MANUAL PART 2 - ACCESS TO MEDICINES OF QUALITY

1.1 VOCABULARY and ABBREVIATIONS for Access to Medicines of Quality

A. 1. Vocabulary

Active substance or **active ingredient** (**AI**) or **active pharmaceutical ingredient** is the substance in a medicine that is 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 authorize 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.

Compulsory licensing. 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 to get benefits. TRIPS allows for compulsory licensing on grounds of public interest. The Doha Declaration extended the compulsory licensing to imports.

Counterfeit medicines (drugs) are deliberately and fraudulently mislabelled (fake) with respect to identity or source. They may or many not have the active pharmaceutical ingredient mentioned. They are the result of deliberate criminal activity. Both branded and generic products can be counterfeited. Counterfeit products may include the correct or wrong ingredients in quality and quantity and may contain harmful products.

Data exclusivity: A legal provision that does not allow the use for a specified period - of data collected as result of clinical trials- to a generic product when the producer wants to obtain the marketing approval by regulatory authorities.

Differential pricing: The practice of setting different prices for different markets, 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 against payment either set by law or determined through some form of arbitration.

Essential medicines are the medicines that satisfy the health care needs of the majority of the population. They are selected regarding to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. The medicines consider as essential in a country remains a national responsibility. Essential medicines are intended to be available within the functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at affordable price.

Essential medicines list (EML) is a list of medicines published by WHO, updated regularly, which provide safe and effective treatment for infectious and chronic diseases affecting the vast majority of the world's population.

Evergreening: A term popularly used to describe patenting strategies that are intended to extend the patent term on the same compound.

First-line drugs: The medicines used as a first resort to treat a disease.

Generic medicine (drug) is a pharmaceutical product, intended to be interchangeable with the originator product, which is usually manufactured without a licence (patent) from the originator company. It has the same active ingredients that the brand-medicine but is marketed under the name of its 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 the creations of their minds. They give the creator an exclusive right for a certain period of time over the use of the creation. Among the IPR are 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 undertaking common objectives, sharing data and ensuring the access to the common 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 in the package but 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 20 years monopoly for that drug. This means complete control over the production, distribution and the price of the drug.

Patent pool for medicines is a structure where patent holders share their medicine 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 then access these patents to produce more affordable versions of the patented medicines. 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 compiled data about Active Pharmaceutical Ingredients (API) or Product with its identification tests, Impurity profile, Assay method, test for impurity, solubility etc. It ensures that the product meets the standards. Many countries have developed their own pharmacopoeia. Of these, 4 have become international benchmarks: the European (EP); the one from the USA (USP), the United Kingdom (BP) and the International one defined by WHO.

Pooled procurement is the joint purchasing of medicines of different countries in order to resolve challenges of price, quality and other difficulties associated with Procurement and Supply Chains of Essential Medicines.

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

Qualification system is a pool of processes used to select the sources of supply of medicines 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 only occasional analysis of the drug. As often only the active ingredient is controlled, it cannot ensure by itself that the medicine tested is of 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. Quality control 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 make 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.

WHO Prequalification assesses and ensures the acceptable standards of quality, safety and efficacy for a certain 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. It has significantly improved access to quality medicines over the past years.

World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations system. 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.

World Trade Organization (WTO) is the international organization dealing with the rules of trade between nations. The WTO agreements negotiated and signed by its members must be ratified in their parliaments. The aim of the WTO is to eliminate all the barriers to trade, in order to help producers of goods and services, exporters, and importers conduct their business.

A. 2. ABBREVIATIONS

ARIPO African Regional Intellectual Property Organisation for Southern and Eastern Africa

API Active pharmaceutical Ingredients

ARV Antiretroviral medicine to treat HIV/AIDS

CAPs Centrally Authorised products

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 property rights

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

OECD Organization for Economic Co-operation and Development

PERF Pan European Regulatory Forum

PhV Pharmacovigilance

PIM Product Information management

R&D Research and development

TB Tuberculosis

TRIPS Trade-related Aspects of Intellectual Property Rights

UN United Nations

UNDP United Nations Development Programme

UNCTAD United Nations Conference for Trade and Development

VL Voluntary licence

WHO World Health Organization

WTO World Trade Organization

1.2 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 essential medicines necessary for the prevention and treatment of prevalent diseases should be available at all times, in adequate amounts, in appropriate dosage forms at a price the community can afford. Yet 270 million people in Africa lack access to the medicines they need. This contributes to millions of deaths and untold suffering from easily treatable diseases, either because the medicines are too expensive for patients or governments to afford, because of bad quality or simply because they are unavailable.

Malaria, HIV/AIDS, TB and other infectious diseases are the main causes of mortality in Africa. Yet there are medicines able to cure these illnesses or improve the life of those suffering from them.

The lack of access to medicines has also 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 pocket 50 to 90 % of essential medicines.

