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**FORUM FOR ACTION**

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**CLIMATE: THE ETHICAL RESPONSIBILITY OF CHURCHES**

*Behind the climate issue, and the economic responses to it, lies everyone's and every nation's responsibility for ethical behaviour and solidarity towards their peers, near and far. The Church, as an authority and a people, has a share in this responsibility.*

***What is at stake for a future climate agreement?***

The 17th session of the UN Framework Convention for Climate Change (UNFCCC), known as COP17 Durban for short, will take place in Durban, South Africa, from 28th November to 9th December. This international meeting hopes to come up with a replacement for the Kyoto Protocol for the reduction of greenhouse gases, an agreement that expires at the end of 2012. However, several major nations have announced that they are not in favour of a future agreement that compromises their economic growth. Among them are Canada, Japan and Russia that, in spite of their Kyoto commitment, have seen an increase in their greenhouse gas emissions. A legal gap risks appearing which allows each state to do as it wishes, according to its own priorities.

With the climate and economic crises being linked, a common solution needs to be found for them and, as the implications are global, this solution has to have solidarity at heart. We know that climate change has serious effects on human life and the environment, in particular the most vulnerable people whose lives depend directly on the survival of the ecosystems. This, on top of the financial crisis, causes a bush-fire effect, bringing with it problems to do with health, access to education and work, potentially leading to grave social crises. The human being is worth more than gas and temperature statistics.

***The destinies of man and of nature together before God***

Remembering that environmental and climate concerns are an integral part of the Catholic faith, Pope John Paul II offered two ways forward: ecological conversion and mankind's ecological vocation. Human beings do not rank above nature but are part of it. They need it in order to live, just as nature needs them to look after it like good parents. Benedict XVI stresses interior conversion. The love of money and a desire for comfort, together with spiritual pride lead us to rejecting the limitations of nature. These personal errors

of judgment have repercussions for the environment and society. Humbly accepting nature's limitations teaches us to become more human before the Creator. Mankind cannot reduce greenhouse gas emissions without first reforming, at domestic and national level, an economic system that disregards human beings and the environment in its search for money and individualism.

### ***Towards climatic, social and economic justice***

For this reason, several Churches are coming together to weave an ethical thread into the global debate on climate change. They are encouraging solidarity with the most vulnerable populations who have mostly scarcely contributed to the climate change that is already afflicting them. For example, between 1970 and 2006, Malawi experienced 40 catastrophes linked to meteorological conditions. Until 2001, only 9 districts in Malawi were deemed to be liable to flooding; this had risen to 22 by 2012. Moreover, the governments of these peoples have fewer resources to guard against the consequences. By contrast, Europe and other wealthy parts of the world, are spending vast amounts on mathematical models and meteorological forecasts that are able to predict and prevent the damage that could be caused by future so-called millennium storms. For example, the Flemish region of Belgium is investing 300 million Euros on strengthening its coastal storm defences as it has calculated that it would cost more than that to repair the damage. France and Great Britain are investing even more. These investments help the wheels of the economy to go round. Carbon markets have been set up and so-called 'adaptation' aids which are in fact a way to create new markets, sometimes virtual, under the guise of the struggle against climate change. The Justice, Peace and Integrity of Creation (JPIC) network, the World Council of Churches (WCC) and other networks are working for social and economic justice and promoting climate justice. They denounce the global development model based on hyper-consumption and avarice that prevails in climate policies.

### ***The duty of the Church***

After considering the climate issue at the 2009 Synod, the African bishops called for the Church and its members to lobby their local and national policy makers. This is a very concrete action. Small farmers need support for climate adaptation. They need to be informed about long-term climate tendencies and their implications for rain, temperature, influxes of pests and crop diseases. They have a right to receive advice on selecting plants and to be trained in agricultural practices that are best suited both to the new ecosystem and to family farming. The Church, having a strong presence and being an extensive network responsible for educating its people, can play its part in sharing information and in training. At the same time, keeping Gospel values in sight, it needs to strengthen the capacity of social and political action groups, such as Justice and Peace groups, in order to deepen the understanding of the relationship between living conditions and political choices. She can also support the demands of family farming networks by lobbying politicians to protect small-scale farming and the respect it has for the ecosystem and human beings. Moreover, the Church needs to take action so that EU aid development and other policies support the networks of small African farmers who are taking climate adaptation initiatives locally. Without these priorities, the local economy and society will die. The prices small farmers receive are declining to such an extent that they no longer have enough to pay for their children's schooling and they have to mortgage their future; sometimes the prices are too low to cover the cost of feeding the family. Each state, however, has the duty to assure a framework that will guarantee the right to food and a decent standard of living. The Church, both the institution and the people, must call out for this and contribute to it actively.

