European Commission

Access to Medicines

EU global health actions for low- and middle-income countries

Fact sheet, April 2016

The Commission has been working actively to improve access to medicines in developing countries through a health-in-all-policies approach and various initiatives, programmes and financial support.

The activities supporting access to medicines in low- and middle-income countries address various issues relating to affordability, availability, accessibility, acceptability and use, as well as safety and quality by supporting:

1) global health organisations and initiatives;
2) low- and middle-income countries' public health systems;
3) research and development (R&D) of medicines needed by low- and middle-income countries;
4) trade rules facilitating access to medicines.

Some examples of action taken in each of these areas are given below.

1. Support for global health organisations and initiatives

The EU supports global health organisations and initiatives in different forms. It provides financing to help provide quality medicines, vaccines and commodities directly to developing countries and supports the supply chain, thereby helping deliver the medicines to end users. The support is not only limited to finance. As a member of the boards of these organisations, the Commission also helps promote and drive policy, while steering the organisations towards market shaping that will benefit developing countries.

A. Commitment to the WHO's Global Strategy and Plan of Action

The Commission, in coordination with the EU Member States, works to ensure that the EU has a strong voice on access to medicine issues in international fora such as the World Health Organisation (WHO). The Commission supports the work of the WHO in drawing up lists of essential medicines and guidance on rational use, and its normative work in these areas. The Commission is also implementing the 'Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property' adopted by the World Health Assembly in 2008.

As part of its commitment to the Global Strategy, the Commission has supported the WHO in implementing four of the Strategy's eight elements. Its support focused on:

1. prioritising research and development needs with a view to identifying and supporting research into developing new, or more targeted, drugs to fight neglected diseases (EUR 2 million);
2. supporting a special WHO tropical diseases programme to help effectively scale up the role of communities in delivering essential health care as part of district-based health systems in Africa (EUR 3 million);
3. building and improving innovative capacity in Africa by establishing the African Network for Drugs and Diagnostics Innovation (EUR 5 million);
4. promoting the transfer of technology through support for local production with a view to identifying the main challenges and obstacles to the local production of pharmaceuticals, vaccines and diagnostics and the obstacles to better access to medicines (EUR 6.66 million).

A further EUR 1.5 million will be provided to build on the work of the Global Observatory on Health R&D and various innovation activities.

B. Contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria

The EU, together with its Member States, is the biggest contributor to the Global Fund, which spends USD 3.5 billion per year on controlling AIDS, tuberculosis and malaria in developing countries. The EU collectively contributes about 50 % of the Global Fund's resources, while the Commission contributes about 5 %. This amounts to EUR 370 million for 2014-2016 from the Development Cooperation Instrument and the European Development Fund. The EC has contributed around EUR 1.5 billion since 2002. The Commission has pledged a further EUR 470 million for the period 2017-2019 which represents an increase of EUR 100 million (27%) in comparison to previous years.

C. Contribution to the Global Alliance for Vaccines and Immunisation (GAVI)

The EU, together with its Member States, is also the biggest contributor to GAVI. The EU collectively (EC and Member States) has committed EUR 5.3 billion to GAVI for 2016–2020. This is 56 % of the total contributions to the organisation. The EC has pledged EUR 25 million per year over the same period (EUR 175 million overall).

GAVI brings together the public and private sectors in the shared goal of giving equal access to vaccines for children worldwide. In June 2014, the GAVI Board approved a new five-year strategy for 2016-2020 to ensure the immunisation of 300 million children in developing countries, saving 5-6 million lives in the long term. The new strategy aims to accelerate the equitable uptake and coverage of vaccines, increase the effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems and improve the sustainability of national immunisation programmes. GAVI continues to support countries in introducing new vaccines with the aim of reaching every child.

D. Contributing to global drug development, safety, quality and efficacy

Under Article 58 of Regulation (EC) No 726/2004, the European Medicine Agency can provide opinions, in cooperation with the WHO, on medicinal products for human use that are intended exclusively for markets outside the EU. As developing countries often lack the capacity to assess and pre-qualify the medicines for entry into their markets, most of them rely on the pre-qualification undertaken by the WHO, or on the assessments carried out by the EU, the US or other 'stringent' regulatory authorities. By offering this assessment, the European Medicine Agency addresses this lack of capacity in developing countries. This can help medicines reach the markets of developing countries and ensure the quality, safety and efficacy of these medicines.

