medicine without patent. This GENERIC contains the same active ingredients and pharmaceutical properties as the patented medicine. As both are identical in dose, strength, safety and efficacy they should produce the same effect. Generic medicines are named after the main active ingredient (healing molecule), while the patented one has a brand name given by the owner of the patent. Generic medicines are legitimately produced but are much cheaper than the brand one because they have no research costs.

TRIPS flexibilities played an important role in the reduction of prices of medicines by allowing the production and export of generics. Lobbying by civil society was instrumental in the introduction of new generic medicines in Africa.

Competition between brand medicines and generics has been very effective in reducing the cost of drugs. In Africa there are generic versions of anti-retrovirals (ARVs) for HIV/AIDS, of antibacterials and of drugs to treat malaria and tuberculosis. The introduction of generic ARVs meant a revolution in HIV/AIDS treatment.

2.5. Essential Medicines

Most common health problems can be treated with a small number of carefully selected medicines. The WHO List of Essential Medicines (EML) contains about 300 active substances. From it, each country selects its own list according to disease prevalence, efficacy evidence, safety, and comparative cost-effectiveness. In theory, they should be available in the country at all times, in adequate amounts, in appropriate dosage forms, with assured quality and at prices individuals and the community can afford.

Because of their prohibitive cost, a number of essential medicines are not included in the EML.
When a country has chosen from the EML, the procurement, distribution and other supply activities are easier as the number of pharmaceutical products is limited. For that reason, the development of a national list of essential medicines is important.

3. ACCESS TO ESSENTIAL MEDICINES IN AFRICA

In some parts of Africa, about 55% of the population lack access to essential medicines. They may be available in private pharmacies but the prices, especially those of branded medicines, are too high.

In Africa, there is little health insurance and most health services, including medicines, are paid in cash by patients. What is more, high prices limit the ability of governments to expand health services and so fewer patients have ready access. In Mozambique, for example, it is estimated that only 40-50% of the population have regular access to public health services and more than 75% of the population relies on traditional medicine.

Improving access to existing medicines could save 4 million lives each year in Africa. Most medicines used in Africa are generics, supplied chiefly by India. In 2006, India supplied 70% of generic antiretroviral drugs, while South Africa supplied 7%, the United Kingdom 6% and the USA 4%[40].

As patients become resistant they need new medicines that are still under patent. These are very expensive and inaccessible for most Africans.

3.1. Africa and the TRIPS

Many African countries have not applied TRIPS flexibilities except for 'parallel imports.' Many have not included flexibilities such as compulsory licensing in their legislation for lack of technical expertise. Others dare not apply TRIPs flexibilities for fear of trade sanctions and other reprisals from rich countries. The 'Competition law in South Africa' contributed to lowering essential medicines prices and two companies were found guilty of excessive pricing. In 2003, Rwanda passed a law requiring generic medicines to be used for all treatment programmes when available. It also imported a generic for HIV/AIDs treatment from a Canadian manufacturing company using the flexibility of the 'compulsory license.'

3.2. The Quality of Medicines

The second main problem regarding medicines is the poor quality. All countries are affected but the developing countries where the means of control are scarce are much more vulnerable.

Lack of quality control of medicines in exporting countries and the absence of guarantee control in the importing countries account for much of the proliferation of low quality medicines. There is a double standard of production: good quality medicines for the West (Europe, America, Australia) and substandard medicines for export to Africa, Latin America and Asia. The governments of the exporting countries put the responsibility for quality control on the country using the medicine. In most African countries the capacity and the means for quality control is non-existent.

The quality of medicines is a key issue for public health as poor quality medicines put lives at risk. For example, some increase resistance because they do not kill all the parasites.

3.2.1. Different Kinds of Poor Quality of Medicines

Substandard medicines are genuine, legal and authorized medicines which do not meet quality specifications as they do not contain the right quantity or quality of active ingredients. Consequently they are ineffective and often dangerous. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or lack of control. They may come from well-known laboratories and are being used in both public and private health practices.

Counterfeit or fake medicines are produced and sold with the intent to deceive. They may have a forged label of another company and unsuitable packaging; the manufacturing processes, transport and storage conditions may have been substandard. They are intended to look like the 'real thing,' but are not what they seem to be. They may include wrong and dangerous ingredients, have few or no active ingredients (the substance that is pharmaceutically active) or the active ingredient may be of bad quality.

Counterfeiting of pharmaceutical products takes many forms, but the risks for the patient are treatment failure, increased toxicity, increased medicine resistance and even death.

[40] Chaudhuri 2008.

The WHO estimates that 200,000 people die annually from counterfeit or poor quality malaria medicines (1/5 of these dying from the disease itself as the medicine is ineffective and 4/5 from the fatal consequences of the medicines).

The high cost of medicines influences quality in two ways. When the prices of medicines become excessive, patients tend to look for cheaper sources outside the normal supply system. This means that counterfeiters can make more money and the health of the community is put in danger.

The production of fake medicines is a pernicious and immoral practice, but very lucrative. It is also a growing business that is estimated to be worth $200 Billion a year and creates 2 to 5% tax losses for governments around the world.

The traffic of counterfeit medicines is flourishing in African countries where institutional capacity to regulate, inspect and enforce the law is weak and adequate funds for regular medicine quality monitoring are lacking.

Of the one million deaths that occur from malaria annually, as many as 200,000 could be avoided if the medicines available were effective, of good quality and used correctly.

While quality generic medicines facilitate access to medicines for all and have a very positive impact on health, counterfeit medicines are causing great health problems in Africa.

3.3.2. The Fight against Low Quality Medicine

The owners of the 'trade-marks' or 'brand names' are seeing their profits decrease and are keen to fight back. They are supported by a series of international agreements and a group of industrialized countries have negotiated the "Anti-Counterfeit Trade Agreement" (ACTA) that will enforce intellectual property rights, but unfortunately also hinder the free circulation of generic medicines. The Council of Europe's MEDICRIME criminalises the manufacturing and distribution of counterfeit medicines that put public health at risk. The World Health Organisation's IMPACT (International Medical Products Anti-Counterfeiting Taskforce) is very controversial. In these agreements, generics and counterfeit medicines are considered similar which is quite untrue as far as quality is concerned. The fact is that these agreements defend the rights of the patent owner but do not consider public interests such as safety and the right to access medicines. The enforcement of IPRs can have serious public health costs as it can affect access to generic medicines in Africa.