Church members also have an advocacy role with the decision-makers at COP17 Durban. The religious implications of climate change will be debated there by Caritas International, Religions for Peace and the WCC who are preparing a parallel event for 7th December. An inter-religious meeting is also being arranged. The faith communities of Africa and of the world have joined together to present a united front at COP 17 and have a secretariat and a website. The education of the younger generation has not been forgotten. At Durban, the WCC and the Lutheran World Federation are organising a seminar called

“Youth for Eco-Justice” for young Christians between 18 and 30. They will learn about environmental and socio-economic justice with a view to their leading projects afterwards in their own countries. It is up to all of us to see where our own share of responsibility lies and decide what action we, our communities and parishes can take.

C. Fouarge, AEFJN Brussels Secretariat

## OGONILAND OIL SPILLS CLEAN UP<sup>1</sup>

The environmental restoration of Ogoniland could prove to be the world's most wide-ranging and long term oil clean-up exercise ever undertaken if contaminated drinking water, land, creeks and important ecosystems such as mangroves are to be brought back to full, productive health. A major new scientific assessment, carried out by the United Nations Environment Programme (UNEP)<sup>2</sup>, shows that pollution from over 50 years of oil operations in the region has penetrated further and deeper than many may have supposed.

Over a 14-month period, the UNEP team collected more than 4,000 samples of soil, fish and air, including water taken from 142 groundwater monitoring wells drilled specifically for the study and soil extracted from 780 boreholes and investigated, in depth, 69 of the many hundreds of oil spills in Ogoniland over the past 50 years. UNEP examined more than 200 locations, surveyed 122 kilometers of pipeline rights of way, reviewed more than 5,000 medical records and engaged over 23,000 people at local community meetings.

### ***Oil exploitation in Ogoniland***

Ogoniland is a region covering some 1,000 km<sup>2</sup> in the south-east of the Niger Delta basin. It has a population of close to 832,000, according to the 2006 National Census, consisting mainly of the Ogoni people. The region has witnessed recurrent social unrest during the past several decades over concerns related to oil industry operations and the distribution of its revenue. More than £30bn of oil has been extracted from the area but the majority of people are worse off than before the companies arrived.

Oil exploration in Ogoniland commenced in the 1950s and extensive production facilities were established during the following three decades. These operations were handled by Shell Petroleum Development Company (Nigeria) Ltd (SPDC), a joint venture between the Nigerian National Petroleum Company (NNPC), Shell International, Elf and Agip. Environmental incidents, such as spills and uncontrolled flares, began in the area as soon as the operations began and responses were slow and inadequate. Partly in response to the environmental consequences of oil production, the Movement for the Survival of the Ogoni People (MOSOP) was founded under the leadership of the Nigerian author Ken Saro-Wiwa. Saro-Wiwa criticized oil companies and the government's oil policy. In 1993 300,000 Ogoni joined a march to demand a share in oil revenues and greater political autonomy. As a consequence of the ensuing violence, oil exploration and production activities in Ogoniland ceased in the same year.

The study concludes that the control, maintenance and decommissioning of oilfield infrastructure in Ogoniland are inadequate. While no oil production has taken place in Ogoniland since 1993, the facilities themselves have never been decommissioned. Some oil pipelines carrying oil produced in other parts of Nigeria still pass through Ogoniland but these are not being maintained adequately. Consequently, the infrastructure has gradually deteriorated, through exposure to natural processes, but also as a result of

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<sup>1</sup> For further information on the oil exploitation in Nigeria also see *Holding Shell Accountable* at <http://www.aefjn.org/index.php/369/articles/holding-shell-accountable.html> and *Oil - Black Gold or Curse* at <http://www.aefjn.org/index.php/370/articles/oil--black-gold-or-curse.html>

<sup>2</sup> UNEP, 2011, *Environmental Assessment of Ogoniland*.

criminal damage, causing further pollution and exacerbating the environmental footprint. As a consequence, even though oil operations have ceased in Ogoniland, oil spills continue to occur in alarming regularity.

Industry best practices and Shell's own procedures have not been applied, creating public safety issues. Ten out of the fifteen investigated sites which Shell's records show as having completed remediation, still have pollution exceeding Shell's (and government) remediation closure values. The study found that the contamination at eight of these sites has penetrated to the groundwater. In January 2010, a new Remediation Management System was adopted by Shell. The study found that while the new changes are an improvement, they still do not meet the local regulatory requirements or international best practices.

### ***The findings of the report***

Pollution of soil by petroleum hydrocarbons in Ogoniland is extensive in land areas, sediments and swamp-land. At two-thirds of the contaminated land sites close to oil industry facilities which were assessed in detail, the soil contamination exceeds Nigerian national standards, as set out in the Environmental Guidelines and Standards for the Petroleum Industries in Nigeria (EGASPIN).

As Ogoniland has high rainfall, any delay in cleaning up an oil spill leads to oil being washed away, traversing farmland and almost always ending up in the creeks. The impact of oil on mangrove vegetation has been disastrous. Oil pollution in many intertidal creeks has left mangrove -nurseries for fish and natural pollution filters - denuded of leaves and stems with roots coated in a layer of bitumen-type substance sometimes one centimetre or more thick. Some areas, which appear unaffected at the surface, are in reality severely contaminated underground and action to protect human health and to reduce the risks to affected communities needs to occur without delay. In one place, Ejama Ebubu, the study found heavy contamination from a spill that took place more than 40 years ago "despite repeated clean up attempts".