Between 2012 and 2015 the European Commission's Directorate-General for Humanitarian Aid funded the establishment of the 'Quamed' consortium of medical humanitarian INGOs, led by Médecins du Monde. Quamed aims to ensure the quality of medicines provided to the beneficiaries of humanitarian assistance, particularly where local procurement is required, and to improve the procurement, storage and delivery of medicines in its humanitarian interventions. This involves assessing essential medicines in local markets, and local and international suppliers. It also includes ensuring that aid agency staff have sufficient knowledge of pharmaceutical quality assurance principles and that they understand the benefits of procuring and delivering quality medicines and act accordingly. This is combined with information sharing, including answering a hotline on the procurement of medicines.

E. UN High Level Panel on Access to Medicines

The Commission contributed to the High Level Panel on Access to Medicines established by United Nations Secretary-General Ban Ki-moon in November 2015. The Commission sent a contribution in February 2016 outlining how it addresses the access to medicines agenda with a health-in-all-policies approach and through various initiatives, programmes, and policy and financial support.[1] It also expressed its availability to work constructively with the Panel on the access to medicines debate.

2. Support for low- and middle-income countries' public health systems

The Commission provides support for the local production of medical products, for the quality assurance of essential medicines for humanitarian interventions and for the research and development of medical products. This includes strengthening local R&D capacities.

The Commission finances the 'Renewed EC/ACP/WHO Partnership to strengthen pharmaceutical systems and improve access to quality medicines in 15 African ACP countries' which will run until October 2016 and has a budget of EUR 10 million.

[1] http://www.unsgaccessmeds.org/inbox/2016/2/16/contributioneuropean-commission

The aim of the Partnership is to help achieve the health-related Millennium Development Goals and ensure universal health coverage in these 15 African ACP countries. It will do so by improving the availability, affordability and use of quality-assured essential medicines for priority acute and non-communicable diseases, thereby helping to make health care more cost-effective and ensuring better patient health outcomes. This will be achieved by developing and implementing relevant medicine policies, developing and enforcing regulations, adopting best practices and strengthening the pharmaceutical systems and capacity of the countries concerned.

The Partnership is expected to:

- improve the availability and supply of essential medicines in health facilities in African ACP countries;
- lower the prices of medicinal products and improve mechanisms for financing and for covering essential medicines in social protection schemes;
- improve the quality and safety of medicines and reduce the occurrence of substandard medicines and of medicines that pose health risks;
- improve the range of medicines and how they are prescribed, dispensed and used;
- improve access to reliable information on the pharmaceutical sector and the pharmaceutical policy of the countries concerned;
- review evidence-based national medicine policies and plans;
- increase transparency and good governance in the pharmaceutical sector.

3. Support for R&D of medicines needed by low- and middle-income countries

The Commission has a strong track record in funding health R&D projects. This is helping to improve access to medicines in low- and middle-income countries. More recently, the Commission has been increasingly engaged in larger-scale, multi-funder partnerships to coordinate funding priorities with other public and private funders and to raise a critical mass of resources and expertise.

The Commission is currently the world's third largest public funder of R&D for new and better medicines to combat poverty-related and neglected infectious diseases. Under FP7, the EU's 7th Framework Programme for Research (2007-2013), the Commission committed a total of EUR 905 million to global health R&D. Of this, EUR 461 million was earmarked for the three major poverty-related diseases HIV/AIDS, tuberculosis and malaria; EUR 168 million for neglected infectious diseases; and EUR 276 million for maternal reproductive and child health. The Commission also committed around EUR 75 million directly to low- and middle-income countries: EUR 50 million for R&D on poverty-related diseases (HIV/AIDS, tuberculosis, malaria) and maternal and child health; and around EUR 5 million for R&D on neglected infectious diseases.