Counterfeiters are organised criminal networks that operate across national borders in activities that include the import, export, manufacture and distribution of counterfeit and illicit medicines. While INTERPOL tackles the counterfeit market at international level, the problem is that it too is more interested in medicines without patents than those of poor quality. In reality, they sometimes do not have even the means to analyse the quality of the medicines.

Counterfeit medicines are a danger, not because they do not respect patents, but because they do not conform to quality standards and so jeopardise the health of users the majority of whom are in developing countries.

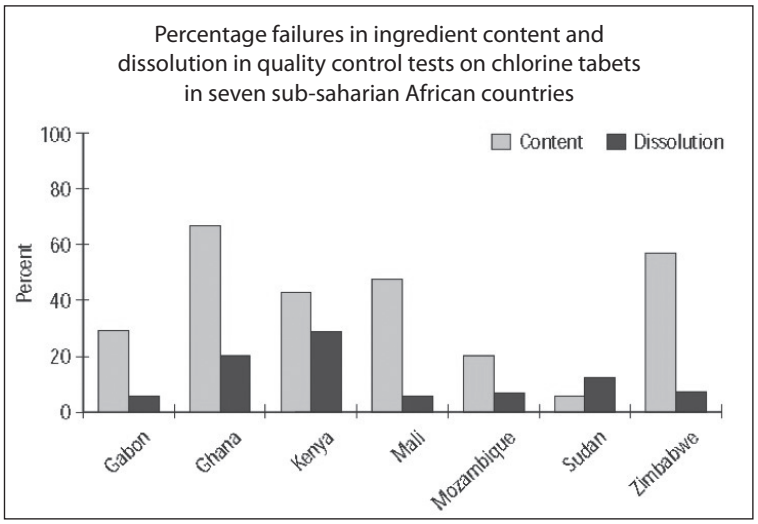
3.3.3. The Problem of Quality of Medicines in Africa

As has already been seen, there are medicines in circulation in Africa whose quality has not been properly controlled. Medical staff are often unaware that the medicines distributed by some health systems are sub-standard. African markets and shops are full of counterfeit (fake) medicines that seem to be the 'real thing'. Millions of people consume ordinary or toxic products believing they are taking good medicine.

In a WHO survey on anti-malarial medicines circulating in six countries of Sub-Saharan Africa, the failure rate for the quality text was 64% for Nigeria, followed by Ghana (39%), Cameroon (37%), Tanzania (11%) and Kenya (5%). No sample from Ethiopia failed. Another study on fake medicines shows a darker picture. In Cameroon and six other African countries, up to 70% of the medicines that claim to cure malaria are fake. 44% in Senegal, 30% from Madagascar and 26% from Uganda are of poor quality.

For many African states, meeting the needs of patients with limited resources and weak regulatory enforcement mechanisms is a real challenge. The two aspirations of seeking economic advantage and improving health do not always converge. There are also some African governments that lack the political will to improve the quality of medicines.

The world's largest pharmaceutical companies gathered in Nairobi in June 2011 to see how to fight counterfeit medicines in East



Africa but they did not mention the low-standard medicines that come from well established laboratories.

In much of Africa, the corner kiosk or the local market is the first source of medicines. They are easily accessible, but customers often receive inappropriate medicines of poor quality which have been badly stored. In Tanzania, over 60% of the population buy their medicines there. To buy medicines from non-pharmaceutical staff, whether well packed or unpacked, in the street or on markets, is dangerous and can put lives at risk. Counterfeit anti-malaria pills cause the deaths of 200,000 people in Africa each year, according to WHO.

Though the market of counterfeiting medicines is illegal, many African countries have not yet enacted deterrent legislation, so counterfeiters rarely fear prosecution.

Influenced by Western governments and companies, Kenya and Uganda have adopted counterfeit legislation to fight the invasion of counterfeit goods. While this is good, the danger remains that, under the guise of fighting counterfeits, these countries will strengthen the protection of intellectual property rights and so make access to generics more difficult. Once again, the poor will suffer.

Buying medicines sold by non-pharmaceutical staff at street kiosks and markets is very dangerous

3.3.4. Towards a Change in the Situation

Many African countries share the same challenges in accessing safe sources of medical supplies, one of them being the lack of national expertise in procurement. One solution could be greater collaboration at regional level to find good medicines for malaria, HIV/AIDS and tuberculosis. They could, for example, share data about trustworthy suppliers who offer both competitive prices and quality. If they also make joint purchases in order to get better terms (known as pooled procurement) they can overcome the challenges connected with costs, quality and availability that are often associated with Procurement and Supply Chains of Essential Medicines.

4. OPENINGS AND POSSIBLE ACTION

New action is needed to ensure quality, affordable basic medicines reach those who need them. It is best if carried out in a variety of ways, locally, nationally and also at international and institutional levels.

4.1 Working Towards better Access

There is a need not only for a change of policies, but first and foremost for a change of heart so that the needs of African countries take priority over the passion of companies to maximise their profits.

At national and international level, we can revisit all agreements that affect the right to health and in particular access to medicines of quality, remembering that tighter rules on intellectual property (IP) benefit pharmaceutical giants, but undermine access to medicines.

We can explore ways of ensuring reliable supplies of quality medicines in African countries.
At national and regional levels, we can advocate for the incorporation and use of TRIPS flexibilities We can increase awareness on IP issues and activities among the Health sector workers.

We can search for new ways of motivating and rewarding research whose outcome will benefit health and health care, e.g. granting prizes instead of patents. We can increase the capacity of local Civil Society Organisations in formulating and implementing health policy.

4.2. Working Towards better Quality Medicines

The work for better quality medicines is multi-faceted:

1. **Countries exporting medicines to Africa** need to be coaxed into enacting legislation – with a clear implementation plan - for the quality control of all exported medicines, whatever their destination.