Control and maintenance of oilfield infrastructure in Ogoniland has been and remains inadequate: the Shell Petroleum Development Company's own procedures have not been applied, creating public health and safety issues. The Ogoni community is exposed to hydrocarbons every day through multiple routes: in outdoor air and drinking water, sometimes in high concentrations. Hydrocarbon contamination was found in water taken from 28 wells in 10 communities adjacent to contaminated sites. At seven wells the samples are at least 1,000 times higher than the Nigerian drinking water standard. Local communities are aware of the pollution and its dangers but state that they continue to use the water for drinking, bathing, washing and cooking as they have no alternative.

At 41 sites, the hydrocarbon pollution has reached the groundwater at levels in excess of the Nigerian standards. The five highest concentrations of Total Petroleum Hydrocarbons detected in groundwater exceed 1 million micrograms per litre ( $\mu\text{g/l}$ ) - compared to the Nigerian standard for groundwater of 600  $\mu\text{g/l}$ . The fisheries sector is suffering due to the destruction of fish habitat and highly persistent contamination of many creeks. Where entrepreneurs have established fish farms for example their businesses have been ruined by an ever-present layer of floating oil.

When an oil spill occurs on land, fires often break out, killing vegetation and creating a crust over the land, making remediation or revegetation difficult. At some sites, a crust of ash and tar has been in place for several decades.

### ***The conclusions of the report***

While some on-the-ground results could be immediate, overall the report estimates that countering and cleaning up the pollution and catalyzing a sustainable recovery of Ogoniland could take 25 to 30 years. This work will require the deployment of modern technology to clean up contaminated land and water, improved environmental monitoring and regulation and collaborative action between the government, the Ogoni people and the oil industry.

Achim Steiner, UN Under-Secretary General and UNEP Executive Director, said the report provided the scientific basis on which a long overdue and concerted environmental restoration of Ogoniland can begin. "The oil industry has been a key sector of the Nigerian economy for over 50 years, but many Nigerians have paid a high price, as this assessment underlines," he said.

"It is UNEP's hope that the findings can break the decades of deadlock in the region and provide the foundation upon which trust can be built and action undertaken to remedy the multiple health and sustainable development issues facing people in Ogoniland. In addition it offers a blueprint for how the oil industry - and public regulatory authorities - might operate more responsibly in Africa and beyond at a time of increasing production and exploration across many parts of the Continent," said Mr Steiner.

The report suggests the creation of an Environmental Restoration Fund for Ogoniland, to be set up with an initial capital injection of US\$1 billion contributed by the oil industry and the government, to cover the first five years of the clean-up project. Environment groups and Ogonis welcomed the report but said \$100bn was needed to clean up the entire delta, beyond just Ogoniland.

The urgent need for action is confirmed by other recent news coming from the Ogoniland. In August, Shell accepted full responsibility for two massive oil spills that occurred in 2008 and that devastated Bodo in Ogoniland where 69,000 people live and may take at least 20 years to clean up<sup>3</sup>. Experts say that the two spills could together be as large as the 1989 Exxon Valdez disaster in Alaska, when 10m gallons of oil destroyed the remote coastline. They believe that it could cost the company more than \$100m to clean up properly and restore the devastated mangrove forests that used to line the creeks and rivers but which have been killed by the oil. Before last August, Shell had claimed that less than 40,000 gallons had been spilt. No attempt was made in 2008 to clean up the oil, which collected on the creek sides, washed in and out on the tides and seeped deep into the water table and farmland. Shell's change of mind and acceptance of full liability for the spills followed a class action suit of local communities in a British court. This could also set an important precedent for other communities in the delta to seek damages for oil pollution against Shell in the British courts.

Thomas Lazzeri, AEFJN Brussels Secretariat

## SPREAD OF LIBYAN WEAPONS IN THE SAHEL

### *Weapons from various sources*

The upsurge of violence in the Sahel since the beginning of the year can be put down to the conflict in Libya which has transformed the country into an unbounded arms depot. This is the opinion of the Algerian minister delegate for Maghreb and African affairs who said that whole sections of Libyan arsenals had been transferred to Algeria and the countries of the Sahel<sup>4</sup>.