Another reason of lack of access is that research and development are not directed to the medical needs of the people of Africa. Only 1% of the new 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 consider the African market too small and not financially viable they do not invest on those diseases. In Africa there is very little research and development on traditional medicine, while laboratories are already patenting some of their curative products.

Another main problem related to medicines is the low quality of many drugs. Paying for medicines can consume a significant proportion of individual or family income. So people seek medicines that are sold more cheaply in markets or kiosks, but whose quality is questionable.

Medicines of poor quality constitute serious risks for people's health such as treatment failure or even death. Low-quality versions of the medicine increase resistance because they do not kill all of 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 (false) medicines affect the health of the population who often receive little benefit for their spending on drugs.

2. The 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 to the aspect of affordable prices.

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

2.1. Trade and Access to Medicines

The international regulation on trade is becoming increasingly important for the health services. Trade policies have a direct impact on people's right to health, as they influence access and price of medicines; government revenue; liberalization of the health sector; trade in health related services.

The liberalization of trade imposes the removal of import and export duties. This affects the tax revenue available to governments to fund public services including health.

The liberalization of services includes health services. The liberalization of the health sector in Africa, would lead to a decline in the quality of the service for the poorest. The public sector will have to compete with the private sector that will attract the best and most qualified health personnel, thus weakening the national health systems. Inequity of access will increase because the private sector favours those who can afford the treatment.

The Intellectual Property Rights, such as patents, and Data exclusivity included in Trade Agreements have a great impact on generics and thus on the price of medicines and on the possibility of poor countries to access to the essential medicines they need.

Please read in the Part on TRADE section 2.2.2 (check numbering final version) of Trade in Services.

2.2. Strengthening 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 benefits. So they lobby hard their governments to strengthen the Intellectual Property Rules.

The Intellectual Property (IP) Rights are a barrier to access to medicines. Strengthening of IP protection makes difficult the access to cheap generics and increases the costs of medicines in Africa. Furthermore, increased IP protection also impedes 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 products developers (IPRs protection) and public health and the interests of users. So 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 USA, the EU and its member states oppose "in practice" the right of developing countries to declare "compulsory licenses".

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

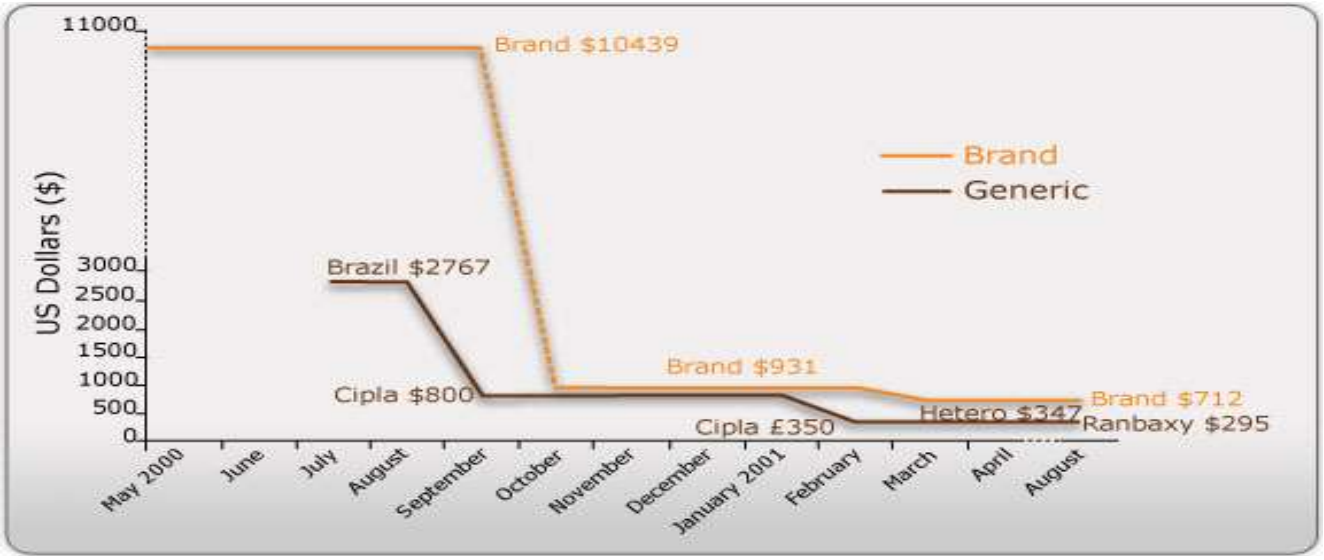
In recent years a number of countries, among them the European Union (EU), are reinforcing IPRs. In their bilateral agreements they introduce **TRIPS-Plus,** clauses that enforce intellectual property protections beyond the requirement of TRIPS. This has severe consequences for public health. A measure being introduced is "protection" of "data exclusivity" up to 12 years. In that case generic companies cannot use for 12 years the

existing clinical data on a medicine to register it, and that 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 the research done to obtain 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, without competition from other manufacturers. During this time other companies cannot produce nor sell cheaper generic versions of the patented medicine. The absence of competition prompts the manufacturer to set high prices in order to get more benefits. As a result medicines are expensive and people in developing countries cannot afford the treatments they need.

