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Unit F5 Food and Healthcare Industries, Biotechnology

Access to Medicines in developing countries with a focus on Africa

How can the European industry contribute?

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Report

1. PARTICIPANTS

Participants were selected in partnership with Unitaid, WHO, EFPIA, EGA and relevant DGs (Development and Cooperation, Health and Consumers, Research and Innovation) and represented a wide range of stakeholders (generics and innovators industry, African authorities, international organisations, NGOs, patients) and Member States.

2. BACKGROUND

The pharmaceutical industry makes a huge contribution to economic growth and employment in Europe. The European Union counts more than 4 500 enterprises in this field, employing more than 600 000 people and producing medicines to a value of some € 190 billion. Given the economic viability and research capacity of this sector, European industry has the potential to make a difference ameliorating public health scourges in Europe and beyond.

In 2009, DG Enterprise and Industry launched a reflection process with a cycle of workshops to explore less known areas of the pharmaceutical landscape[1].The process is divided into three separate platforms: (1) ethics and transparency, (2) access to medicines in Europe and (3) access to medicines in Africa.

1. The objective of the platform on ethics and transparency is to exchange information and establish a common denominator for good practices.

[1] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1170&format=HTML&aged=0&language=EN

2. The platform on access to medicines in Europe aims to reinforce collaboration between the Member States and stakeholders in order to explore the non-regulatory conditions for ensuring fair and timely access to medicines following their market authorisation. It will bring together certain specific and innovative initiatives, in particular to facilitate access to innovative treatments after their market authorisation or to help develop a responsible environment for access to medicines. Working in the context of prices and reimbursements, the subsidiarity principle will be fully respected.

3. The goal of the platform on access to medicines in Africa is to reflect on the contribution made by European companies, their value-added and the challenges with which they are faced. It goes without saying that this platform will not duplicate the work already performed by other Commission departments or international organisations.

Since 2000, The European Commission "has become increasingly active in the international debate to increase developing countries' access to affordable key pharmaceutical products. This has involved extensive consultation and review of multiple issues including; infrastructure, financing mechanisms, international pricing and licensing mechanisms, intellectual property rights, tariffs and appropriate incentives to increase investment in global health, including key pharmaceuticals"[2]. Increasing access to medicines in developing countries, particularly for was a key concerning of major Communications of the Commission in 2000 and 2002[3].

Access to health and medicines in the developing countries became a recognised and high-profile issue, with the international organizations, pharmaceutical industry, Member States' governments and the non-governmental sector expressing political commitment (for instance, EU and Member States are signatories to the 2001 Doha Declaration on the TRIPS Agreement and Public Health) and taking tangible actions in the field of global health.

The European Union shares this commitment and has already made significant contributions to resolving some of the issues related to access to pharmaceuticals in the developing countries. Examples include

- Council Regulation (EC) 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines[4] which facilitated the development of tiered pricing of pharmaceuticals for the poorest countries;

- The Decision of the WTO General Council of 30 August 2003[5], which was strongly influenced by the EU and which, by waiving the obligation that production under compulsory licensing must be predominantly for the domestic market, allowed

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0585:FIN:FR:PDF

[3] http://eur-lex.europa.eu/LexUriServ/site/en/com/2002/com2002_0129en01.pdf

[4] http://eurolex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2003&nu_doc=953

[5] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health Decision of the General Council of 30 August 2003 http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

countries without sufficient production capacity to benefit from the TRIPS Agreement flexibilities.

On 12 July 2007, the European Parliament adopted a resolution on the TRIPS agreement and access to medicines. In the follow-up to this resolution the Parliament commissioned two preparatory actions to the European Commission on pharmaceutical technology transfer and local production and on research capacity development for neglected diseases. The action on pharmaceutical technology transfer is being implemented with WHO, UNCTAD and ITCSD with a contribution of €2.184 million.

This is matched by significant aid effort in the area of research. In the first three years of FP7 (Framework Program 7) (2007-2009) alone, the EU has invested over €200 million in research projects on controlling and treating HIV/AIDS, malaria and tuberculosis. Several Directorates General of the Commission are active in Global Health initiatives.

Furthermore, at the beginning of 2010, the European Commission called to enhance EU role in Global Health through a Communication jointly prepared by the Directorates-General for Health, Research and Development[6]. The four main areas of action for the EU are:

- Enhance global governance on health: EU should defend a single position within UN agencies and work to reduce multiplicity of health projects;
- Progress towards universal health coverage, building sustainable health systems and promoting division of labour among all actors, public and private;
- Ensure better coherence of EU internal and external policies in relation to global health;
- Increase global health knowledge.

