EUROPEAN COMMISSION ACTIVITIES ON

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

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DG TRADE
EUROPEAN COMMISSION

INTERNATIONAL CONFERENCE
ON PATENTS AND HEALTH INNOVATION,
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- **Political and Policy Dialogue on Access to Medicines**
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- **EU legislation with flexibilities in trade, patent protection, customs and pricing**
- **EU Instruments contributing to global drug development, safety, quality and efficacy**

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

SETTING THE SCENE

Setting the Scene

Commission Communication, March 2010

- **The EU Role in Global Health**

Council Conclusions, May 2010

- **An EU vision to Global Health**
  - **strengthening comprehensive health systems in low- and middle income partner countries**
- **Universal Health Care Coverage through effective**
  - **Health workforce, access to medicines, logistics, financing and management, manufacturing and regulatory capacity**

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

EUROPEAN COMMISSION INSTRUMENTS

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

POLITICAL AND POLICY DIALOGUE ON ACCESS TO MEDICINES

International relations and health diplomacy

Ensuring a strong EU voice in access to medicine issues

- **WHO, ECOSOC, UNGA**
- **Stakeholder dialogues**

Promoting the role and engagement of European industry

- Process on Corporate Responsibility in the Field of Pharmaceuticals
- Platform on Access to Medicines in developing countries with a focus on Africa
  - **Working Group on Patent Information System**
  - **Working Group on Local Capacity Building**

Engagement with other stakeholders

- **Global Health Policy Forum**
- **Civil Society Dialogue**: Trade Instruments to Improve Access to Affordable Medicines in Developing and Least-Developed Countries
- **Cooperation with WHO**:
  - Contribution to WHO's "Report on Priority Medicines for Europe and the World"
- ***Global Partnerships***
  - GAVI Alliance
  - The global Fund to Fight AIDS, TB and Malaria

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

FINANCIAL SUPPORT TO ACCESS TO MEDICINES

Financial support to Access to Medicines

Funding North-South collaboration research projects and related capacity development actions

- **Contributing financially to global initiatives that aim at alleviating the access problem through the supply of medicines or capacity building**
- **Multi-funder initiatives**

Development of new and better medicines and optimised delivery

AMSA

IMI

EDCTP

E-RARE-2

GACD

CHEPSAA

SEVENTH FRAMEWORK PROGRAMME

MONITORING MEDICINES

IMI2

GloPID-R

REDMAL

ATP

SURE

MM4TD

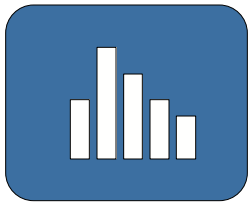
EDCTP2

PRD COLLEGE

IRDiRC

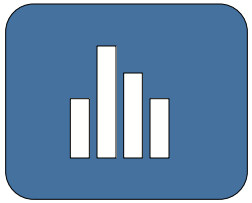
Research Funding programmes and activities

7th Framework Programme for Research and Technology Development (2007-2013)



200 Projects on
HIV / AIDS , Malaria and TB

> 456 Million Euro



65 Projects on
neglected infectious diseases

> 168 Million Euro

Research Funding programmes and activities

7th Framework Programme for Research and Technology Development (2007-2013)

A few examples:

- **AMASA – Accessing Medicines in Africa and South Asia (3 Million Euro)**
- **ATP – Access to Pharmaceuticals (1.8 Million Euro)**
- **MONITORING MEDICINES – Optimizing drug safety monitoring to enhance patient safety and achieve better health outcomes (2 Million Euro)**

Strengthening health systems and health research capacity:

- **CHEPSAA – Consortium for Health Policy and Systems Analysis in Africa**
- **SURE – Supporting the Use of Research within African Health Systems**
- **PRD COLLEGE – Poverty related diseases college**
- **REDMAL – Clinical Development of a malaria transmission blocking vaccine**

Research Funding programmes and activities

Horizon 2020 (2014-2020)

- **Topics relevant to access to medicines:**
- **E.g. Vaccine development for poverty-related and neglected infectious diseases: HIV/AIDS and TB**

Various others:

- **European and Developing Countries Clinical Trials Partnership (EDCTP)**
- **Innovative Medicines Initiative**
- **Contribution to global research initiatives:**
  - *WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*

Building capacities for research and local production

WHO Global Strategy Plan of Action on Public Health, Innovation and Intellectual Property (GSPA)

- **Joint initiatives with the WHO**

4 of 12 activities are in direct relation to access to medicines

- **Activity 1:** improving access to medicines in developing countries through technology transfer and local production
- **Activity 2:** addressing role of intellectual property in local production- opportunities and challenges
- **Activity 3:** Development of a method to measure the link between domestic production of medicines and access to medicines
- **Activity 8:** Improving access to medicines in developing countries through technology transfer and local production