The following graph illustrates the effect of generic competition on medicine prices between 2000 and 2001.



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

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strategies to extend the patent term (life) on the same compound. This is called **evergreening**. Some of those strategies is giving new uses to the same medicine, or putting two medicines in one.

Patents offer great benefits to the pharmaceutical companies while being an obstacle to access medicines for poor patients and countries.

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 privileges the profit of pharmaceutical companies over the public health interest of developing countries, which costs millions of lives.

As soon as a generic comes into 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 substantially lowers the price of the medicine for both, the original brand product and the generic forms.

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 medicines are identical in dose, strength, safety and efficacy they are supposed to produce the same effect. Generic medicines are named by 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. The lobbying of civil society contributed largely to 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 most medicines used are generic versions of anti-retrovirals (ARVs) to treat HIV/AIDS, anti-malarial, anti-tuberculosis and antibacterial medicines. 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. Out of this list each country selects its own list according to disease prevalence, evidence of efficacy, safety, and comparative cost-effectiveness. Because of its prohibitive cost, a number of essential medicines are not included in the EML.

Essential medicines are medicines that satisfy the priority health care needs of a population. They are intended to be available in the country health system at all times in adequate amounts, in appropriate dosage forms, with assured quality, and at prices individuals and the community can afford.

When a country decides on an EML the procurement, distribution and other supply activities can be carried out most efficiently as the number of pharmaceutical products is limited. In that sense the development of a national list of essential medicines is an important means of facilitating access to medicines.

3. Access to essential medicines in Africa

In some regions of Africa about 55% of the population, about 270 million people lack access to essential medicines. Medicines may be available in private pharmacies but the prices, especially those of branded medicines are unaffordable for most Africans who need them.

In Africa health insurance is negligible and most health services included medicines are paid out-of-pocket by patients. High prices limit the ability of governments to expand health services and means less patients having access to them. As an example, in Mozambique, it is estimated that only 40-50% of the population have regular access to public health services and more than 75% of the population uses traditional medicine primarily to treat health-related problems.

Improving access to existing medicines could save 4 million lives each year in Africa.

Most medicines used in Africa are generics. India is the big supplier of generics for Africa. In 2006 India supplied 70% of generic antiretroviral drugs, while South Africa supplied 7%, the United Kingdom supplied 6% and the United States of America supplied 4%[1].

Patients become resistant and need new medicines still under patent that are very expensive and inaccessible for most Africans.

3.1. Africa and the TRIPS

Many African countries have not applied TRIPS flexibilities, except "parallel imports". Many have not included flexibilities such as compulsory licensing in their legislation for lack of technical expertise. Others do not dare to 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 generic manufacturing company using the flexibility of the "compulsory license".

3.2. The quality of medicines

The second main problem regarding medicines is the low or bad quality of many of the medicines being sold and used today. All countries are affected but the developing countries where the means of control are scarce are much more vulnerable to this problem.

The lack of quality control of the medicines in exporting countries, and the lack of guarantee control in the importing countries is one of the main reasons of the proliferation of low quality medicines, as it facilitates the export of substandard medicines to Africa. Laboratories profit from the lack of quality control capacity, means and mechanisms in the receiving countries of those continents to lower the control and quality of their medicines. The result is a double standard of production: good quality for medicines to be consumed in Western countries (Europe, America, Australia) substandard quality for medicines produced for export to Africa, Latin America and Asia.

There is a lack of international regulation and enforcement. The governments of the exporting countries put the responsibility of the control of quality of medicines within the country using the medicine. In most African countries the capacity and the means for quality control is non-existant.

Medicines of poor quality are a serious risk for people's health as they cause treatment failure or even death. Low-quality versions of medicines increase resistance because they do not kill all of the parasites. The quality of medicines is a key issue for public health. There are different kinds of poor quality of medicines.

Substardard 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 to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources, or lack of control. Low-standard medicines may come from well-known laboratories and are being used in both public and private health practices.

[1] Chaudhuri 2008

Counterfeit or fake medicines are produced and sold with the **intent to deceive** regarding its origin and effectiveness, e.g. when it has a false label of another company, inappropriate packaging, poor manufacturing processes, and improper conditions during transportation and storage. They intend to appear like the "real one", but they are not what they declare to be. They may include wrong and dangerous ingredients, may have none or not enough active ingredients (the substance that is pharmaceutically active) or the active ingredient is of bad quality.

Counterfeiting of pharmaceutical products can take all kinds of form, but the end result is, when administered to a patient, that the consequences range from treatment failure, increased toxicity, increased medicine resistance to malaria, TB and AIDS, and even outright death as a result of any of the above.

