Process on Corporate Responsibility in the Field of Pharmaceuticals
Platform on Access to Medicines in Developing Countries with a Focus on Africa

EU-Africa Pharma Business to Business Forum

An exchange of views between regulators and business community from Europe and Africa

FINAL RECOMMENDATIONS

Brussels, 16 September 2013

1. Introduction – The framework

Health is one of the fundamental rights of every human being. Health plays a major role in the development of a society and its citizens; it makes a substantial contribution to improving the living conditions. This is particularly true in developing countries where access to medicines is one of the main obstacles in improving public health.

The pharmaceutical industry plays globally an important role for citizens. The European Commission's Vice-President Antonio Tajani, responsible for Industry and Entrepreneurship, launched the **Process on Corporate Responsibility in the Field of Pharmaceuticals** (Process) in September 2010. The initiative aimed at facilitating discussions on improved access to medicines, ethics and transparency in the sector.

The Process consisted of three platforms (work streams):

- Access to medicines in Europe
- Ethics and transparency
- Access to medicines in developing countries with a focus on Africa

In its Conclusions on Innovation and Solidarity in Pharmaceuticals, in December 2010 the Council of the European Union invited the European Commission and the Member States to "foster dialogue with stakeholders on: […] access to medicines in developing countries, with a focus on Africa, particularly by cooperating in the process of corporate responsibility in the field of medicinal products".

Based on this mandate, the goal of the platform **Access to Medicines in Developing Countries with a focus on Africa** and the **EU-Africa Pharma Business to Business Forum**, held on 16 October 2013, was to reflect on the contribution Europe can make, the value-added of industry's involvement and the challenges society, governments and industry are facing. The added value of the initiative consists in the more effective involvement of the European pharmaceutical industry. This initiative enhanced collaboration between governments, international organisations, pharmaceutical companies and civil society so as to discuss activities which are aimed at improving access to quality medicines in resource restricted parts of the world.

2. The gap

Adequate and timely access to health and quality medicines in developing countries remains a challenging issue which results in millions of deaths each year, caused not only by the "big three" pandemic diseases (malaria, TB and HIV/AIDS) but also by other communicable or non-communicable diseases. This problem seems to be even more acute in the least developed countries and in sub-Saharan Africa.

To date, African pharmaceuticals have only been able to make a limited contribution to the needs of the continent. Almost all the continent's needs in medicines are covered by imports (mainly from Asia), thus jeopardising the security and timely availability of supply. These imported products are also more likely to be sub-standard in quality due to the lack of financial and skilled human resources of the local regulatory authorities for effective compliance monitoring.

Most African countries do not have an appropriate policy and regulatory framework in place which would secure affordable prices as well as reliable and effective procurement and supply of medicines. This problem is further aggravated by shortcomings in national healthcare financing - even in relation to essential medicines - which first of all affects the economically most vulnerable citizens.

An insufficient regulatory and quality assurance framework as well as a limited capacity in skilled human resources often leads to an inappropriate use of medicines with negative effects on public health and public expenditure. Moreover, factors like weaknesses in infrastructure and equipment may also affect stock management, leading either to medicines stock-out or waste.

Initiatives at international level are already targeting the issue of access to medicines in developing countries. For example, the WHO's "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property", aiming at the creation of favourable conditions for research and development on diseases which are disproportionately affecting developing countries.

Another important initiative is the "Renewed EC/ACP/WHO Partnership: strengthening pharmaceutical systems and improving access to quality medicines in countries in Africa", co-funded by the EU in line with the 2nd Joint AU-EU Action Plan 2011-2013.

One of the main recent initiatives is UNIDO's "Global Project on Strengthening the Local Production of Essential Medicines in Developing and Least Developed Countries", already in progress in Ghana and Kenya and planned to be further extended to other African nations. In this context, since July 2011 UNIDO has been

cooperating with the African Union Commission (AUC) towards the implementation of the Business Plan for the "Pharmaceutical Manufacturing Plan for Africa" (PMPA BP).

Regarding the facilitation and promotion of business partnerships and linkages, UNIDO is building on its earlier 2012 initiative U4P (Pharmaceutical Production Partnership Platform) with expanded activities addressing the partnership and corporate development needs of DC/LDC pharmaceutical manufacturers.