2. **Quality control of laboratories and the products they produce** (specialist work) It is important at least to know/identify which medicines cause problems, are ineffective or produce strong reactions. In Africa, health workers need to be attentive to medicines causing problems and make this information known.

3. **African countries** need to enact legislation – with clear implementation plans – to counter the production, sale, import or export of counterfeits. Such legislation will be a clear indication of the responsibility leaders at all levels feel towards their people.

4. **The World Health Organization (WHO)** needs to take responsibility for the quality standard of all essential medicines used in developing countries, as it does for HIV/AIDS, malaria and TB.

5. WHAT AEFJN DOES TO PROMOTE ACCESS TO QUALITY MEDICINES FOR ALL IN AFRICA

AEFJN has worked for years to promote access to quality medicines at affordable prices for people with modest incomes in Africa. AEFJN works on both access and quality.

Access: AEFJN works to lower the prices of existing drugs, by lobbying when trade agreements and other agreements that strengthen IPRs threaten to have negative impacts on health and access to generic medicines. AEFJN works with both the EU and the WTO to enable African countries to protect public health and use generic medicines even when the original medicine is still under patent protection.

In recent years AEFJN has been innovative in stimulating Research and Development (R&D) of new medicines for diseases common in Africa, as well as more efficient and adapted diagnosis tests.

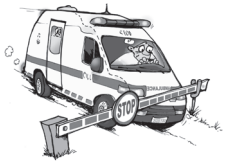
Quality: with other international Organisations, AEFJN has established the Charter for the Quality of Medicines, an ethical code for those buying medicines that offers benchmarks to assure the quality of the medicines they buy. Signing it implies a commitment to adopting essential quality criteria for the purchase of these products, thus contributing to a Quality Assurance (QA) system for medicines.

At the level of the EU institutions and member states, AEFJN advocates for a change of legislation to enhance the quality control, safety and efficacy on medicines exported to Africa, so that there is a common policy and implementation whatever the destination of the medicines. AEFJN advocates for quality control to become the responsibility of the developed country exporting the medicines - or of WHO.

5.1. AEFJN Advocacy Successes

AEFJN influenced the EU Communication on Global Health with the result that the 'Aid to Health' initiative of the EU Institutions and member states is geared towards the strengthening of national health systems and access to essential medicines for all.

AEFJN contributed to the lowering of the treatment cost for HIV/AIDS (Antiretrovirals- ARVs). This was the result of the advocacy and lobbying work done by civil society in Europe, Africa and Asia, where African patients' Organisations played an important part. As a consequence many more patients were treated for the same money.



6. TOOLS FOR ACTION ON MEDECINES

A general introduction on how to carry out action following the various steps of the Pastoral Circle can be found in the first part of this manual. Below, you will find suggestions and tools for an action specifically to do with Access to Quality Medicines; these will complement those found in the Pastoral Circle.

6.1. Knowing the Situation

Focussing on an issue. As the Healthcare system is very large it is a good idea, after a short time getting to know the main health/ medicine problems, for you to choose an issue to focus on, e.g. access to health, access to medicines, production of medicines, economic accessibility, physical access, providing accurate information, quality, etc.

Where can I find information? From health personnel (doctors, nurses, clinical staff, pharmacists, etc.), administrators of Health Institutions, organisations working on health, government health offices (the Ministry of Health), consumer associations, patient associations, journalists dealing with health issues. Gather patient testimonies and personal stories about access to health and medicines and the quality of medicines.

Possible questions to ask. Here are some questions intended to help you find information. You do not need to ask all of them! Choose those you believe more relevant to the work you want to do.

6.1.1. Questions about the Health Situation

What are the country's health priorities?

What is the government budget for health care? What percentage is this of the total budget?

How does your government live up to the commitment of all African Union members to spend 15% of the national budget on health care?

Are health services liberalized in your country? What are the consequences for the public health system?

What are the gaps in the health care system?

Is there denial of access to health care for members of certain groups? How is this discrimination manifested?

What are the problems of physical access to health care facilities in your area?

Where do the health care services in your area get the money from to run the health institutions?

Are there research and development institutions working on health products? What are those institutions and what do they do regarding health products? Are there studies regarding traditional medicines?

Find out if there are groups working on Health policies, access to Medicines, quality, etc. Get in touch with them to find out what they do and how they do it.

6.1.2. Questions about Access to Medicines

What are the national and international commitments of your government regarding availability of essential medicines in public health facilities? (Human Rights, social and economic rights, agreements, commitments to the AU, at the WTO, at the WHO, electoral promises, etc).

Does your government provide free essential medicines at all public health institutions? If not, why not? If it does, where do they get the funding for it? What difficulties are experienced?

What is your government commitment to ensure access to medicine for all?

What are the inefficiencies in the supply chain of medicines? Where in the chain?

Is there a governmental supply Agency for medicines? Do the Churches have a supply Agency? How do they work?

What are the supply chain problems (supply, transport, security of supply, procurement, etc)?

Does your country have a list of Essential medicines (EML)? What is the percentage of medicines used from the EML?

What is the percentage of Generics used in the health system?

What are the main barriers to access to medicines (import taxes, price, health budget, supply chain, procurement, etc)?

Are there regional policies or agencies to facilitate access to medicines?

What work is being done in the region on the rational use of medicines and on medicines promotion?
What is the pricing policy? Is there an existing regulation on access?

What is the impact of poverty on the access to medicines?

What do you consider to be the biggest challenge in achieving universal access to essential medication?

6.1.3. Policies Regarding Intellectual Property Rights (IPRs)

In your country, are there groups that do Advocacy on trade issues? Get in touch with them to see the impact of trade on health and more specifically on medicines.

Become aware of the current WTO rules. What about IPRs? Find out if your country is negotiating an EPA on services and IPRs. Follow the EPA negotiations on services (health).

Gather concrete information on difficulties caused by the IPR, e.g. patents, prices, in your country or region.

Does your country have patents? How has it used TRIPS flexibilities?

How do CSO participate in policy reviews?

6.1.4. Questions about Quality

Find out the studies on the quality of medicines in your country and region. What do they say about your country?

Where do the health institutions get the medicines from?