Nevertheless, these arms do not all come from Libyan arsenals, according to a Malian security source and a Malian consulate. Fighters of Malian and Libyo-Malian origin apparently have arms that were dropped by French planes into western Libya – but the quantity and types are unknown. Claims vary: while the spokesperson for the French Chief of Staff speaks of small arms that can be handled with ease by civilians

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3. 'Shell accepts liability for two oil spills in Nigeria', *The Guardian*, 03/08/2011, <http://www.guardian.co.uk/environment/2011/aug/03/shell-liability-oil-spills-nigeria>

4. "AQIM: how Algeria protects itself from kamikazes". *Jeune Afrique*, 5 August 2011. (AQIM = Al Qaeda in Islamic Maghreb); Corroboration: detonators of the same model as used in suicide attacks in Algeria had been intercepted by border guards in Debdeb, an Algerian city on the border with Libya; in fact, both Gaddafi troops and insurgents trade with dealers who themselves trade with AQIM machine guns and boxes of ammunition were also seized by the same border guards; western weapons from the arsenal of Libya were also recovered during clashes with terrorists in Kabylia and in northern Mali.

for their own protection, the French daily paper, Le Figaro, refers to rocket launchers, assault rifles, machine guns and light infantry antitank missiles<sup>5</sup>.

### ***The type of arms in circulation***

The information available about Colonel Gaddafi's arsenal since the Libyan crisis has come from witness statements of NGOs, western information services, the security forces of neighbouring countries, insurgents and the National Transitional Council.

American officials have been able to identify certain weapons: SA-7 ground-to-air missiles (of Soviet origin) in Mali and MANPADS (Man Portable Air Defence System missiles) that, according to Africom (US Africa Command) could number 20,000 although French sources suggest a lower figure. This is worrying as it poses a threat to western aircraft flying over the Sahel as part of Operation Harmattan and of cooperation in the fight against terrorism<sup>6</sup>.

The following weapons are also supposedly in circulation: 200 SA-24 missiles in the hands of a brigade of bodyguards, anti-tank weapons fitted with thermobaric charges, AT-14 missiles and TBG7 rockets which can have devastating consequences for the population.

Of the 400 SCUD missiles that the Libyan army had, apparently only 20 are operational thanks to poor storage conditions. As for the light infantry antitank missiles sold by France, without the necessary firing station training, much information is missing as tracing systems are inadequate. At the end of September, NATO highlighted the disappearance of almost 10,000 ground-to-air missiles whose exact type is unknown. At the same time, the section of the National Transitional Council (NTC) responsible for arms said it did not know the whereabouts of some 5,000 SA-7 ground-to-air missiles.

On 22<sup>nd</sup> September, the International Atomic Energy Agency (IAEA) revealed that the rebel forces of the NTC had discovered far out in the Sahara a military depot containing large quantities of "yellowcake", a uranium concentrate. The provisional government rapidly secured the sites and contacted international organisations with a view to destroying these stocks.

### ***Who benefits from the diffusion of the arms?***

The first to benefit from the circulation of these arms was the Al Qaeda terrorist movement AQIM. This is confirmed by their use - for attacks in Algeria this summer - of Semtex, a powerful explosive that came from the Libyan arsenals.

With its significant information sources and its special forces in the Sahel, France claims that AQIM also has heavy weapons, ground-to-air missiles that come from the Libyan stocks. Nonetheless, Eric Dénécé, director of the French Information Research Centre, is doubtful about the terrorist group's technical competence to maintain arms and equipment in a functioning state and therefore doubts its capacity to cause damage, all the more so as the Libyan crisis has not increased its numbers – they amount to no more than about 350 fighters<sup>7</sup>.

### ***Possible solutions***

In late September, the Joint Chiefs of Staff of the group of "5 +5", bringing together the five Maghreb countries, Morocco, Algeria, Tunisia, Mauritania and Libya (Libya was absent) and five European countries bordering the Mediterranean (Portugal, Spain, France, Italy, Malta) met in the Mauritanian capital to study

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5. Le Figaro. « La France a parachuté des armes aux rebelles libyens ». 29 June 2011.

<sup>6</sup> Cf the incident in 2002 when an Israeli company aircraft was targeted by AQIM as it flew over Kenya.

<sup>7</sup> Le Matin DZ. art.cit.

forms of cooperation to set up together in the fight against the spread of weapons produced by the Libyan crisis. The priority is border security.

Bérangère Rouppert, Researcher at GRIP

Drawn from "Monitoring de la stabilité régionale dans le Bassin Sahélien et en Afrique de l'Ouest"

[http://www.grip.org/en/siteweb/images/NOTES\\_ANALYSE/2011/NA\\_2011-10-27\\_FR\\_B-ROUPPERT.pdf](http://www.grip.org/en/siteweb/images/NOTES_ANALYSE/2011/NA_2011-10-27_FR_B-ROUPPERT.pdf)

## TOWARDS GREATER PRODUCTION OF MEDICINES IN AFRICA?

### *Current situation*

Despite the efforts done in the last decade by governments and global organizations, about 2 million Africans have no access to essential medicines. 74% of drugs against HIV/AIDS are still under the monopoly of big pharmaceutical groups and 77% of Africans still lack access to treatment. As a result, tuberculosis, AIDS and malaria still kill more than 6 million people on the continent each year. A possible solution to this situation would be the production of generic drugs in the continent. Being 70-90% cheaper than brand name drugs, generic drugs are more affordable for a large majority of Africans.