3. The event - An exchange of views between regulators and business community from Europe and Africa

To address the shortcomings, an EU-Africa Pharma Business-to-Business Forum was organised by the European Commission's Directorate General for Enterprise and Industry in close co-operation with both, the European Generic medicines Associations (EGA) and the European Federation of the Pharmaceutical Industries and Associations (EFPIA) as well as DG Development and Co-operation, and DG Research and Innovation.

As the challenge of providing access to safe drugs is a multi-faceted issue, business players as well as representatives of public administrations play key roles. Based on the identified needs and a collaborative approach, the European Commission invited EU and African industry representatives, regulatory bodies and NGOs to identify major obstacles related to responsible business-to-business and public-private relations and reach a consensus on how European stakeholders could best share their technical knowledge with their African counterparts.

It was intended to highlight case studies, giving participants insight into experiences while addressing obstacles hampering access to quality medicines in Africa. The identified solutions could serve as best practices worth emulating in similar settings.

In addition, the EU-Africa Pharma Business to Business Forum (Forum) aimed to establish networks between market players with complementary skills and interests, *i.e.* the European and the African business community involved in pharmaceuticals.

The following chapters recapitulate the main issues examined in the three sessions of the Forum. Furthermore a non-exhaustive list of recommendations is put forward based on the deliberations of the participants. By way of introductory remark, it should be emphasised that the views expressed do not necessarily reflect the Commission’s position but are paraphrased statements made during the sessions of the Forum.

4. Addressed topics

4.1. How can dialogue between public bodies and industry contribute to an efficient regulatory system?

In order to enable an efficient regulatory system, the private and public sectors must enter into a dialogue identifying common ground in terms of objectives and methods.

There was general agreement that an efficient regulatory system and regional harmonisation of the legal framework governing medical products would lead to improved predictability, clarity and transparency and could be one of the drivers for developing a more efficient local pharmaceutical industry and strengthening business-to-business cooperation between EU and African economic operators.

Europe and Africa already collaborate to address current gaps and challenges in the health sectors of African countries. However, the current European aid is focused at country-level and supports national health systems to address challenges in a focused way, while regional approaches seem to be supported to a lesser degree.

The EU is preparing the next "Agenda for Change", setting the European development policy goals for the period 2014-2020. New forms of partnerships and collaboration pathways with the private sector are to be explored in order to meet current and future challenges.

In African countries, more resources dedicated to health and the regulatory institutions management should be envisaged to improve in a concrete and achievable way.

However, notable results have been accomplished in terms of regional harmonisation of pharmaceutical regulations and collaborations as demonstrated by the example of the West African Economic and Monetary Union (*Union Economique et Monétaire Ouest-africaine)* and the Organisation of Coordination against Endemics in Central Africa (*Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale)*. These activities clear the path for sustainable improvements in healthcare systems by showing leadership at regional level.

Other examples of cooperation between public authorities are the bilateral agreements signed between Portugal and Angola, Mozambique and Cape Verde, concerning various health related areas and actions. These agreements have led to a strong and sustainable relationship between all actors involved (regulatory agencies, Ministry of Health, etc.). The harmonised data register for drugs and medical devices facilitates and enhances collaboration. Difficulties remain though: the lack of regional contact points and bureaucratic obstacles still need to be overcome.

There was general agreement that the close cooperation between regulatory bodies, either between Europe and their African counterparts or among African countries,

creates a solid ground for public-private partnerships in the African countries. Concrete ideas, like building capacity e.g. by organising four-week training courses for health inspectors from Africa in EU Member States, supported by both, the European Union and the EU industry could be worth further exploring.

However, certain basic conditions have to be met in order to prepare the ground for an efficient regulatory environment which is to be provided by public authorities.

The first challenge to be faced is the perceived lack of political will and commitment. Political commitment demonstrated through action remains the basis for a sustainable healthcare system and ultimately a prerequisite for a thriving local industry. The participatory approach has been proven effective for building an efficient system with a clear allocation of responsibilities and identified conflicts of interest, and therefore needs to be pushed further.

The second challenge to be addressed is the establishment of a harmonised legislation at regional level in Africa which would create a more efficient and business–friendly environment. All players should be consulted and involved so as to create ultimately a mutually beneficial system.

The third and last challenge is to ensure the implementation of the pharmaceutical legislation at national level with a coherent plan covering all aspects, e.g. ranging from human resources to pharmacovigilance. Leadership from public authorities is necessary in this respect to supervise implementation and ensure effective application by all actors involved.