Where do the people buy the medicines? (Mapping can help).

Where do the medicines used and sold in your country come from? (You can go to the kiosks and check the boxes). Do they come from the 'official' distribution system (deviated or stolen) or are they imported from other countries? Try to find out a percentage, the countries of origin, the producer, etc.)

Go to markets and kiosks selling medicines. Pretend you want to buy some (or buy some) to get to know the origin of the medicines: country of origin, laboratory of production, packeting, conditions of storage, sell by date…

What is the quality of the medicines consumed by the population? How do you know?

Have you heard about bad outcomes from using certain medicines? Which ones? What happened?

Ask the health personnel and the patients for cases where the medicines have not cured or have done more harm than good. Gather those stories. Try to find out the name of the medicine, country of origin and name of the producer. You can gather "cases" where medicines had a fatal or dangerous effect on patients.

Look for secondary effects of medicines taken in your country.

Which medicines are ccounterfeits/fakes? Which ones are low standard and which ones are good?

What legislative efforts has your government made to fight the proliferation of counterfeit medicines? Are there anti-counterfeit laws? What are they? How are they implemented? What is problem with the existing laws?

Are medicines produced in your country? Which ones? What quality control is there?

Are they approved by WHO? Do they have other standards of quality? What are the price and quality of these medicines?

6.1.5. Mapping of Health Institutions and Access to Medicines

You can do different kinds of mapping according to your interest. Here are some ideas:

Health institutions in your area. Map out the health centres in the locality or area. Are they public or private (Church, NGOs, other organisations, owned by individuals)?

Places where medicines are sold and used. Origin of the medicines, users, sellers,

Map the origin and the path the medicines follow before they arrive where you are.

Map the producers of medicines in your country or region.

6.1.6. The Main Problem Related to the Issue you are Working on

Define the problem concretely. E.g. Some medicines (if possible name which ones) from the market have had bad side effects and have even caused death.

6.2. Analysing the Situation

There is a series of international treaties/obligations that affect health care and access to medicines of quality. What influence do they have on your issue?

Become familiar with some of these: the WHO Essential Medicines List; TRIPS Agreement; TRIPS flexibilities; African Charter obligations (the right to health); International Covenant on Economic, Social and Cultural Rights; ACTA; bilateral agreements that your country has signed with the EU (EPAs), the USA, China or Brazil that affect health care and access to medicines.

6.2.1. Analysis of the Causes and Consequences of bad Quality Medicines

Study the problems caused by medicines either because of high price, bad quality, or non-availability.
Pay attention to the analysis of the Budget.

6.3. Christian Reflection on Health and Access to Quality Medicines

6.3.1. The 2nd African Synod Proposals Regarding Access to Quality Medicines

The bishops recognize that AIDS, malaria and tuberculosis are decimating African populations and severely damaging their economic and social life. They denounce the injustice of African patients not receiving the same quality of treatment as elsewhere and recommend that African patients receive the same quality of treatment as in Europe. They ask manufacturers of medicines to make them affordable so as to save more lives.

Proposition 51 on HIV/AIDS and 52 on Malaria of the 2nd African Synod

"HIV/AIDS is a pandemic, together with malaria and tuberculosis, which is decimating African populations and severely damaging their economic and social life. It is truly an issue of integral development and justice, which requires a holistic approach and response by the Church."

"Those who are sick with AIDS in Africa are victims of injustice, because they often do not receive the same quality of treatment as in Europe."

The Church asks that funds destined for those with AIDS be actually used for this purpose, **and recommends that African patients receive the same quality of treatment as in Europe……..**

"Malaria remains the worst killer on the African continent and its Islands, contributing enormously to the aggravation of poverty. We appreciate all the initiatives directed towards combating this sickness. However, we acknowledge that more needs to be done if any remarkable results are to be expected. Therefore the Synod proposes the following…"

1. That governments be urged to develop more consistent and sustained policies and programmes aimed at the eradication of malaria.
2. That manufacturers of medicines make them affordable, so as to save more lives.
3. Sustain efforts to develop a vaccine against malaria.

6.3.2. The Social Teaching of the Church

In Catholic social teaching, as in the Declaration of Human Rights, access to health care is a human right – not just another commodity. From a Catholic standpoint, health care is a right of each human person, independent of his/her economic status or market concerns. The Common Good requires that all individuals have access to affordable health care and to the medicines of quality.

6.3.3. The Compendium of the Social Doctrine of the Church[41]

N. 166. The demands of the common good [….] concern above all the commitment to [….] and the provision of essential services to all, some of which are at the same time human rights [….] basic health care…

182. The principle of the universal destination of goods [….].

385. The preference for the poor, and the decisions which it inspires in us, cannot but embrace…. those without health care [….]

222. …. the elderly …. need health care services and appropriate assistance [….].

245. …. health care for children [….].

6.4. Planning the Action

Look for events which could be opportunities to observe advocacy and lobbying on your issue. These activities often involve the press, targeted groups and general public.

Work out how to monitor the national Budget, target ministries and parliamentary committees to influence discussions in parliament.

How are you monitoring the government? How are you holding them accountable to the commitment on health expenses?

Depending on the issue you have chosen, see how to orientate your advocacy: Medicine pricing? Compulsory Licenses? Parallel Importing? Reduction of import duties? Other? Direct Service provision? Research?

How are you going to disseminate the information gathered (written); workshops (oral); other? community outreach?

How do you see the possibility to interact with the local and national government (e.g. lobbying, advocacy, participation in legislative processes)? For rights not being met? Legislation? commitments? lobbying for appropriate legislative, administrative, budgetary, judicial, and other measures? Involvement in the legislative process? Protest?

How do you foresee being involved with the international effort to achieve access to medicines?

Engage in discussions with Parliamentary Committees for Health, Trade and Foreign Affairs (often dealing with International Trade). When you go to meetings with government or other bodies, institutions or corporations, check who is taking the notes and preparing the Agenda. Offer yourself as volunteer as you can influence the outcome of the meeting.