The continent has 14% of the world population but produces only 3% of the world medicines. While the overall pharmaceutical market in sub-Saharan Africa is worth USD 3.8 billion annually, the pharmaceutical manufacturing sector in Africa contributes only 25-30 per cent of the continent's needs. The production of life-saving drugs is furthermore concentrated in very few African countries: 70% of pharmaceutical manufacturing takes place in South Africa and an additional 20% in Nigeria, Ghana and Kenya. Apart from Morocco, more than 85% of drugs sold in Africa are imported. Senegal imports 80% of its medicines. Currently most generic come from India. Though they are cheap the high cost of transport makes it difficult for governments and national health systems to provide treatment for all those who need it. In Kenya, more than 400,000 HIV-positive people are receiving ARVs, but another 600,000 require the drugs and have no access to them. An estimated 1.5 million Kenyans are infected with HIV.

Today no African country, whatever its size and level of economic development, is entirely self-sufficient in pharmaceuticals. This is a concern for governments and patients. To answer this need, in 2001 the 55 members of the African Union (AU) signed the Abuja Declaration to support the development of a plan for pharmaceutical innovation in Africa. The 2005-AU Assembly decided to develop a Pharmaceutical Manufacturing Plan for Africa within the framework of NEPAD. The AU Conference of Ministers of Health that followed with the support of some partners decided took practical steps to produce generic medicines on the continent and to make full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health.

The 59th World Health Organization Regional meeting for Africa discussed the issue and the AU Commission in collaboration with the World Health Organization (WHO) conducted a drug production capacity mapping exercise. A series of questions were raised: was it better to strengthen local production of essential medicines or to import essential medicines from reputable sources? A realistic appraisal and analysis was needed before deciding on local manufacturing. A number of issues had to be taken into account: technical feasibility, financial viability, sound regulatory systems, market size necessary to ensure sustainability as well as technical and financial viability.

### *Current Production*

Pharmaceutical production occurs at three levels:

1. **The primary level** includes the manufacture of active pharmaceutical ingredients and intermediates from basic chemical and biological substances.

2. **Secondary production** includes the production of finished dosage forms from raw materials and excipients.
3. **The tertiary level** is limited to packaging and labelling of finished products or repackaging of bulk finished products.

Out of the 46 countries in the WHO-African Region<sup>8</sup> 37 have pharmaceutical industries, of them 34 have secondary level production and 25 have tertiary production. Only South Africa has limited primary production. Nine countries have no production capacity.

Many countries in the continent rely mainly on India and in less measure on China for imports of affordable generics and raw materials. The fact that since 2005 India had to comply to the TRIPS and change its patent laws is seen as a potential threat to affordability and access to essential drugs in Africa. Patents often make drugs more expensive. Added to this is the fact that Indian producers target more and more rich countries markets and they are less orientated towards African countries diseases. African countries need to decide on alternatives for African specific diseases such as malaria.

### ***Medicines and international AID***

The role played by the global health community has been decisive in the supply of affordable drugs to fight against neglected diseases. International Health organizations and Western governments have provided the majority of medicines that the continent needs. They have played an important part in the diminishing of deaths from malaria, HIV/AIDs and TB, and of the diminishing cases of river blindness among others. They have also contributed to the increasing number of HIV/AIDs patients treated by antiretroviral drugs (ARV). But these advantages bring with them some dangers. These International groups set up the agenda for health research and drug development in Africa. It is important that countries be allowed to set their own priorities and formulate their own strategies in order to meet the needs of their populations. They need to take measures not to rely so much on international aid.

### ***The efforts towards medicine production***

Till now in most African countries the production units were made up of subsidiaries of foreign pharmaceutical firms. They import almost all of the raw material. In the ECOWAS region there are 17 production units including 8 in Ivory Coast, and 4 in Senegal, but they ensure only 10% of the needs of the region.

Backed by the African Union (AU), several African countries have launched into the production of generic drugs for HIV/AIDS, tuberculosis, and malaria. Kenya, Nigeria, South Africa and Tanzania, among others, have adopted policies to invest into the development, production and procurement of drugs for their populations.

**Cameroon and Gabon** have developed their own production of generic drugs. In April 2010, Cinpharm-Cameroon opened a factory in Douala, that is the most modern pharmaceutical company in West and Central Africa. It will produce painkillers, antibiotics, anti-malarial, intestinal parasiticide, anti-inflammatory, antibiotics (repetition), antiretroviral and TB drugs. Eventually, the production should meet 25% of national needs.

With the help of the government Aspen Pharmacare in Port Elizabeth (**South Africa**) produces under license eight generic antiretroviral drugs. Aspen in (is) Africa's largest pharmaceutical manufacturer and has become the world's leading manufacturer of generic triple therapy and is also among the three producers

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<sup>8</sup> The World Health Organization (WHO) African Region is formed by all countries of the continent except Morocco, Tunisia, Libya, Egypt, Sudan and Somalia that belong to the WHO-Eastern Mediterranean region.

of generic ARVs (the other two are Indian) approved by the World Health Organization (WHO). Aspen has four sites in South Africa, one in Kenya and one in Tanzania.