The WHO estimates that 200,000 people die annually from counterfeit or poor quality malaria medicines (1/5 of those dying from the disease itself, as the medicine does not cure it, and the rest 4/5 from the fatal consequences of the medicines). Fake medicines cause resistance and a lot of suffering.

The high price of medicines influences the quality in two ways. When the prices of medicines become excessive and unaffordable, patients tend to look for cheaper sources outside the normal supply system. At the same time high prices means more benefts for counterfeiters of drugs, and greater danger for the health of the community.

The production of fake medicines is a pernicious and immoral practice, but it goes on because it is a very lucrative business. The counterfeiting of medicines is growing. Counterfeiters make huge benefits without regarding the consequences on people's health. The counterfeit medicines industry is estimated to be worth $200 Billion a year and creates 2 to 5 per cent tax losses for governments around the world.

The traffic of counterfeit medicines is flourishing in African countries where institutional capacity in regulation, inspection and law enforcement is weak and adequate funds for regular medicine quality monitoring are missing.

Of the one million deaths that occur from malaria annually, as many as 200,000 would be avoidable 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. The fight against low quality medicine

The owners of the "trade-marks" or "brand names" fight against fake medicines because it reduces their profits. There are a series of international agreements to fight the illegal trade of fake goods. A group of industrialized countries have negotiated the "Anti-counterfeit Trade Agreement" (ACTA) that will enforce intellectual property rights, hindering the free circulation of generic medicines. MEDICRIME from the Council of Europe criminalises the manufacturing and distribution of counterfeited medicine risking public health. The IMPACT (International Medical Products Anti-Counterfeiting Taskforce) of the WHO is very controversial. In these agreements generics and counterfeit medicines are considered similar, what is completely false from the view of quality. The fact is that all defend the rights of the patent owner but do not consider the public interests such as health safety and the right to access to medicines. This enforcement of IPRs can have serious public health costs, as it can affect access to generic medicines in Africa.

Counterfeiters are organized criminal networks that operate across national borders in activities that include the import, export, manufacture and distribution of counterfeit and illicit medicines. INTERPOL intervenes in fighting the counterfeit market at international level. The problem is that like all the others they search more for medicines without patents than for bad quality medicines. In reality sometimes they do not have even the means to analyze 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, thus jeopardizing the health of the users who are mainly in developing countries.

3.4. The problem of quality of medicines in Africa

In many African countries there are medicines in circulation whose quality has not been properly controlled. The medical staff is not aware that the medicines distributed in some health systems are sub-standard medicines. African markets and shops are full of counterfeit (fake) medicines with the appearance of "good drugs". Millions of people consume ordinary or toxic products, believing they are taking good medicine.

In a survey of the WHO on antimalarial medicines circulating in six countries of Sub-Saharan Africa the failure to pass the **quality text** was of 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.

The **lack of medicine controls** in the exporting and importing countries leads to lower-quality medicines. African countries often do not have the capacity or the means to do this control. Parts of the medicines exported from Europe to Africa are low-standard medicines that do not meet the quality standards set for them.

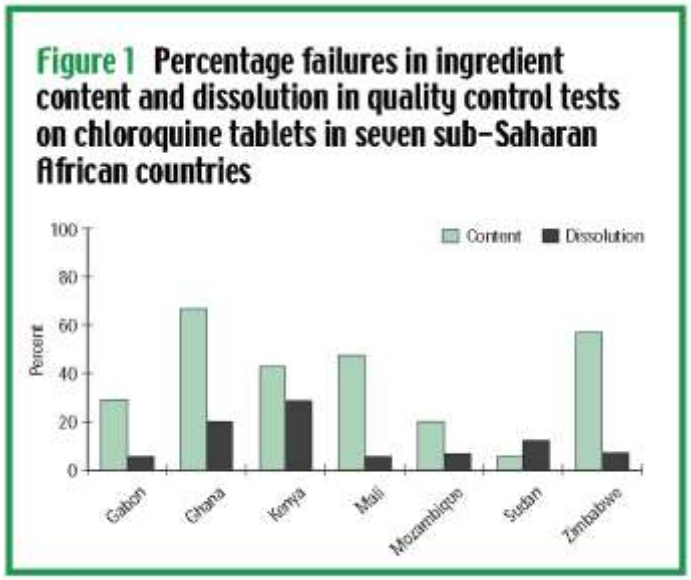

Figure 1 Percentage failures in ingredient content and dissolution in quality control tests on chloroquine tablets in seven sub-Saharan African countries

Source: The quality of antimalarials. A study in selected African countries. Geneva: World Health Organization; 2003.

Many African states strive between the needs of patients, limited resources and weak regulatory enforcement mechanisms. They desire to meet standards on access and quality, but the two aspirations of seeking economic advantage and improving health outcomes do not always converge. The complicity of some African governments that lack political will to fight the absence of quality of medicines is also part of the problem.