[41] http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html

ANNEXE 1 – DOCUMENTS AND INFORMATION ON ACCESS TO QUALITY MEDICINES

Documents on Access to Medicines of Quality

- Access to Essential Medicines as a Component of the Right to Health By Stephen P. Marks. http://www.swisshumanrightsbook.com/SHRB/shrb_03_files/04_453_Marks.pdf
- Access to Medicines at Risk across the Globe: What to Watch out For in Free Trade Agreements with the United States. MSF – 2004. http://www.doctorswithoutborders.org/publications/reports/2004/ftaa_05-2004.pdf
- Access to Medicines: Key to MDGs on Child Health – Contact N. 191 – 2011 - A publication of the World Council of Churches. http://www.oikoumene.org/fileadmin/files/wcc-main/documents/p4/contact/Contact191_EN.pdf
- All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines. Oxfam Briefing paper 102 – March 2007. http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf
- Contact Magazine - World Council of Churches (WCC). http://www.oikoumene.org/en/programmes/justice-diakonia-and-responsibility-for-creation/health-and-healing/contact-magazine.html
- Does Price Reveal Poor-Quality Drugs? Evidence from 17 countries. 2011 – By R. Bate, G. Zhe Jin, A. Mathur. http://www.aei.org/files/2011/08/18/Does-Price-Reveal-Poor-Quality-Drugs.pdf
- Doha Derailed: A Progress Report on TRIPS and Access to Medicines – MSF 2003. http://www.doctorswithoutborders.org/publications/reports/2003/cancun_report.pdf
- Ensuring the Quality of medicines in Resource-Limited Countries – An Operational Guide – In collaboration with the WHO. http://www.usp.org/pdf/EN/dqi/ensuringQualityOperationalGuide.pdf
- Equitable access to essential medicines: a framework for collective action. WHO 2004. http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf
- Essential Medicines in Health Primary Care – Contact n. 187 – 2009 – A publication of the World Council of Churches. http://www.oikoumene.org/fileadmin/files/wcc-main/documents/p4/contact/con-187.pdf
- FBOs on a Mission: 30 years of supporting Pharmaceutical Services – Contact N. 193, 2011 – A publication of the World Council of Churches. http://www.oikoumene.org/fileadmin/files/wcc-main/documents/p4/contact/Contact%20193_EN.pdf
- Free Trade of pharmaceutical Products. The Limits of intellectual property enforcement at the Border. By Xavier Seuba; Universitat Pompeu Fabra, Barcelona. http://ictsd.org/downloads/2011/12/free-trade-of-pharmaceutical-products.pdf
- FTAs; Civil Society and Access to Medicines By Germán Holguin, 2008. Power Point. http://www.haiweb.org/05062008/(6)%20German.pdf
- Health system strengthening: Focus on Church Based Pharmaceutical Human Resources. Contact N. 189, 2010 – World Council of Churches. http://www.oikoumene.org/fileadmin/files/wcc-main/documents/p4/contact/Contact%20189%20English.pdf
- How do Patents and Economic Policies Affect Access To Essential Medicines in Debeloping Countries By Amir Attaran. http://content.healthaffairs.org/content/23/3/155.full
- Life-Saving or Life-Threatening? India and the Medicine Quality Conundrum. By Roger Bate. 2009. http://www.aei.org/files/2009/06/22/20090622-HPO-June.pdf

- Local Production and Access to Medicines in Low- and Middle-Income Countries. A literature review and critical analysis. WHO. 2011. http://www.who.int/phi/publications/Local_Production_Literature_Review.pdf

- Local Production for Access to medical products: Developing a Framework to Improve Public Health. WHO – 2011. http://www.who.int/phi/publications/Local_Production_Policy_Framework.pdf

- Local Production of Pharmaceuticals and Reated Technology Transfer in Developing Countries. A series of case studies by the UNCTAD Secretariat. http://www.who.int/phi/publications/Local_Production_Case_Studies.pdf

- Medicine registration and medicine quality: a preliminary analysis of key cities in emerging markets. R. Bates, L. Mooney, K. Hess. http://www.dovepress.com/getfile.php?fileID=8349

- Medicine prices surveyx and proposed interventions to improve sustainable access to affordable medicines in 6 Sub-Saharan African countries – WHO and HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf

- MSF – Access to Medicines Campaign. http://www.msfaccess.org/

- Pharmaceutical Production and Related Technology Transfer: Landscape report- WHO 2011. http://www.who.int/phi/publications/Local_production_and_access_to_medicines.pdf

- Prescription for healthy development: increasing access to medicines. By Beryl Leach Joan E. Paluzzi, Paula Munderi. UN Millennium Project – 2005. http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf

- POWERPOINT: Cracking Down on Killer Medicines in Nigeria. The NAFDAC Experience. Dora N. Akunyili. http://www.aei.org/files/2008/04/14/20080414_AkunyiliPowerpoint.pdf

- Survey of the Quality of Selected Antimalarial Medicines Circulating in Six Countries of Sub-Saharan Africa – WHO 2011. http://www.who.int/medicines/publications/WHO_QAMSA_report.pdf

- Survey of the Quality of Selected Antimalarial Medicines Circulatin in Madagascar, Senegal and Uganda – USP and USAID – 2009. http://www.usaid.gov/our_work/global_health/hs/publications/qamsa_report_1109.pdf

- The Danger of Substandard Medicines in Emerging Markets: An Assessment of Basic Product Quality. By Roger Bate & others. 2012. http://www.aei.org/files/2011/06/28/Pharmacologia-Published.pdf

- The Global politics of Pharmaceutical Monopoly Power by Ellen F.M. 't Hoen; AMB 2009. http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/aem_20090312/politics_20090312.pdf

- The market for inferior medicines: Comparing the price of falsified and substandard products with the legitimate medicines in emerging markets. By Roger Bate. 2011. http://www.aei.org/files/2011/12/14/-the-market-for-inferior-quality-medicines_122143586079.pdf

- The Primacy of Public Health Considerations in Defining Poor Quality Medicines. PaulN. Newton and others. PLoS Medicine 2011. http://www.aei.org/files/2011/12/07/-the-primacy-of-public-health-considerations-in-defining-poor-quality-medicines_094342491251.pdf