The Communication reflects the commitments made by the European Union on policy coherence for development. In particular, "On trade, the EU should work to ensure more effective use of TRIPS provisions to increase the affordability and access to essential medicines. The EU should support the priority actions identified in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. This should address the challenges expected after 2016 when the TRIPS framework enters into force in least developed countries. The EU should continue to ensure that EU bilateral trade agreements avoid clauses which may undermine access to medicines. Generic competition and rational use of medicines are of major importance to ensure the sustainability of healthcare systems".

On innovation, in the Council Conclusions on Global Health, the EU reiterates the aim that research should benefit the health for all: "Towards that aim the EU will ensure that innovations and interventions produce products and services that are accessible and affordable. This should be achieved by the EU and its Member States through: a.

[6] Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions from 31.3.2010: The EU Role in Global Health. For the full text of the Communication, see Annex.

working towards a global framework for research and development that addresses the priority health needs of developing countries and prioritises pertinent research actions to tackle global health challenges in accordance with the WHO Global Research Strategy. …c. exploring models that dissociate the cost of Research and Development and the prices of medicines in relation to the Global Strategy and Plan of Action on Public Health, innovation and intellectual property, including the opportunities for EU technology transfer to developing countries."[7]

In its Conclusions on Innovation and Solidarity in Pharmaceuticals, on December 2010 the 2nd, the Council 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" (point 22).

During the workshop, experts from different fields were invited to participate, in their personal capacity, in an open and informal discussion about challenges and opportunities related to access to medicines in developing countries with a special focus on Africa. Chatham House rule was applied, encouraging participants to express their ideas freely and put forward the most challenging proposals.

3. GAPS AND CHALLENGES IDENTIFIED

- **Data gaps**

There are no studies available on how to define a need and how to measure it. Especially there is a lack of analysis on public health expenditures at regional and local level in developing countries and too much emphasis put on the three big diseases.

- **Health literacy**

There is a need to improve general health literacy. Civil Society Organisations in developing countries play an important role in advocating access to rational use of medicines. Supporting their capacity development is of high importance in order to ensure adequate patient information Also the training for pharmacists should be improved as several (available) drugs are and remain unknown.

- **Safety of medicines**

Drug exports from the EU have often not had the same quality requirements than it has inside of the EU. Ongoing EU support to improving the quality and safety of medicines through WHO needs to be continued. Also the control of EU exports needs to be improved.

- **Supply chain and distribution system**

The infrastructures as such can create obstacles in the medicines delivery from port or warehouse to the patients. The formulation can also be inappropriate in certain conditions (heat, humidity). There is a need to register doctors in order to improve the distribution.

[7] http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/EN/foraff/114352.pdf

- **Registration /Regulatory**

Every single country has its own registration system for drugs. Also, drugs are sometimes available but not registered. There is a lack of co-ordination of registration systems and drug regulations at regional (interstate) level. Also, there is a need for capacity building for the regulatory authorities in order to be able to improve e. g. the priority review of drugs.

- **Sustainability of supply**

Inadequate budget allocations for health by governments and unpredictable donor funding for health constrain medicines supply in developing countries. The volume of available funds is very volatile and is dependent on competition with other global issues (e.g. climate change), global economical crisis but also "trends" in the charity field. Local production capacities are too weak to balance these effects.

- **Formulations**

Drugs are mainly designed to be used in developed countries often targeting adults as patients. These drugs can not be easily dispensed in developing countries, adapted formulations are needed. Children as a patient target group are generally neglected.

There are not enough clinical trials carried out in Africa (except in South-Africa) and no comprehensive overview on clinical trials in Africa is available.

- **Patents**

Due to the lack of information on patent status and registration at national level drug distribution and access is difficult. Patent offices are often working on paper basis and applying non-harmonised rules.

4. RECOMMENDATIONS

- (*Data gaps*) Identify real needs also beyond the three big diseases and reflect whether the public health expenditure is appropriate at state and regional level

- *(Registration / regulatory)* The EU could assist to African Medicines Agencies to improve the prioritisation of the review. Registration has to have a regional approach.

- *(Financing):* EC should consider increasing its commitment, along with the World Bank and WHO flanked by innovative financing instruments like funding the R&D as donation.

- *(Pricing & incentives):* Consider a differentiated pricing system for drugs, as it is used for vaccines. It would help create incentives for the industry since public procurements drive prices down.