In November 2011, Universal Corporation, a **Kenyan** pharmaceutical company has been granted the prequalification certification by the World Health Organization (WHO) allowing the production of Lamizido, a combination ARV drug of Zidovudine and Lamivudine, that will be produced in 150 and 300 gram doses. The prequalification means that the WHO has tested the safety, quality and efficacy of medicinal products before they are released to the public. The cost of the Kenyan drugs is supposed to be cheaper by at least 30% than the drugs bought currently from foreign manufacturers.

The Quality Chemicals plant, in Kampala (**Uganda**), has got a WHO pre-qualification process, which means the manufacture plant has passed a severe quality check. It is the first production plant in sub-Saharan Africa, except from South Africa, to get WHO pre-qualification. Now the company is trying to get the pre-qualification, for the malaria and HIV/AIDS drugs the firm produces. Once it is obtained, international agencies such as UNICEF, will be allowed to buy from the company. The success of Quality Chemicals is in part due to one of India's leading generic pharmaceutical companies, Cipla, which designed the plant (a carbon copy of Cipla's facility in Goa, India). Cipla sent its experts to train Ugandan staff and even applied for WHO pre-qualification certification on behalf of Quality Chemicals.

SOGAMA in **Gabon** was the first plant to produce generic antiretrovirals and antimalarials. The plant supplies also the member countries of the CEMAC (Economic and monetary Community of Central Africa) which represents a market estimated at 30 million people.

In **Senegal** there are four production units (Sanofi Aventis, Pfizer, Canon and Valdafrique WestAfrica Pharma) that provide the licensed production of specialty and generic, which is exported (20 to 30%). A project for the production of generic ARVs is finding a lot of difficulties.

**South Africa, Nigeria, Ghana, Marroco**, but also **Ethiopia, Tanzania, Uganda, Kenya** and other countries have different kind of pharmaceutical production.

Pharmaceutical companies from Democratic Republic of the Congo to Ethiopia are being helped to reach international standards too. German development agency GTZ is even sending individual inspectors from the German regulator to Africa to do personal plant assessments. Although no substitute for a full WHO pre-qualification, the process helps identify improvements necessary to reach international standards.

Today even Western Pharmaceutical Companies are targeting the main African countries. They have realized that big African countries are a "potential market". They try to get a part of this market either by buying small production companies or through licensing agreements with local manufacturers.

### ***Benefits of local production***

The lack of access to basic generic medicines is a good reason to produce local medicines and to be less dependent from other countries. Local production can facilitate access to medicines for those in need.

Most Africans have no health insurance, so either the government buys and import the drugs from foreign companies to distribute them in the national health system; or the patient has to pay from his own pocket.

A series of benefits are expected as a result of local production: save of foreign exchange; creation of jobs; increase of exports; technology transfer; raw materials produced locally will be cheaper; improvement of self-sufficiency in drug supply. The problem is that these benefits are not always there when drugs are produced. Local manufacturing is supposed to make the drugs cheaper, accessible to more people, thus resulting in significant savings for the government's treatment programmes, but sometimes the price cannot compete with those from India and China.

## ***Difficulties in the path to production***

A series of bottlenecks make difficult the production and the selling of medicines produced in Africa: heavy taxation, lack of access to inputs and raw materials, strong competition from foreign laboratories, lack of research and development, a proven system of pharmacovigilance and qualified human resources ... These factors are sometimes responsible of pharmaceutical production behind in Africa.

**Intellectual Property Rights.** To help Africa produce its own drugs, it is urgent to remove the barriers of intellectual property, which block the rapid spread of cheap versions of existing life-saving drugs. Specific provisions of international law already exist. The flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health allow for "compulsory licensing". This means that a country for reasons of public health can lift the patent on certain drugs, provided royalties on the sale of the generic versions are paid to the laboratory that owns the patent.

**Infrastructure.** Unreliable water and electricity supplies, difficulties of transport, the need to import machinery, packaging, and active pharmaceutical ingredients (APIs) result of a weak chemical production in many African countries are constant difficulties that contribute to making the product more expensive. Furthermore the business environment in Africa has many deficits.

**Quality.** The big challenge is to produce high quality drugs. The operating environment can be difficult and the weaknesses at plant level in reaching and maintaining quality standards in line with established international standards (WHO) can be hard.

**Human Resources.** The production of good medicines and the maintenance of the facilities needs pharmaceutical experts and technical personnel with high and specialized skills that are missing in many African countries. The lack of high quality education at university is the main cause. Another difficulty is the lack of expertise and of means in drug regulatory authorities, responsible for approving the marketing of these drugs. To succeed in the production of medicines Africa needs good pharmacists, biologists, chemists, doctors, and technicians.

**Material Resources.** Low level of investments and of capital constitutes a main strain. The drug regulatory authorities often are understaff and they have not funds. This makes it difficult to approve the medicines.