- Trading Away Health. Intellectual property and Access to medicines in the Free Trade Area of the Americas (FTAA) Agreement. MSF 2003. http://www.doctorswithoutborders.org/publications/reports/2003/FTAA_Advocacy.pdf

- Trends in Local production of Medicines and Related Technology Transfer. WTO 2011. http://www.who.int/phi/publications/Trends_in_Local_Production_of_Medicines.pdf

- Video: Counterfeit Medicines in African nations by Roger Bate – 2010. http://www.aei.org/media/roger-bate-on-counterfeit-drugs-in-african-nations-video/

- Which tablets to buy – AEFJN 2010. http://www.aefjn.org/tl_files/aefjn-files/medicines/meds_mat_aefjn%20eng/110517_Which_tablets_to_buy_eng.pdf

- Essential Medicines Monitor. http://www.who.int/medicines/publications/monitor/en/

- The world Medicines Situation 2011 – Pharmacovigilance and Safety of Medicines. http://apps.who.int/medicinedocs/documents/s18771en/s18771en.pdf

Eastern African Region

- Medicine prices in the East African Community - Medicine prices surveys and proposed interventions to improve sustainable access to affordable medicines in 6 Sub-Saharan African countries. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf

Southern African Region

- Supporting the retention of health resources: SADC policy context 2005. http://www.equinetafrica.org/bibl/docs/DIS37HRes.pdf

ANNEXE 2: ORGANISATIONS AND DOCUMENTS BY COUNTRY IN AFRICA

INTERNATIONAL ORGANISATIONS

Action Medeor. http://medeor.de/en/medeor-market-en.html
EPN - Ecumenical Pharmaceutical Network –Secretariat in Kenya. http://www.epnetwork.org/
Because Health – Health Network with a Quality Medicines working group – Secretariat in Belgium. http://www.be-causehealth.be/en
Doctors without borders (Médecins sans frontières) Access to Medicines. http://www.msfaccess.org/
HAI - Health action International– Secretariat in Amsterdam. http://www.haiweb.org/
HAI – Africa - Health Action Africa – Secretariat in Nairobi. http://www.haiafrica.org/
International Network for the Rational use of Medicines. http://www.inrud.org/
IMA - Interchurch Medical Assistance, World Health. http://www.imaworldhealth.org
DIFAEM - The German Medical Mission. http://www.difaem.de/about-difaem/pharmaceutical-services.html
PHM - People's Health Movement. http://www.phmovement.org/
PSF - Pharmaciens sans Frontières International. http://www.psfci.org/
UAEM - Universities Allied for Essential Medicinces - California – USA. http://essentialmedicine.org/
WEM - Worldwide export management. www.wem-world.de
WHO - World Health Organization – Essential Medicines. http://www.who.int/topics/essential_medicines/en/index.html

BENIN

Organisations
BETHESDA-BENIN. http://www.bethesdabenin.org/Bethesda/index.html

BURKINA FASO

Organisations
Doctors without Borders – Burkina Faso. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=13
ACCEDES - Alliance Chrétienne pour la Coopération et le Développement Social. http://www.accedes.org/
AEAD - Association Evangélique d'Appui au Développement. http://www.aead.info/AEAD_English/index.htm
ODE - Office de Développement des Eglises Evangéliques. http://www.ode-burkina.org/

CAMEROON

Organisations
OSEELC - L'oeuvre de santé de l'Eglise Evangélique Luthérienne au Cameroun - The Association of Evangelical Lutheran Churches in Cameroon. http://www.oseelc.org/
CBCHB - Cameroon Baptist Convention Health Board. http://www.cbchealthservices.org/
Doctors without Borders – Cameroon. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=16

CHAD

Organisations
Doctors without Borders – Chad. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=18
Union Nationale des Associations Diocésaines de secours et développement UNAD - SECADEV.

Materials
Les prix des médicaments au Tchad – Etudes des prix des médicaments et interventions proposées pour améliorer durablement l'accès aux médicaments dans 6 pays de l'Afrique subsaharienne. WHO – HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf

CONGO BRAZZAVILLE

Organisations

Doctors without Borders – Congo Brazzaville. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=21

DR CONGO

Organisations

Doctors without Borders – DR Congo. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=22
Santé Rurale-THE SANRU PROJECT - (Protestant Church of Congo (ECC) and Interchurch Medical Assistance (IMA). http://www.sanru.org/about_sanru.htm

GHANA

Organisations

CHAG - The Christian Health Association of Ghana. http://www.chagghana.org/chag/

Material

Medicine prices in Ghana - Medicine prices surveys and proposed interventions to improve sustainable access to affordable medicines in 6 Sub-Saharan African countries – WHO and HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf

ETHIOPIA

Organisations

Doctors Without Borders – MSF - Ethiopia - http://www.doctorswithoutborders.org/news/allcontent.cfm?id=26
Ethiopian Catholic Secretariat ECS. http://www.ecs.org.et/
EECMY - Ethiopian Evangelical Church Mekane Yesus Development and Social Services Commission. http://www.eecmy.org/

Material

Case Study 4 Ethiopia in Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries. A series of case studies by the UNCTAD Secretariat. http://www.who.int/phi/publications/Local_Production_Case_Studies.pdf

GHANA

Organisations

Catholic Medicine Centre – Ghana. http://www.nchs.org.gh/
CHAG - Christian Health Association of Ghana. http://www.chagghana.org/
Catholic Pharmaceutical Services(CPS) – Ghana.
AHRO - Africa Health Research Organization - Ghana. http://www.afrihero.org/
HANGHANA - Health Access Network - Ghana. http://www.hanghana.org/

GUINEA CONAKRY

Organisations

MEDECINS SANS FRONTIERES – Guinée Conakry. http://www.msf-me.org/en/mission/in-the-field/msf-projects-worldwide/guinea-conakry-1.html

KENYA

Organisations

HAI AFRICA - Health Action International - Office in Nairobi. http://www.haiafrica.org/
MEDS – Mission for Essential Medicines and Supplies Kenya. http://www.meds.or.ke/
EPN – Ecumenical Pharmaceutical Network. http://www.epnetwork.org/
CHAK - Christian Health Associations of Kenya. http://www.chak.or.ke/
Doctors Without Borders (MSF) - Kenya. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=39
MAP Medical Assistance Programs International - Kenya. http://www.map.org/what-we-do/provide-medicines/
KETAM - Kenya Treatment Access Movement. http://www.ketam.org/

Material

Access to Essential Medicines in Kenya – A Health Facility Survey. Ministry public Health – 2009. http://apps.who.int/medicinedocs/documents/s18695en/s18695en.pdf
Medicine prices in Kenya - Medicine prices surveys and proposed interventions to improve sustainable access to affordable medicines in 6 Sub-Saharan African countries – WHO and HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf

LESOTHO

Organisations

Doctors without Borders (MSF) - Lesotho. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=110
Christian Health Association of Lesotho CHALE.