Though counterfeit medicines are much more dangerous, sub-standard medicines have also negative impacts on health. Substandard and Counterfeit medicines have no therapeutic benefits and are a real danger in Africa.

The world's largest pharmaceutical companies gathered in Nairobi in June 2011 to see how to fight counterfeits medicines in East Africa, but they did not mention the low-standard medicines coming from well established laboratories.

In much of Africa the first source of medicines are informal medicine sellers at the corner kiosk or at the local market. These sources are easily accessible, but customers often receive inappropriate medicines of poor quality and badly stored. In Tanzania such shops provide medicines for over 60% of the population. The extension of the vast and very profittable counterfeit medicines market in Africa constitutes today a serious and growing problem. To buy medicines well packed or unpacked, on the street and markets, sold by non-pharmaceutical staff is dangerous and can have serious consequences for health and may cause even death.

Counterfeit anti-malaria pills cause the deaths of 200,000 people in Africa each year, according to the World Health Organization.

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

Though the market of counterfeiting medicines is illegal many African countries have not yet enacted deterrent legislation,

therefore counterfeiters rarely fear prosecution. African governments often do not have the capacity, the means and often not even the political will to fight the proliferation of false medicines, despite the numbers of deaths they cause.

Influenced by Western governments and companies Kenya and Uganda adopted counterfeit legislation with the intention to fight the invasion of counterfeit goods. The danger is that, under the guise of fighting counterfeits, these countries will strengthen the protection of intellectual property rights making the access to generics more difficult. The patients needing them will be the victims.

3.5. Towards a change in the situation

Many African countries have the same needs for medicines in accessing certain sources of supply, and the same difficulties due to the lack of national expertise in procurement. An example is the need for malaria, HIV/AIDS and tuberculosis medicines. A solution could be a greater collaboration at regional level. They could share data to select which medicines actually could address the largest proportion of diseases that commonly affect the population, sharing information on pricing and suppliers to identify the supplier that offers best competitive pricing and quality terms. This joint purchasing, called “pooled procurement”, is an efficient strategy to resolve challenges such as high medicines prices, poor quality and other bottlenecks generally associated with Procurement and Supply Chains of Essential Medicines. Buying big quantities gives a leverage to diminish the price.

4. Openings and possibilities of action

The problems of access and of quality of medicines need to be tackle at different levels and at different institutions and countries. New action is needed to allow quality, affordable basic medicines to reach those who need them.

4.1. Working towards better access

There is need not only a change of politics but even more of a change of mind so that the necessity of African countries comes before the desire of companies to maximize their profits, and to open up markets for Western companies

Working to diminish the price of good medicines. We can work at different levels:

At national and international level to revisit trade related agreements and any other agreement in light of their impact on the right to health and in particular on access to medicines of quality. Tighter rules on intellectual property benefit pharmaceutical giants, but undermine the access to medicines.

Advocacy on incorporation and utilization of TRIPS flexibilities at national and regional levels.

Increase awareness on IP issues and activities in the Health sector and workers

To search for new ways of motivating and rewarding researches whose outcome will be of benefit for health and health care. Ex. Granting prizes instead of patents.

To work towards a reliable supply of medicines of quality in the African countries.

Increasing capacity of local CSOs in health policy formulation and implementation.

4.2. Working towards better quality medicines

The work for better quality medicines has to be done in different fronts:

1. Countries exporting medicines to Africa, must be coaxed into controlling the quality of the medicines they sell. They need to establish a legislation and implementation that takes care of the quality control of medicines exported to all countries.

2. At the level of the laboratories. To do a monitoring for quality in the laboratory and in the products they produce. This is the work of specialists, but they need to know the medicines that produce problems, do not cure or produce strong reactions, sickness, etc. In Africa, health workers must be attentive to medicines causing problems and make this information known.

3. At the level of the African countries to ask for legislation and its implementation in the case of production, sale, import or export of counterfeits. Leaders at all levels have to act in responsibility towards their population, create legislation and implement it.

4. At the World Health Organization (WHO) so that it takes 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 for the 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 aspects: access and quality.

On access AEFJN works towards lowering the high price of existing drugs, by doing advocacy on Trade agreements and any other agreement that strengthens IPRs and having a possible impact on health and on access to generic medicines. AEFJN works with both institutions, the EU and the WTO to allow African countries to protect public health and to use generic medicines even when the original medicine is still under patent protection.

In the last years AEFJN works towards innovative means to stimulate the Research and Development (R&D) of new medicines, namely diseases that affect Africa, as well as for more efficient and adapted diagnosis tests.

AEFJN with other international organizations has established **the Charter for the Quality of Medicines**, an ethical code for the buyers of medicines, offering them landmarks for quality medicines to ensure 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 the setting up of 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 wherever the destination of the medicines. AEFJN advocates so that the quality control becomes the responsibility of the developed country exporting the medicines or of the WHO.