**Legislation.** The lack of regulation and of clear political will does not allow an investment security. The pharmaceutical sector lacks effective support functions among others by regulatory authorities and quality control labs.

**Small domestic markets.** In Africa markets are small because the countries are small and the many in the population do not have the means of buying the medicines. The small size of domestic markets diminishes the prospects for achieving optimal production efficacy. E. g. Uganda has a population of 30 million, not enough market for a production unit. The creation of bigger markets like the East African Community can be a solution. The difficulty is that each country wants to have its own production unit.

**Prize.** Manufacturers in Africa face a multitude of expenses: high cost of inputs (energy, packaging), transport and imported commodities, together with small volumes produced raise the cost of medicines beyond those from India and China. Prizes offered by local producers are cheaper than those from Northern companies but higher than those from India and China, that can produce cheaper thanks to their huge markets.

**Economic viability** of local production, is hard particularly where the production is undertaken by private entrepreneurs as a commercial venture. The sustainability of the production will depend on factors such as the size of the market and the demand for the produced medicine, as well as the ability to export such medicines.

## **Conclusion**

Despite the difficulties met by the production of medicines in Africa, the adventure continues and Africa is developing its own production of generic drugs. This is a sign of hope for all those who care for a better health for the African people.

For the local production of pharmaceuticals to be effective and efficient, African countries, donors and International Health Institutions need not only words, but the political will, investments and actions that will lead to a local production of essential generic medicines of quality in the continent, so that all Africans may have access to medicines of quality.

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## **EUROPEAN COMMISSION WANTS TO FORCE ACP COUNTRIES TO SIGN EPAS**

In the last year, EPA negotiations had largely come to a standstill: only a few negotiation rounds took place and they produced no significant outcome. Frustrated with this lack of progress in the negotiations, the EU has decided to step up the pressure on the ACP countries. On 30th September the European Commission adopted a proposal amending Regulation 1528/2007 governing the market access of 36 ACP countries to the EU. The proposal for amendment provides that, unless the 36 countries listed in the Annex ratify and implement EPAs by January 2014, they will be taken off the list. This means that they will lose the duty/quota free access of their goods to the European market. This now marks officially the beginning of the endgame in the EPA process. To become effective, the proposal needs to be adopted by the Council and by the European Parliament.

### ***AEFJN Secretariat Brussels How did we get here?***

The Cotonou agreement in 2000 made provision for bilateral trade agreements (EPAs) to replace the unilateral duty/quota free access of ACP countries were enjoying by the end of 2007. However, negotiations progressed far more slowly than foreseen and as the 31 December deadline approached, no country was ready to sign an EPA. The delay in the negotiations was partly due to the European Commission's insistence on including trade in services, investments, government procurement and the protection of intellectual property rights, although this would not have been necessary to make EPAs compatible with the rules of the World Trade Organisation as well as the EU's excessive insistence on market opening.

Regulation 1528 was therefore adopted in December 2007 as a temporary solution to allow for more time to conclude the EPA negotiations and the ratification process. Even after 2007, however, negotiations continued at a much slower pace than the European Commission would have liked. Only with the Caribbean countries was an agreement for a full EPA concluded. In the negotiations with various African regional formations, disagreements over various aspects of the EPAs continued. Although some African countries initialed or signed interim EPAs, they generally refrained from implementing them. The main underlying reason is that Africans do not share the EU's vision that EPAs will help their development. They rather see them as an instrument to defend European interests in Africa and as harmful to Africa's long term development perspectives.

### ***The GSP reform***

The decision of the European Commission to remove countries that do not sign an EPA from the Annex to regulation 1528/2007 has to be seen in parallel with the proposal for reform of the Generalised System of Preferences (GSP) presented in May this year. GSP is a trade arrangement through which the EU provides

developing countries and territories with preferential access to the EU market. This takes the form of reduced tariffs for their goods when entering the EU market. There is no expectation or requirement that this access be reciprocated. It has however to be noted that this represents an increase in tariffs for ACP countries which hitherto have benefited from duty free access to the EU market. The current GSP will terminate at the end of 2013 which means that the new system will be put in place in January 2014, at exactly the same time the Commission intends to remove ACP countries from the annex of the market access regulation.

Like the proposal to change regulation 1528/2007, the Commission proposal for GSP reform has yet to be approved by the Council and the European Parliament and is likely to be amended. According to the reform plans of the European Commission, countries benefiting from GSP should be radically reduced and this would also have negative consequences for some African countries as we will see in the section below. One of the main reasons behind the Commission's decision to reduce the number of beneficiary countries is to make GSP a less attractive option and to force developing countries to sign trade agreements with the EU.