LIBERIA

Organisations

Doctors without Borders (MSF). http://www.doctorswithoutborders.org/news/allcontent.cfm?id=42
Christian Health Association of Liberia CHAL.

MADAGASCAR

Organisations

SALAMA – Centrale d'Achats de médicaments Essentiels et matériél médical. http://www.salama.mg

MALAWI

Organisations

CHAM - Christian Health Association of Malawi. www.cham.org.mw
MHEN - Malawi Health Equity Network.
DOCTORS WITHOUT BORDERS - Malawi. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=45

Material

Country Health Equity Analysis –Malawi 2006 - Equinet. www.equinetafrica.org/bibl/docs/REQMalawi06.pdf
Equity in Health Sector Responses to HIV/AIDS in Malawi 2003 – Equinet. www.equinetafrica.org/bibl/docs/aidsmalawi.pdf
Documents of MSF on Malawi. http://www.doctorswithoutborders.org/publications/research/?tag=45
Assessment of equity in the uptake of anti-retrovirals in Malawi 2008 – Equinet. www.equinetafrica.org/bibl/docs/DIS-58FINmuula.pdf

MALI

Organisations
Doctors without Borders (MSF) - Mali. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=46

Material
Les prix des médicaments au Mali –WHO – HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall-8files.pdf
Evaluation du système d'approvisionnement et de distribution des médicaments au Mali 2008. http://apps.who.int/medicinedocs/documents/s17535fr/s17535fr.pdf
Etude sur la disponibilité et les prix des médicaments dans le secteur privé au Mali (Search in Google).
Evaluation du secteur Pharmaceutique au Mali 2003- Ministère de la Santé - (Search in Google).

MOZAMBIQUE

Organisations
Doctors without Borders (MSF) - Mozambique. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=51

Material
Access to medicines. Medicine Supply: Lessons learnt in Tanzania and Mozambique. By Karin Wiedenmayer.
http://apps.who.int/medicinedocs/documents/s18422en/s18422en.pdf

NIGER

Organisations
Centre Medico Social ALOMAR. www.musuhum.org
MEDECINS SANS FRONTIERES - Niger. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=55
Union des Eglises Evangéliques Protestantes au Niger.

Material
Rapport de l'étude sur les prix des médicaments au Niger – 2006 – (Search in Google).
Etude Distribution des antipaludéens sur le secteur privé au Niger 2010 – (Search in Google).

NIGERIA

Organisations
Christian Health Association of Nigeria CHAN. http://www.chanmedi-pharm.org/
CHAN Medi-Pharm Ltd. www.chanmedi-pharm.org
Doctors without Borders (MSF). http://www.doctorswithoutborders.org/news/allcontent.cfm?id=56
ECWA Central Pharmacy. http://www.ecwang.org/site/Departments/ECWACentralPharmacies/tabid/66/Default.aspx

RWANDA

Organisations
Doctors without Borders (MSF). http://www.doctorswithoutborders.org/news/allcontent.cfm?id=65
BUFMAR - Bureau des Formations Médicales Agréées. http://bufmar.org/

SIERRA LEONE

Organisations
CHASL - Christian Health Association of Sierra Leone.
Christian Outreach Justice Mission – Sierra Leone.
Doctors without Borders (MSF) - Sierra Leone. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=68

SOMALIA

Organisations
Doctors without Borders (MSF) – Somalia. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=67

SOUTH AFRICA

Organisations
Catholic Health Care Association of Southern Africa (CATHCA). http://www.cathca.co.za/
AMFA - Affordable Medicines For All – South Africa. http://www.amfa.org/
Doctors without Borders (MSF) – South Africa. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=69

SUDAN

Organisations
CHAS - Christian Health Association of Sudan. www.chasudan.org
Doctors without Borders (MSF) - Sudan. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=72

Material
Sudan, Pharmaceutical Country Profile. http://www.who.int/medicines/areas/coordination/sudan_pharmaceuticalprofile_december2010.pdf

SWAZILAND

Organisations
Doctors without Borders (MSF) – Swaziland. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=159

TANZANIA

Organisations
Action Medeor Tanzania.
CSSC - Christian Social Services Commission. http://www.cssc.or.tz.
CSSC - The Christian Social Services Commission formed by the Tanzania Episcopal Conference (TEC) and the Christian Council of Tanzania (CCT) - Dar Es Salaam.
Doctors without Borders (MSF) – Tanzania. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=74
Mission for Essential Medical Supplies MEMS. http://elct.health/projects/mems/html

Material
Access to medicines. Medicine Supply: Lessons learnt in Tanzania and Mozambique. By Karin Wiedenmayer. http://apps.who.int/medicinedocs/documents/s18422en/s18422en.pdf
Medicine prices in Tanzania - Medicine prices surveys and proposed interventions to improve sustainable access to affordable medicines in 6 Sub-Saharan African countries – WHO and HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf
Documents from Mediceins Sans Frontieres. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=74

TOGO

Organisations
APROMESTO - Association Protestante des Œuvres Médico- sociales et Humanitaires du Togo.