1.1.1. AEFJN Advocacy successes

AEFJN influenced the EU Communication on Global Health so that the Aid to Health 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 diminishing 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 organizations played an important part. As a consequence many more patients were treated with the same amount of money.

6. TOOLS FOR THE WORK ON THE PC

A general introduction on how to carry out an action following the various steps of the Pastoral Circle can be found in the first part of this manual. In this section you will find indications and tools for an action specifically on the Access to Quality Medicines that will complete those found in the Pastoral Circle.

6.1. Knowing the situation

Focussing on an issue. As the Healthcare system is very large it is good that after a short time dedicated to know the main problems regarding health or medicines you focus on an issue: access to health, access to medicines, production of medicines, economic accessibility; physical access; providing accurate information; access to medicines; quality, etc.

Where to get information. You can get your information from Health personnel (doctors, nurses, clinical staff, pharmacists, etc), administrators of Health Institutions, organizations working on health, government offices in charge of Health Institutions, Ministry of Health), Consumers associations, patient associations, journalists dealing with health issues. Gather patient testimonies, involvement of consumers, personal stories regarding the access to health, to medicines and the quality of medicines.

Possible questions to know the situation. We offer you a series of questions that want to be a help in finding information. You do not need to work at all of them. Choose those you believe more convenient for the work you want to do.

6.1.1. Questions regarding the situation on Health

What are the country priorities regarding health?

What is the government budget dedicated to Health care? Which percentage of the total budget?

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

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

What are the gaps on the health care system?

Is there discrimination and 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? Which are those institutions and what do they do regarding health products? Is there studies regarding traditional medicines?

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

6.1.2. Questions to know the situation on 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, what are the reasons? If it does, where do they get the funding for it? What are the difficulties experienced?

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

What are the inefficiencies in the supply chain of medicines? At what level 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 the access to medicines (import taxes, price, health budget, supply chain, procurement, etc)?

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

What is the rational use and medicines promotion work in the region?

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 to achieving universal access to essential medication?

6.1.3. Policies regarding Intellectual Property Rights (IPRs)

Are there in your country groups of Advocacy on trade? 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 is the situation of the IPRs? Find out if your country is negotiating and EPA on services and IPRs. Follow the EPA negotiations on services (health).

Gather concrete information on the difficulties caused by the Intellectual Property Rights (IPR): patents, prices, in your country or region.

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

What is the participation of CSO in policy reviews?

6.1.4. Questions to know the situation on 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? (the 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. Make as if you want to buy some (or buy some) to get to know the origin of the medicines sold: country of origin, labboratory of production, packeting, conditions of storage, selling…

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

Did you hear about negative consequences of use of certain medicines? Which ones? Which consequences?

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 know the name of the medicine, country of origin and name of the producer. You can gather "cases" where medicines had a fatal or dangerous impact on patients.

Look for secondary effects due to the consumption of medicines in your country?

Which medicines are counterfeit – fake, which ones are low standard and which ones are good quality?

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

Are medicines produced in your country? Search the medicines they produce and the quality control they follow. Are they approved by the 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 and the orientation you would like to give to your action.

Some possibilities of mapping:

Health institutions in your area. Do a mapping on the health centers in the locality or area. Are they public, private (Church, NGOs, organizations, personal owned)?

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

Map the origin and the path the medicines follow till arriving at your locality.

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 concretely the problem: ex. Some medicines (if possible name which ones) from the market have caused great hazards and even have produced deaths.

6.2. Analysing the situation

There are a series of international treaties/obligations that affect health care and access to medicines of quality. Find out the influence of these policies on your issue. Look at 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, Brazil regarding the impact on health care and access to medicines.

6.2.1. Analysis of the causes and consequences of bad quality medicines

See the problems caused by medicines either because of high price, bad quality, or non existence.

Pay attention to the analysis of the Budget.

6.3. Christian Reflection on Health and Access to Quality Medicines

6.3.1. 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

"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; and"
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. common good requires that all individuals have access to affordable health care, and to the medicines of quality.

6.4. The Compendium of the Social Doctrine of the Church[2]

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 [….] they need health care services and appropriate assistance [….]

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

1.2. Planning the action

Search events, opportunities to look at, and to take into account regarding advocacy and lobbying on your issue. Advocacy and awareness activities involving the press, targeted groups and general public.

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

See how to monitor the national Budget, target ministries and parliament commitees 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 to be involved with the international effort at achieving access to medicines?

Engage in discussions with Parliament Committee on Health, the Committee on Trade, the Committee on 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.