In the first two years of Horizon 2020, the EU's current R&D programme (2014-2020), the Commission released EUR 365 million for R&D on neglected diseases through different funding mechanisms. This is broken down as follows:

- EUR 108 million on collaborative R&D grants: HIV/AIDS (EUR EUR45 million), tuberculosis (EUR 26 million), Ebola (EUR 24 million); other grants (EUR 13 million);
- EUR 40 million on European Research Council grants and Marie Slodowska-Curie fellowships;
- EUR 8 million on SME-specific grants;
- EUR 85 million to the second European and Developing Countries Clinical Trials Partnership (EDCTP2) programme with sub-Saharan Africa;
- EUR 114 million to the Innovative Medicines Initiative (IMI2) programme to address Ebola;
- EUR 10 million to the InnovFin Infectious Diseases (InnovFin ID) pilot initiative for the first two of its new loans.

In 2014, the Commission awarded the first Horizon 2020 Challenge Prize on Global Health Innovation to the German university spin-off company CureVac GmbH. The prize of EUR 1 million honoured a ground-breaking innovation for the development of thermostable vaccines. The prize winner then received follow-on funding of EUR 46 million (USD 52 million) from the Bill and Melinda Gates Foundation to further develop this vaccine technology.

The Commission has also organised two ongoing contests:

- the AMR prize of EUR 1 million to reward the development of a rapid diagnostic test which tells whether a patient needs to be treated with antibiotics or not; and
- the Birth Day Prize, worth EUR 1 million each from the EC and the Bill and Melinda Gates Foundation, for a breakthrough solution aimed at reducing maternal and new-born mortality in low and middle-income countries.

Ebola: rapid R&D in response to global health emergencies:[2] After a worldwide emergency was declared in August 2014, the Commission quickly mobilised EUR 24.4 million in September 2014 from Horizon 2020, its research and innovation programme, via an exceptional procedure. Work on the funded projects began as early as 1 November 2014. In addition, EUR 200 million in EU funding for Ebola and related viruses was mobilised by the Innovative Medicines Initiative (IMI), Europe's largest public-private initiative between the European Commission and the pharmaceutical industry. The aim of the IMI is to speed up the development of better and safer medicines for patients in Europe. Work on the projects began as early as in January 2015.

Global Research Collaboration for Infectious Disease Preparedness (GloPID-R): The recent Ebola outbreak has also clearly demonstrated the urgent need for and the usefulness of global coordination of R&D activities funded from different international sources. In 2013, the Commission founded GloPID-R, a network of research funders at global level that aims to facilitate a coordinated R&D response within 48 hours of a significant epidemic outbreak. GloPID-R today has 23 funders from Australia,

[2] http://ec.europa.eu/research/health/index.cfm?pg=area&areaname=ebola

Argentina, Brazil, Canada, France, Germany, India, Italy, Japan, Mexico, Norway, South Korea, South Africa, Spain, Thailand, the USA, as well as the Wellcome Trust, the Bill & Melinda Gates Foundation and the African Academy of Sciences. For more information see www.glopid-r.org

European and Developing Countries Clinical Trials Partnership (EDCTP): In 2003 the EU initiated the EDCTP to accelerate clinical R&D and testing of new or improved drugs, vaccines, microbicides and diagnostics against neglected and poverty-related diseases in sub-Saharan Africa. For the next 10 years, the Partnership received a pledge of over EUR 2 billion, with nearly EUR 700 million from the EU for the EDCTP2 programme. The Partnership is a good and proven financing and coordination mechanism and it may serve as a global partnership model to address market failure and promote access to medicines for neglected diseases. It also builds up regional R&D capacity and infrastructure and strengthens national health systems in sub-Saharan Africa. The EDCTP was established as an association tasked with implementing the EDCTP2 programme (2014-2024).14 African and 14 European countries are full members and are represented in the EDCTP General Assembly with equal voting rights. See www.edctp.org