- *(Technology transfer [TT]*)): In order to increase access to medicines, pharmaceutical technology needs to be promoted. Ongoing work of Member States, International Organisations (WHO, UNCTAD, UNIDO, UNITAID) and other institutions (MPP, ICTSD, DNDi) should be supported. In particular initiatives to dissociate the cost of Research and Development and the prices of medicines in relation to the Global Strategy and Plan of Action on Public

Health, deserve further attention. Access-friendly licensing, such as through innovative mechanisms like the Medicines Patent Pool, should be promoted and supported. Technology transfer could be strengthened via subsidies for the industry for technology transfer. Setting up TT partnerships requires a TT friendly political/regulatory environment (rule of law, policy for enhancing investment capacity, procurement, health policy). TT needs to be related to public health objectives. There is a need to differentiate between areas, where a "business solution" via TT, local capacity building etc. possible and areas when the government needs to jump in.

- (*Sustainable supply*) Regarding local capacity building, the EU industry could play the role of a catalyst for the local industry. For the capacity building it is crucial to create a local and sustainable demand. It is important to focus on a certain number of priority medicines and try to build up the capacity for these products. The local governments need to care for delivering of conditions like predictability. An important condition for a sustainable capacity building for the local industry is the regional coordination and the co-ordination of regulation. It would be important to have a B2B exchange between EU and local industry rather than only a philanthropic approach from the EU industry. Also setting up collaborations in terms of jointly run pharmaceutical laboratories, research institutes, industrial training institutes for skilled workers on a larger scale is crucial.

- *(Public procurement)* Tenders should include supply criteria in public procurement to minimize the waste and focus on distribution criteria and not only price. Tenders should be centralized on a local or regional level to manage stocks better and select the relevant drugs. Also, to set up a local exchange of procurement specific information exchange between the African countries would be crucial. Transparency and simplicity need to be increased in the procurement process. In order to pool tenders, a list of 100-150 drugs could be drawn and shared among a limited number of centres in Africa. Yet it was underlined that national drug registrations are a source of revenue for countries so they are interested in keeping the registration at national level. The need for better diagnostics was stressed because the lack leads to inappropriate drug tenders.

- *(Formulations)*: Early collaboration between stakeholders and industry is important in order to make sure, that the product target profiles (target groups, formulation) meet the real needs. The multi-stakeholder approach in design of an R&D agenda for the neglected diseases is needed.

- *(Patents):* EPO, WIPO and the Medicines Patent Pool gave the idea of building a database with patent status and registrations in relevant countries in order to make sure a continuous exchange of patent information locally and also in order to bring this information into the global IP-network. A crucial condition therefore will be the improvement of IP information quality. It was raised the idea to set up a public information platform in order to improve the level of publicly available information.

5. PROPOSAL FOR STAKEHOLDER COOPERATION

A number of possible initiatives of stakeholder cooperation were identified:

- **Regional co-ordination of authorisations, exchange of information between patent authorities**

  Regarding public patent information (such us identification of patent holders, whether a health-related technology is patented or not) transparent and accessible data is needed as it has implications on research, development and procurement. In order to bridge the gap between the data asymmetries and territoriality, with countries for which data is critically needed being different from which countries where data is available, a working group with a co-lead by EPO and WIPO, could elaborate the concrete need and the possibilities to improve the patent information.

- **Consolidation and sustainability of distribution channels**

  There are manifold initiatives on improving the access to medicines in developing countries, often establishing distribution channels for the treatment of a certain disease. A working group could elaborate possibilities and document good practices how such distribution channels can be consolidated and maintained.

- **Enhancing of local production of essential medicines**

  A working group could focus on the different aspects of healthcare and industrial policies which are crucial for a sustainable development of local production capacities in Africa. The group could explore the opportunities for collaborations based on mutual benefits of the industry sectors with a special focus on quality standards and affordability. This working group should closely co-ordinate with the existing initiatives supported by the EU and Member States.

- **Mapping of existing partnership activities**

  A working group could be set up in order to prepare a mapping exercise involving all main stakeholders on the African-European partnerships related to access to medicines in order to avoid overlaps and maximise efficiency in a context of budgetary austerity on donors countries.

- **Mainstreaming of the focus on children's access to medicines in developing countries**

  In terms of specific treatments and medicines children in developing countries as a target group are often neglected. A working group could focus on the challenge, how access to medicines for children could be improved regarding research and development, clinical trials, formulation, etc.

6. NEXT STEPS

- The European Commission will set up two working groups in the first quarter of 2012.