The European Union was requested to play a role in supporting political decision-making to address the above mentioned challenges. Ultimately its support may enable African countries to establish sustainable healthcare systems in sub-Saharan African countries. In this respect, collaborative actions could take multiple forms and involve all actors concerned from the public and the private sector, both from Africa and Europe.

The European Union should continue advocating the position of the crucial importance of health for society and for a country’s wealth, its financial implications and its positive impact for business and citizens in general.

The African Union should also be called upon to play a stronger role in collaborating with regional authorities and managing partnership opportunities both, with the private sector and with the European Union. In November 2013, a meeting of the African Union Specialized Technical Committee on Health, Labour and Social Affairs took place in Ghana in order to assess the best paths for private sector investments. The purpose was to set common objectives and, based on this, to develop a coordinated working plan which may reflect some of the recommendations of the meeting.

4.2. Strengthening quality standards: How can healthcare systems sustain responsible manufacturing practices ensuring quality medicines?

With regard to quality in pharmaceutical manufacturing, consensus existed that sub-Saharan African countries are still dependent on medicines imports to a significant extent. The (often imported) sub-standard medicines jeopardise public health. Concerns about an uneven playing field for African manufacturers were also voiced, this argument was particularly emphasised with regards to generic products originating from India.

Several obstacles have been identified as factors hampering the high emergence of quality standards for medicines in sub-Saharan countries.

On the regulatory side, the different levels of regulatory capacities amongst African countries and the often limited resources of the National Medicine Regulatory Authorities (MNRA) with regard to registration, documentation, quality management systems, etc., complicates the regulatory harmonisation at (sub) regional level. Without sufficient human resources and a minimum of technical infrastructure, the required range of regulatory support for the industry cannot be ensured.

With regard to the local pharmaceutical production in Africa, the majority of local operators feel constrained by numerous challenges which hinder up-scaling and upgrading their production. Apart from South Africa, active pharmaceutical ingredients are hardly manufactured in Africa. Although there are some rather isolated exceptions, the concept of responsible manufacturing practices is not yet adhered to. Fast movers, who have been able to implement good manufacturing practices (GMP, including in the context of WHO pre-qualification), struggle to survive because they are operating on an uneven playing field.

Very often the legal and fiscal environment is not appealing to investors in new technologies, and sustainable access to finance is a big challenge for most of the operators.

More generally, the perceived policy incoherence (health and industrial policy objectives may diverge), was identified as counterproductive for a viable local production.

In any case one fundamental issue remains, it is the question as to how would it be possible to strengthen the quality standards of medicinal products.

General agreement existed that in the regulatory field, a clear and long-term committed political will is essential. National Medicines Regulation Authorities need to be established or re-organised in a more efficient way. Critical elements of the regulations (e.g. with regard to manufacturing, distribution, pharmacovigilance, etc.) need to be implemented effectively and efficiently. The establishment of an African Drugs/Medicines Regulatory Agency would facilitate the regional regulatory

harmonisation efforts. Joint inspections and mutual recognition at regional or pan-African level could have a positive effect.

According to the participants, the local pharmaceutical industry in Africa often faces undue hurdles which put them at a disadvantage vis-à-vis foreign producers, namely with regard to generics originating from emerging economies. To establish a viable local industry, a stable level playing field is needed. This would require non-discriminatory practices and the enforcement of high regulatory standards which could contribute to combat substandard and counterfeit medicines.

Given the multitude of areas affected and their interdependencies, the public sector must follow a holistic approach and differentiate adequately between different levels of action. There is a need for an overall regulatory framework; national regulatory bodies should be established and/or improved. The establishment of a resilient infrastructure for quality management needs to be supported. Investments in research and development, human resources, access to loans need to be set high on the national and regional agenda. The African Union's Pharmaceutical Manufacturing Plan for Africa – Business Plan may provide the political backing for such an approach.

However, the private sector has also to assume its role. Individual companies have to be open to implement quality upgrading programs and seek commercial and non-commercial partnerships.

African pharmaceutical business associations at country, sub-regional and continental level should advocate the importance of strengthening the National Medicine Regulatory Authorities (GMP know-how improvements, inspections, enforcement), raise awareness and offer tailor-made services to their members vis-à-vis governments and public bodies.

With regard to the role the European and more advanced African industry could play, a broad range of activities could be identified:

- Commercial partnerships like licensing/ contract manufacturing, joint ventures and technology transfer agreements could create an added value for both sides.