So far, only three African countries have used the EU's GSP scheme: Congo-Brazzaville, Gabon and Nigeria. All three are oil-rich countries with a Gross Domestic Product which is too high to qualify them for the 'Everything but Arms' programme of the European Union for Least Developed Countries (LDCs). These three countries decided not to sign an EPA with the EU and backed out of the negotiation process years ago. As oil is the main commodity these countries export, they could afford not to sign an EPA and to fall back on GSP as oil does not face tariffs when imported to the EU. Now, according to the reform proposal of the Commission, Gabon would no longer qualify for GSP. As Gabon's oil exports will not face import duties in any case, it is unlikely Gabon will be persuaded to sign an EPA. However, at the same time, it limits Gabon's future possibilities to diversify its economy and to develop its own industrial sector, as these goods would face considerable tariffs if exported to the European market and therefore become less competitive.

### ***The consequences of the decision***

The regulation of 2007 allows the 36 ACP to continue benefiting from duty free/quota free access to the European market. Of these 36 countries 18 (14 Caribbean countries, Madagascar, Mauritius, Seychelles and Papua New Guinea) are seen as "good guys" by the Commission, meaning they have taken the necessary steps towards the ratification and implementation of the EPA. If they continue implementing the EPAs these countries will not be taken off the Annex of regulation 1528/2007.

Of the other 18 "bad guys" Burundi, Ghana, Kenya, Namibia, Rwanda, Tanzania, Uganda and Zambia, have concluded negotiations but have not signed their respective Agreements. Botswana, Cameroon, Ivory Coast, Lesotho, Mozambique, Swaziland, Zimbabwe as well as Fiji and Haiti have signed but have not taken the necessary steps towards ratification or implementation of their respective Agreements. They now face the choice of either ratifying and implementing an EPA or being removed from the market access regulation.

The impact of being removed from the market access regulation would be different for the various countries. Burundi, Comoros, Haiti, Lesotho, Mozambique, Rwanda, Tanzania, Uganda and Zambia are LDCs. These countries can benefit from the European Union's 'Everything But Arms' (EBA) scheme, which foresees duty free/quota free access to the European market for LDCs. These countries have therefore little to worry about.

On the other hand, Cameroon, Fiji, Ghana, Ivory Coast, Kenya, Swaziland and Zimbabwe are low income or lower middle income countries and cannot benefit from EBA. They would fall back on the GSP scheme, meaning that their main exports will be taxed when entering the European market. These countries would therefore face serious consequences if they do not sign an EPA.

Botswana and Namibia are in an even trickier situation. They are upper middle income countries and, according to the European Commission's current proposal for reform of the GSP, would no longer even qualify for GSP. They would therefore revert to the higher, normal level of tariffs on their exports to the EU. According to estimates for Namibia, this means an average of 19.5% duties on its exports (almost 60 million Euro as the EU is Namibia's main export market outside Southern Africa and accounts for about 30 per cent of Namibia's exports).

### ***Reactions to the decision of the European Commission***

Given that it is one of the countries that is hit hardest by the Commission's decision, it comes as no surprise that Namibia reacted strongly to it. "This is not the way to go," Trade and Industry Minister Hage Geingob complained. "This is not a partnership. By setting an arbitrary deadline the EU is trying to put pressure on us to sign the economic partnership agreement." "There must first be progress in action regarding the outstanding issues before a deadline can be set," he added. Namibia's Deputy Minister of Finance, Calle Schlettwein stated that Namibia will not sign a 'bad' Economic Partnership Agreement that limits its ability to solve domestic developmental agenda problems. "The bad part of the EPA is that, as long as we export raw materials to the EU markets, they impose no tariffs, but the more value we add, the higher the tariffs. If we sign the EPA in its current form, we will be deprived of the opportunity to develop our own industries and to export finished goods to other large markets," he said. Namibia also lamented that during his visit to the country in September, Commissioner for Trade Karel de Gucht did not mention his intention to set the January 2014 deadline.

The Ghanaian government has signaled that it is likely to sign its interim EPA soon and not to wait for the other countries of the West African region (ECOWAS) to find a regional agreement on EPAs. The Trade and Industries Minister, Hannah Tetteh, told the media that the country would have preferred to join other member-countries within ECOWAS to sign the EPA as a body; however, negotiations on the trade agreement with the European Union have stalled - pushing the government to consider its options. "For the past three years, we haven't really gone far with the ECOWAS EPA" she declared. She also underlined that Ghana's decision was directly related to the Commission's decision to set a deadline.

Meanwhile, civil society organisations including the Third World Network (TWN) have urged the government to forgo the EPA in order to secure regional integration in the West-Africa sub-region. The Head of Economic Unit of TWN, Gyekye Tanoh, recently argued that the EPA is a threat to re-positioning the national economy and to regional integration in the Economic Community of West African States bloc.

The negotiations between South Africa and the EU made progress on agricultural goods. South Africa is not directly affected by market regulation 1528/2007 as its trade relations with the EU are regulated by a bilateral Trade, Development and Cooperation Agreement (TDCA). However, South Africa is negotiating an EPA with the EU as part of the SADC group comprising also Namibia, Botswana, Lesotho, Swaziland Mozambique and Angola. Moreover, Zimbabwe seems likely to bow to the pressure of the EU and ratify the EPA it signed in 2009 by the end of the year, according to recent statements.

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