1.3 ANNEXES

ANNEX 1 - ORGANIZATIONS AND MATERIAL ON ACCESS TO QUALITY MEDICINES BY COUNTRIES AND REGIONS

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 – Network on Health with a working group in Medicines of quality – Secretariat in Belgium. http://www.be-causehealth.be/en
- Doctors without borders (Medecins sans frontières) Acess 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

General Material 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
- WHO Essential Medicines Monitor - http://www.who.int/medicines/publications/monitor/en/
- The world Medicines Situation 2011 – Pharmacovigilance and Safety of Medicines – WHO - http://apps.who.int/medicinedocs/documents/s18771en/s18771en.pdf

Organizations and Material by country in Africa

BENIN

Organizations

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

BURKINA FASO

Organizations

- Doctros 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/

CAMEROUN

Organizations

- 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

Organizations

- 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

Organizations

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

DR CONGO

Organizations

- 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

Organizations

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

Material

- Medicine prices in Ghana - 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

ETHIOPIA

Organizations

- Doctors Hithour 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 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

GHANA

Organizations

- 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

Organizations

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

KENYA

Organizations

- 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 – Ecumanical 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 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

LESOTHO

Organizations

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

LIBERIA

Organizations

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

MADAGASCAR

Organizations

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

MALAWI

Organizations

- 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 hHealth 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.**equinet**africa.org/bibl/docs/DIS58FINmuula.pdf

MALI

Organizations

5. 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/Medpricesall8files.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

Organizations

- 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

Organizations

- 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

Organizations

- 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

Organizations

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

SIERRA LEONE

Organizations

- 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

Organizations

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

SOUTH AFRICA

Organizations

- 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

Organizations

- 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

Organizations

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

TANZANIA

Organizations

- 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 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
- Documents from Mediceins Sans Frontieres - http://www.doctorswithoutborders.org/news/allcontent.cfm?id=74

TOGO

Organizations

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

UGANDA

Organizations

- JMS - Joint Medical Store - www.jms.co.ug/
- UCMB - The Uganda Catholic Medical Bureau - http://www.ucmb.co.ug/index.php
- UPMB - Uganda Protestan 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 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 prices in Uganda - 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
- 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

Organizations

- 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

Organizations

- 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 ORGANIZATIONS

Organizations

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

1.3. Eastern African Region

Materials

- Medicine prices in the East African Community - Medicine prices survey 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

1.4. Southern African Region

Materials

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

ANNEX 2 - CRITERIA TO ENSURE QUALITY MEDICINES

Taken from AMFA (Affordable Medicines for Africa)

7. Criteria to ensure quality of medical products

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

8. 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.

1.5. 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 andWondemagegnehu, 2002).

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

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:

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

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

1.6. 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:

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

1.7. Key points to effectively maximize resources

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

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

ANNEX 3 - TECHNICAL GUIDELINES (CHECK-LIST) FOR PHARMACEUTICAL PRODUCTS

1. Regulatory status

The supplier (distributor)

5. It is authorized by the competent regulatory authorities
6. It can show a valid (not expired) copy of this authorization

The distributor definitely needs to be able to show a copy of this authorization in his country of origin. Otherwise he will not be retained.

The manufacturer

- The manufacturer is known and its name is clearly mentioned on the packaging
- The manufacturer or supplier (if different from the manufacturer) can prove that the manufacturer - is approved of by the competent regulatory authorities
- The manufacturer or supplier can show a copy of a valid GMP certificate (WHO Model Certificate) for the concerned manufacturing site

If one of the above points is not fulfilled, the supplier (distributor or manufacturer) cannot be considered.

- The manufacturer or supplier (if different from the manufacturer) can prove that the manufacturing site has been approved by the inspectors of the Pre-qualification Project of the World Health Organization (WHO) or by the inspectors of PCS (Pharmaceutical Inspection Cooperation Scheme)

If this last point is fulfilled, this is considered to be an asset. However this is not a mandatory requisite.

The product

First of all, the regulatory status of the product must be verified. These are some of the possibilities:

- The medicine is registered in the country of origin, but NOT MARKETED

(We ask for the registration number. and the date: …)

- The medicine is registered AND marketed in the country of origin (We ask for the registration number. and the date: …)
- The medicine is registered AND marketed in an ICH country (International Conference on Harmonization = EU + US + Japan)

(We ask for the country, the registration number and the date: …)

- The medicine is manufactured for export only

(We ask for a copy of the export certificate)

The supplier (distributor) needs to have a recent/specific CPP (WHO Model Certificate of a Pharmaceutical Product) for the product he is proposing/selling, and he has to be able to show a copy on demand.

2. Specifications of the final product

There are two possibilities:

a. A monograph of this product exist in an accepted international Pharmacopoeia (British Pharmacopoeia or BP, United States Pharmacopoeia or USP, International Pharmacopoeia)

- The proposed product complies with the specifications of the monograph one of these reference pharmacopoeias (specify the Pharmacopoeia and which edition).
- On the assumption that the product is in accordance with the specifications of the monograph of another pharmacopoeia (e.g. Indian, Chinese, Russian, …), please specify which Pharmacopoeia and which edition.
- On the assumption that the *in house* specifications have been developed, the analytic method has to be communicated to us upon demand.

b. A monograph of this product does not presently exist in accepted international Pharmacopoeia (BP, USP, International)

- On the assumption that the product is in accordance with the specifications of another pharmacopoeia (e.g. Indian, Chinese, Russian, …), please specify which Pharmacopoeia and which edition.
- On the assumption that the *in house* specifications have been developed, the *in house* specifications and the analytic method have to be communicated to us upon demand.
- Can the supplier prove that the *in house* specifications have been accepted by the competent national authorities?