Support to the strengthening of public health systems and policies

COUNTRY SUPPORT:

- **Comprehensive and coordinated support to developing countries:**
  - Development of sector strategic plans
  - Pharmaceutical strategic plans

SUPPORT TO THE DELIVERY OF SERVICE:

- **Financial contribution to global health organizations and initiatives addressing access to medicines and vaccines**
  - eg. UNFPA, WHO, UNICEF, GAVI Alliance, The Global Fund to Fight AIDS, TB and Malaria
- **EC as member of boards of these organisations: Aiding to promote and drive the policy agendas**

Specific Support to the strengthening of national ATM policies and capacities

- **EC/ACP/WHO Partnership on Pharmaceutical Policies (2004-2010)**
  - EC Key financial contributor
  - Achievements: Development of national medicines policies / review of the intellectual property legislation to protect public health / price monitoring / participation in good governance / assessment of the regulatory system.

- **Renewed EC/ACP/WHO Partnership on strengthen pharmaceutical systems and improve access to quality medicines in 15 African ACP countries (2012-2016)**
  - Aim: To contribute to the achievement of health related MDGs and of UHC in African ACP countries.

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

EU LEGISLATION WITH FLEXIBILITIES IN TRADE, PATENT PROTECTION, CUSTOMS AND PRICING

WTO, TRIPS, Doha Declaration and EU Compulsory Licensing Regulation

Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with population health needs

- **Eligible countries:**
  - LDCs
  - WTO members which have notified the Council for TRIPS of their intention to use the system as importers
  - Non-WTO members which are listed as low-income countries by the DAC and have notified the Commission of their intention to use the system as importers

Revision of the regulation concerning customs enforcement of IPR

- **Review on Council Regulation 1383/2003** on customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed those rights
- **New Council Regulation 6249/13** replaces the previous one (as of 1 January 2014)
  - Emphasis on interpreting and implementing the agreement in a manner supportive of WTO members' right to protect public health and in particular to promote access to medicines for all

Regulation on tiered pricing and trade diversion for Access to Medicines

Council Regulation 953/2003 to avoid trade diversion into the EU of certain key medicines

- **Enables pharmaceutical companies to sell essential medicines to less developed countries and prevents their re-importation**
- **Problem: External Reference Pricing (ERP)**

  Middle income countries ask for a reduced price as well

ACCESS TO MEDICINES AT THE GLOBAL LEVEL

EU INSTRUMENTS CONTRIBUTING TO GLOBAL DRUG DEVELOPMENT, SAFETY, QUALITY AND EFFICACY

Incentives for research, development and placing on the market of orphan medicinal products

Regulation 141/2000 on orphan medicinal products

- **Establishing a centralised procedure for the designation and introducing incentives for research, marketing and development of orphan medicinal products**
- **Support to the development of orphan medicines by international regulatory cooperation. (EMA, FDA, MHLW/PMDA (Japan))**
- **Development of ORPHANET. (Providing information on rare diseases, publicly accessible around the world)**

- ***Relevance for global access to medicines: Incentive for the pharmaceutical industry.***

Legislation on the quality of medicines and active pharmaceutical ingredients

Directive 2001/83/EC on the community code relating to medicinal products for human use

Directive 2003/94/EC on the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use

- **Supplemented by detailed GMP guidelines**
- **Mutual Recognition Agreements with third countries covering GMP**

→ Setting of global standards.

Legislation on falsified medicines

Directive 2011/62/EU on the community code relating to medicinal products for human use as regards the prevention of the entry into the legal supply chain of falsified medicinal products

- **Addresses also the importation of active substances into the EU**
- **It sets high standards and enhances global standards of GMP**

  → Contributes to the global access to quality and safe medicines

Legislation on clinical trials

Directive 2001/20/EC detailed by ***Directive 2005/28/EC***
on the principles and guidelines for good clinical practice as regards investigational medicinal products for human use as well as the requirements for authorization of the manufacturing or importation of such products

2014: ***Regulation on clinical trials on medicinal products for human use***

- Will replace 2001/20/EC, Expected to come into effect by 2016
- It reforms authorization procedure for clinical trials: simplified reporting, more transparency
- + Commission may conduct controls in MS other countries to make sure the rules are supervised and enforced

Regulatory harmonization

- **International Conference on Harmonisation (ICH): Efforts to expand**
- **International Pharmaceuticals Regulatory Forum**
- **Include generic medicines in the scope of ICH: International Generic Drug Pilot**

This **harmonization effort at global level shall promote access to medicines** through increased exchange of information and decreased regulatory burdens in assessing safety, quality and efficacy during approval and authorization of new products, as well as assessing generics.

Thank you for your kind attention!

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