InnovFin Infectious Diseases (InnovFin ID): The European Investment Bank and the European Commission created the InnovFin ID financial instrument to incentivise investment in R&D for uncertain markets such as the one for infectious diseases. InnovFin ID aims to promote the development of novel interventions against infectious diseases by providing investments at the pre-commercial stage and by attracting co-investment from other investors. It operates via risk-sharing loans of between EUR 7.5 million and EUR 75 million which are repaid depending on the project's success. The projects and/or the IP development (such as clinical trials) can be undertaken outside the EU. A first EUR 10 million long-term loan was provided in June 2015 to the Swedish biotech company Cavidi AB for developing a next-generation automated testing device for HIV viral load. In January 2016 a second loan of EUR 20 million was granted to a French biopharmaceutical MidCap (Transgene) for the clinical development of their candidate immunotherapies (based on viral vector technology) for chronic hepatitis B, HPV-induced cancers and tuberculosis. More information can be found at http://www.cavidi.se/cavidi-newsroom/#.

Global Alliance on Chronic Diseases (GACD): The goal of the GACD is to tackle chronic non-communicable diseases (NCDs) in low and middle-income countries by systematically building the evidence base for sound policymaking, as guided by global experts on NCDs. GACD is currently made up of ten major health R&D funders from nine countries, and the Commission. New members who share the GACD's vision are encouraged to join and participate in funding chronic disease research. So far, GACD members have launched calls on hypertension (2010), type II diabetes (2013), lung diseases (2014) and mental health (2016).

As an example, the GACD's second ambitious joint programme on type II diabetes committed over USD 30 million to funding implementation and intervention research in low- and middle-income countries and vulnerable populations in high-income countries. In order to maximise the impact of the joint call, research teams applying for funding consisted of researchers from low- and middle-income countries and high-income

countries. The emphasis of this initiative was on existing approaches to prevention and control of type II diabetes rather than developing new treatments. The GACD is addressing the significant knowledge gap between innovations in health and the interventions that research has shown to be effective and how these can be delivered to communities and applied in practice. More information is available at www.gacd.org.

4. Trade rules facilitating access to medicines

The EU has eliminated tariffs for medicines because they act as a tax and make the medicines more expensive. It hereby implemented the Pharmaceutical Tariff Elimination Agreement to reduce to zero its WTO binding of duties on certain pharmaceutical products, including active ingredients and intermediate products.

The EU supported for permanently exempting least developed countries from obligations to provide pharmaceutical patents to give them legal certainty to procure or produce generic medicines.[3] A first step was the November 2015 World Trade Organisation Decision to exempt them until 2033.[4]

The EU also supported the November 2001 Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health.[5]

The Doha Declaration highlights that TRIPS does not and should not prevent WTO Members from taking measures, including compulsory licences, to protect public health. In its trade agreements the EU proposes to refer to the need to make provisions dealing with intellectual property compatible with the Doha Declaration.

To ensure WTO Members can issue compulsory licenses for the manufacture of generic medicines for export to countries facing serious public health problems, on 30 August 2003 the WTO General Council adopted a Decision that allows WTO Members to export patented medicines to countries with no manufacturing capacity in the pharmaceutical sector, by making use of compulsory licences.

The EU adopted a Regulation to allow the export of patented medicines under compulsory licences to countries with no manufacturing capacity.[6] As early as 2007 it accepted the Protocol to amend TRIPS to make the system permanent and legally binding. The EU encourages and offers assistance to other WTO Members to accept the Protocol so it can enter into force.

[3] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2015.271.01.0033.01.ENG
[4] https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm
[5] A WTO factsheet outlining all rules is available at: https://www.wto.org/englis/tratop_e/trips_e/factsheet_pharm02_e.htm
[6] Regulation (EC) No 816/2006 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00010007.pdf

The EU adopted a Regulation encouraging companies to sell medicines at lower, tiered prices in poor countries.[7] The Regulation was part of a 2001 EU strategy to boost measures aimed at tackling HIV/AIDS, malaria and tuberculosis in the drive to reduce poverty. It addresses a specific issue as part of the wider strategy. It aims to encourage producers to supply medicines in developing countries at heavily reduced prices by ensuring that the medicines would not be diverted back into the EU.

[7] Council Regulation (EC) No 953/2003 to avoid trade diversion into the European Union of certain key medicines. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al21166