- Non-commercial partnerships in terms of human capacity building and training in Europe, staff exchange, internships and mentoring programs for GMP (good manufacturing practices), expert missions to leverage the effect of co-operations and make them more sustainable. Assistance for National Medicine Regulatory Authorities and in business model optimisation could also create added value.

As for the lack of required human resources, a comprehensive human resource capacity building strategy is deemed necessary. First of all, the existing capacity has to be utilized more efficiently, requiring modifications of *curricula*, skill audits, better regional co-ordination and co-operation.

4.3. Public-private collaborations and the engagement of the actors

In this part of the Forum, the issue of concrete examples of Public-Private Partnerships and the lessons learned from them was addressed.

Effective delivery of adequate medicines to patients is dependent on very complex sets of issues which require the intervention of multiple actors, both, public and private. Effective and sustainable solutions can be designed and implemented only through collaborations and partnerships. These solutions need to be tailored to the realities of each country. Particularly on the African continent with its wide-ranging specifics as a consequence of history, traditions and geography, country-specific approaches are quintessential. In any case, an active involvement of local actors, in particular government authorities to ensure alignment with national policies and priorities, is required.

Historically, the issue of access to HIV drugs initiated a process which made civil society a key stakeholder in public health issues. The complexity and urgency of the issues led to the realization that neither the private nor the public sector alone could sustainably improve the situation. As a result, public-private partnerships have developed in recent years as a way to harness the specific sets of expertise and the resources of complementary stakeholders towards common objectives.

During the Forum, the factors for success and failure of such public-private partnerships were discussed. Speakers were invited to present concrete case studies to exemplify the challenges and opportunities that public sector organisations and pharmaceutical industries are faced with when venturing global health challenges together.

Case study: The African AIDS crisis

By early 1990s, HIV was spreading fast. The numbers of people living with AIDS in sub-Saharan Africa in 1993 was estimated to be 9 million out of a global total of 14 million. In 1996, Highly Active Anti-Retroviral Therapy (HAART) became available in developed countries, and AIDS death rates in these countries dropped by 84% over the following four years. However, over 70% of the infected lived in sub-Saharan Africa and were without access to anti-retrovirals (ARV) because of the exorbitant cost (US-$10,000-15,000 per person per year).

South Africa, with the highest numbers of AIDS patients in the world, approached pharmaceutical corporations either to allow local manufacture of low cost generics (compulsory licensing) or allow parallel importation from other countries. Citing Patents law and TRIPS agreement, pharmaceutical companies responded by taking court action to block South African implementation of the 1977 amendment for compulsory licensing and parallel imports. This resulted in worldwide civil society protests and in December 1999 the pharmaceutical companies involved withdrew the case promising increased access.

By 2001, there were an estimated over 5 million people in immediate need of Anti-Retroviral Therapy in Africa, but only 8,000 people in the entire continent had access to adequate drug treatment. Consequently millions were exposed to a preventable death. This moral imperative brought on board UNAIDS, WHO and the UN and eventually led to the establishment of the Global Fund and PEPFAR (United States President's Emergency Plan for AIDS Relief).

However, it became clear that it would be impossible to treat the large number of patients at the high cost of branded products from pharmaceutical companies in developed countries; consequently both programs predominantly relied primarily on generic drugs from India.

The G8 negotiations over the Gleneagles Communiqué of July 2005 called for universal and equal access for all people to ARV by 2010.To date, this goal has not been achieved and a significant number of patients in sub-Saharan Africa still have no access to ARV or sufficient funds to pay for the drugs. With regard to second and third generation drugs, which still enjoy intellectual property protection, issues related to affordability should be addressed.

Solutions for second/third generation medicines, therefore, still need to be found.

Public-private partnerships bridge and leverage opportunities for health innovation and delivery of health services by exploiting the respective comparative advantages. In particular in rural areas of sub-Saharan Africa, public-private partnerships, e.g. between public authorities/services and private NGOs, have significantly contributed to increase the quality, equity and efficiency of healthcare service delivery. However, even though patient organisations played a driving role in the debate and movement for access to HIV medicines, patients in Africa still play a relatively limited role in improving access to healthcare services for diseases other than HIV/AIDS.

Public-private partnerships – a way forward

Public-private partnerships can play a major role. Their contribution was generally appreciated by participants. In order to exploit their full potential, however, certain conditions have to be met.