A certificate of analysis needs to be provided for every sold batch.

The analysis has to be made by:

○ the manufacturer

○ an independent accredited laboratory

3. Stability

- The manufacturer (or distributor, if different from the manufacturer) has a report of stability studies performed in compliance with the recommendations of the WHO.

In the absence of a stability study, the product cannot be purchased.

The impossibility of providing a written report has to be justified.

- The product has been tested under climatic conditions of Type IV.

  This test is advisable, but it is not a mandatory requisite.
- A summary report of the stability studies has to be communicated upon demand.
- The expiry date has to be consistent with the result of the stability studies.
- The proposed/sold product has to be identical (active ingredients, packaging, size of batch) with those used for the stability studies.

4. Labels/packaging

Basic rules:

* The primary and secondary packaging must ensure the preservation of the medicine until the expiry date declared by the manufacturer.

* The labeling has to be clear and has to guarantee a safe usage of the medicine.

The manufacturer (or distributor, if different from the manufacturer) has to communicate upon demand the accurate technical information on the proposed packaging (materials, specifications).

The primary packaging has to be labeled or printed in indelible ink. The following information has to be clearly indicated:

- International Non-proprietary Name (INN)
- The batch number
- The expiry date in explicit form (no coded)
- The administration route
- The name of the manufacturer and the country of manufacturing

The secondary packaging has to be labeled or printed in indelible ink.

- The labels or printing have to be preferably written in French/English/ Spanish and, in any cases, they have to be written in a language which is clearly understandable for the health personnel who will have to use it.
- Self-adherent labels are preferred
- Paper labels have to be attached in such a way that they won't detach in warm and humid climatic conditions
- At least the following information has to be on the labels or printing:

→ The International Non-proprietary Name (INN)

→The complete list of the active pharmaceutical ingredients and the precise amount of each, by the respective dosage unit

→ The manufacturer's name and address

→ The name and the country of location of the license holder (if different from the manufacturer)

→ The registration number of the product in the country of origin (when applicable)

→Any special storage conditions or handling precautions that may be necessary, preferably in English, French and Spanish

→ The instructions for use, and any warnings or precautions that may be necessary, preferably in English, French and Spanish.

→ The batch number assigned by the manufacturer

→The manufacturing in a clearly understandable form (month/year; coded forms are not acceptable)

→ The expiry date in a clearly understandable form (month/year; coded forms are not acceptable)

→The information given in the labelling or printed on the packaging, must comply with the recommendations of the WHO

→ The storage conditions and the expiry date given in the labelling or printed on the packaging, should be consistent with the results of the stability studies, performed by the manufacturer in accordance with the WHO recommendations.

1. Active pharmaceutical ingredients (APIs)
    - The name of the manufacturer of every API has to be known by the supplier and has to be communicated on demand, by the manufacturer or distributor.
    - The manufacturer(s) of the **APIs** has/have to be authorized in their country of origin. A copy of their authorization has to be shown on demand.
    - The supplier has to make sure that the **APIs** comply with the specifications of at least one of the following pharmacopeia: European Pharmacopoeia (EP), British Pharmacopoeia (BP), United States Pharmacopoeia (USP) or International Pharmacopoeia of WHO
    - In case the API isn't described in one the Pharmacopeias mentioned here above, the *in house* analytic methods must have been evaluated and approved of by the manufacturer.
    - A copy of the Certificate of Analysis (CoA) of each **API** has to be shown on demand.

9. Therapeutic equivalence

The therapeutic equivalence:

- o Has been demonstrated *in vivo*
- o Has been demonstrated *in vitro*
- o Does not need to be demonstrated for this product (justify why)
- o Has not been demonstrated

10.Commitment

The manufacturer and/or distributor must commit himself on his word of honor to guarantee that all the communicated information is genuine and accurate.

4. ANNEX - *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

For the products that do not meet the criteria previously mentioned in this Charter (not qualified or pre-qualified by the WHO, not qualified by the ISBT, not authorized in a high-regulated country, not included in the Annex II A and B of the Directives 98/79/EC from the European Union) and while waiting for more adapted international norms, the manufacturer has to provide:

(i) Proof of certification, issued by an independent competent body, of compliance with quality standards established for *in vitro* diagnostic medical devices, as for instance in ISO norms 13485:2003 or in FDA 21 CFR 820.

(ii) Proof of stability of the *in vitro* diagnostic medical device, carried out in accordance with the norms issued by the WHO.

We reserve ourselves the right to ensure the conformity of these products with the quality criteria mentioned above.