UGANDA

Organisations

JMS - Joint Medical Store. www.jms.co.ug/
UCMB - The Uganda Catholic Medical Bureau. http://www.ucmb.co.ug/index.php
UPMB - Uganda Protestant Medical Bureau. http://www.upmb.co.ug
Doctors without Borders (MSF) – Uganda. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=78
HEPS- Health Consumers' Organisation - UGANDA. http://www.heps.org

Materials

Access to medicines in Uganda: intersections with poverty. http://www.unmillenniumproject.org/documents/TF5-medicines-Appendixes.pdf
Case Study 8 Uganda in Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries. A series of case studies by the UNCTAD Secretariat. http://www.who.int/phi/publications/Local_Production_Case_Studies.pdf
Medicine prices in Uganda - Medicine prices surveys and proposed interventions to improve sustainable access to affordable medicines in 6 Sub-Saharan African countries – WHO and HAI. http://www.who.int/medicines/areas/technical_cooperation/Medpricesall8files.pdf
The push for local production, costs and benefits – A case study of Uganda's Quality Chemicals. Africa Fighting Malaria Policy Paper – 2009 By J. Taylor, R. Bate, E. Putze, R. Tren. http://www.fightingmalaria.org/pdfs/localproduction_september2009.pdf

ZAMBIA

Organisations

CHAZ - The Churches Health Association of Zambia - Lusaka. http://www.chaz.org.zm/about.php
Doctors without Borders (MSF) – Zambia. http://www.doctorswithoutborders.org/news/allcontent.cfm?id=82

ZIMBABWE

Organisations

Doctors Without Borders. http://www.doctorswithoutborders.org/news/country.cfm?id=2294
EQUINET, the Regional Network on Equity in Health in Southern Africa. http://www.equinetafrica.org/
ZACH - Zimbabwe Association of Church-related Hospitals. http://www.zach.org.zw

CONTINENTAL AND REGIONAL ORGANISATIONS

Continental Organisations

Africa Christian Health Associations Platform –Secretariat in Nairobi. http://www.africachap.org/
AMFA Foundation – Affordable Medicines for Africa. http://www.amfa.org/

[42] Taken from AMFA (Affordable Medicines for Africa)

ANNEXE 3 - CRITERIA TO ENSURE QUALITY MEDICINES

1. CRITERIA TO ENSURE QUALITY OF MEDICAL PRODUCTS

- o Essential medicines formulary.
- o Source pharmaceuticals primarily from local suppliers.
- o Competitive prices with current suppliers.
- o 4 - 6 week delivery improves cash flow, reduces inventory costs.
- o Products backed by excellent quality control.
- o Dedication to excelling in long-term customer service.
- o Bulk packaging appropriate for hospitals, clinics & dispensaries.
- o Regional distribution centres insure rapid turn-around.

2. KEY PLAYERS AND THEIR RESPONSIBILITIES

Manufacturers are primarily responsible for the quality of the medicines they produce by following the tenets of good manufacturing practices (GMP). After a product leaves the manufacturer's premises, distributors, procurement agencies (purchasers), dispensers and users are responsible for maintaining the quality of the product through proper storage, transport, distribution, dispensing and use.

National governments are responsible for ensuring that manufacturers comply with current GMP requirements. This may present a challenge for countries with limited resources.

Guidelines for meeting current GMPs are available from the World Health Organization and from countries with progressive medicine regulatory agencies.

2.1. Government Leaders and Policymakers

National government leaders and policymakers are responsible for defining national medicines policies that cover access, quality assurance, rational use and other considerations; however, few low- and middle-income countries include quality assurance in their national medicines policies. Many countries that have established quality assurance programs under national policies have met with notable success.

Experience in Australia, Canada, and the United States, for example, has shown that adequate legislation and its enforcement result in fewer poor-quality medicines and greater public confidence in the quality of the medicines (Ratanawijitrasin and Wondemagegnehu, 2002).

By contrast, when the pharmaceuticals market is poorly regulated because of inadequate legislation or weak enforcement, counterfeit and substandard medicines proliferate (World Health Organization, 1999).

Legislation and regulation form the foundation of assuring medicines quality. In brief, national leaders and policymakers are responsible for formulating and updating legislation and regulations to cover all aspects of national pharmaceutical trade and use. Legislation and regulations form the foundation of assuring medicines quality.

Establishing a national Medicines Regulatory Authority (MRA) that incorporates the medical, scientific, and technical knowledge and skills necessary to control medicines quality.

For an MRA to function properly, a national government must:

- o Enact legislation to empower the MRA.
- o Provide appropriate organisational structure.
- o Allocate adequate and sustainable financial resources.
- o Assign qualified, trained, competent personnel.
- o Provide the necessary facilities and tools.

If these resources are inadequate or lacking, an MRA will not be able to properly perform its functions, which may lead to substandard and counterfeit medicines entering the marketplace.

2.2. National Medicines Regulatory Authorities

MRAs are responsible for ensuring the safety, efficacy, and quality of imported and locally produced medicines. Their authority should encompass both public and private sectors alike.

The key activities of an MRA include:

- o Registering medicinal products (that is, authorizing the marketing of medicines).
- o Licensing pharmaceutical establishments (manufacturers, importers, distributors or wholesalers, and retailers).
- o Issuing, amending, and revoking registration for products because of unacceptable quality, safety, or efficacy, including product recall notification.
- o Inspecting manufacturing, distribution, and retail premises for compliance with respective guidelines and practices, including GMP, good storage and distribution, and good dispensing practices.
- o Performing post-marketing surveillance to secure the quality and safety of medicines in the marketplace.
- o Controlling activities designed to promote and advertise medicines.
- o Approving clinical trials.

2.3. Key Points to Effectively Maximize Resources

Countries with limited economic and technical resources may want to prioritise the activities listed below in the following manner to maximize the effectiveness of their resources:

- o License importers, wholesalers, and retailers (pharmacies and medicines outlets/stores).
- o Require registered importers or wholesalers to notify a central body about which products they intend to import or have already imported.
- o Recognize the Pharmaceutical Inspection Cooperation Scheme (PIC/S), International Conference on Harmonization (ICH) guidelines, and WHO prequalification scheme.
- o Perform appropriate evaluation of both multisource (generic) and branded medicines registration. (This topic is explored more fully in Chapter 4.).

You can find a User's Guidelines for the Control of Pharmaceutical products on AEFJN website

http://www.aefjn.org/index.php/358/articles/charter-for-the-quality-of-medicines.html