Public-private partnerships require first and foremost a shared understanding of the respective areas of responsibility and of legitimacy of each stakeholder.

A clear set of measurable objectives to be reached by the partnership must be defined very early on. The partnership must be based on a contractual document that spells out which specific tasks/responsibilities are allocated to the parties, how budget responsibilities are split between partners, and very importantly what the governance of the partnership should look like. The latter aspect is of particular relevance in case of disagreement between the parties.

Collaboration between public and private actors must also proactively address potential conflicts of interests in order to dispel the risk of suspicion of undue favors between the partners. It is also important for partnerships to have a clear vision on how the specific tasks they will perform will fit into the broader political landscape. In any case, the medium to long-term commitment of such a partnership also requires to deal with issues like anticipating how a new drug will be registered, manufactured, distributed to reach patients in need, etc. This may require coordination with other stakeholders who will perform other complementary tasks.

The challenge is, therefore, to be focused on achieving specific project-related objectives and aligning the work of the partners with that of other stakeholders who may have an impact on achieving the overall objective.

Particularly in the field of diseases such as HIV/AIDS, tuberculosis, malaria and Neglected Infectious Diseases, several examples of successful public-private partnerships attest to the value of such operating models. The success of these Product Development Partnerships, so-called PDPs (such as Aeras, DNDi, IAVI, MVV, PATH), relies upon the combined strengths of the partners, but also on the value of confronting different and sometimes opposed agendas to foster creativity. The new collaborative models developed for these diseases might also help address the challenges posed by other public health issues such as, among others, the increasing global burden of non-communicable diseases.

One innovative example of a public health driven business model was highlighted in the Forum. The Medicines Patent Pool (MPP, a United Nations backed organization) aims at lowering the prices of HIV medicines and facilitating the development of better-adapted HIV medicines in developing countries. It was founded in 2010 at the request of the international community through the WHO-based financing mechanism UNITAID.

The Pool negotiates for licenses from key HIV medicine patent holders in order to both lower the prices of needed medicines and spur development of needed new formulations. It is the first patent pool for HIV medicines. By sharing patents through voluntary licensing, the Pool makes innovative products accessible in developing countries, provides incentives for further innovation, and stimulates innovation targeted at developing country needs.

5. Recommendations

5.1. Improvement of regulatory systems through public-private dialogue

- Political will remains the main driver and the essence of a sustainable health system and, ultimately, of a potential industry contribution. Therefore political decision-makers in developed and, particularly, in developing countries are called upon to show commitment to creating an environment conducive to establishing an efficient healthcare system.
- Creating a regionally harmonised legislation could trigger and sustain a business–friendly environment.
- Leadership from public authorities is necessary to ensure the implementation of the regulatory framework at national level and to bring together all stakeholders/sectors in the healthcare system in order to know, understand and respect the health system. A solid, clearly defined implementation plan is needed, covering all aspects, from human resources to pharmacovigilance.
- The collaboration with the European Union could play a significant role to support political decisions and to put in place better regulatory systems. The European Union should keep on advocating the crucial importance of health, its benefits for the society and the country's wealth, but also the benefit with regard to the development of the local pharmaceutical industry.
- The African Union has to play a stronger role in collaborating with regional authorities, and managing the opportunities of partnerships with the private sector and the European Union as well.

5.2. Strengthening quality standards

- Creation of a quality improvement road map and a credible intervention plan to be developed in a country and product specific manner.
- Cooperation among the different actors at all levels (manufacturers/public/ private).
- Create an environment conducive to the pharmaceutical industry so as to reap their full potential.
- AU Member States which consider the pharmaceutical industry as a key sector should apply the holistic approach agreed on in the Pharmaceutical Manufacturing Plan for Africa Business Plan.

- The short term costs related to regulatory improvements and quality should be assessed on the basis of medium/long term gains.
- Patients' associations should work with industry to fight counterfeited products.

5.3. Public-private partnerships and co-operations

To increase access to medicines there is a need for public private partnerships. These need to:

- Involve patients and civil society (which have been very vocal driving forces on HIV/AIDS but not yet on other diseases).
- Understand the application and implication of TRIPS and patents laws.
- Assure sustainable funding for pharmaceutical products.
- Clarify the roles of governments, donors, and international community.
- Have a clear mutual understanding of each party's responsibility.
- Establish clear, focused and milestone-based planning and decision-making.
- Have a common vision and understanding of the objectives and definition of success.