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on improving access to basic health systems, notably to medicines for infectious diseases

Committee on Social Affairs and the Environment

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Background:

Science and technology have immense potential for advancements in medicine and healthcare, and yet we face serious challenges in the form of gaps and failures in addressing existing disease burdens and re-emerging infectious diseases in many countries and communities.

People often do not receive the healthcare they need as a result of multifaceted, interrelated problems caused by failures in basic healthcare, in turn caused by a number of different factors, such as:

- Poverty and basic health education;
- General infrastructure (access to drinking water, electricity, roads, etc.);
- Healthcare facility networks;
- Medical personnel (doctors, nurses);
- Availability of medicines and equipment;
- Regulatory barriers;
- Lack of access to health insurance;
- Social exclusion;
- Stigma;
- Discrimination and exclusive marketing rights.

Furthermore, investment in research and development (R&D) in the area of health technologies fails properly to address a number of important public health needs linked to resource availability in developing countries, in particular as regards the neglected tropical diseases (NTDs). This is due primarily to the relatively low purchasing power of people disproportionately affected by such conditions.

Analysis:

The quality of public health is determined to a large degree by the underlying conditions in which people live. Drinking water, food and shelter are the necessary preconditions for healthy living that medical treatment cannot replace, only complement.

The proliferation of free trade agreements (FTAs) containing expansive patent and test data protections on health technologies, which exceed the minimum standards for intellectual property protection required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), may impede access to health technologies. Political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violates the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement, as reaffirmed by the Doha Declaration. This pressure undermines the legitimate efforts of states to meet their human rights and public health responsibilities and obligations.

Global public health research is hampered by the fact that universities and public research institutions are allowed to patent the results of publicly funded research and license private enterprises to develop them. This limitation of access to academic discoveries can obstruct the development of medical innovations and force taxpayers to pay twice for the benefits of research funded by public budgets.

While its research is largely funded publicly, the biomedical industry recovers the costs of its R&D and marketing by charging high prices protected by patent monopolies and data and market exclusivities. As a result, new health technologies and medicines are rarely developed to treat public health conditions, such as bacterial infections, the 18 parasitic and related infections that constitute the NTDs, and other poverty-related neglected diseases (PRNDs), since they cannot deliver high returns.

Governments, civil society and the private sector are taking various steps to resolve the incoherence between the market-driven approach and public health needs. However, the measures taken tend to be fragmented, disparate and insufficient to deal with priority health needs on a sustainable, long-term basis.

Furthermore, a methodological issue has arisen: the thresholds used to allocate official development assistance (ODA) according to the gross national income of countries have an adverse effect on over 70% of the world's poor living in the 105 countries classified as middle-income. A new analysis entitled 'Blue Marble Health' reveals that the majority of cases of NTDs and PRNDs occur among poor people living in the G20 economies and Nigeria[1]. This includes Southern Europe, where there has been a sharp rise in NTDs and PRNDs[2]. Current efforts by donors to change the modalities and channels of assistance to countries in this bracket could see the health needs of people living in these countries deprioritised with national health expenditure unable to replace external support.

The European Union is a major contributor to health-related aid. However, development policy coherence between health-related EU development goals and trade policies is sometimes lacking. The Commission's aid packages have often included intellectual property protection clauses that have hampered or downgraded access to medicines. While health-related aid from the EU can provide substantial benefits for public health systems and capacity building around the world, high medicine prices can limit the benefits that such assistance may bring.

On the other hand, the African, Caribbean and Pacific Group of States (ACP countries) often fail to regard public health and access to affordable and suitable medicines as priorities in their national development plans. Domestic health care funding is not high enough to set up and maintain necessary healthcare infrastructure. The lack of affordable medicines is the result of a combination of local health systems unequipped to produce generic drugs and insufficient safeguards of the fair pricing of medicines.

The way forward

The abovementioned lack of investment by pharmaceutical companies into R&D for poverty-related and neglected diseases necessitates increased public support and financing. Sustainable financing for R&D is urgently required, both to make up existing shortfalls and to stimulate future innovation in the public interest. These funds could be channelled towards major product development partnerships (PDPs) and their academic partners. They could include partners in developing countries and European and North American organisations, of

[1] https://jhupbooks.press.jhu.edu/content/blue-marble-health
[2] Hotez PJ (2016) Southern Europe's Coming Plagues: Vector-Borne Neglected Tropical Diseases. PLoS Negl Trop Dis 10(6): e0004243.

which the latter are not ordinarily eligible for EU support.

Beyond R&D, the strengthening of health systems should be focused on both low-income countries and areas of poverty within middle-income and the Blue Marble Health G20 nations. Through its 'Agenda for Change', the EU has committed to supporting social inclusion and human development, including health, by allocating at least 20% of all EU development assistance to those fields. The 20% commitment to basic social services under the Development Cooperation Instrument (DCI) Regulation should be monitored during the DCI and Multiannual Financial Framework mid-term reviews to ensure that it is kept. Investments in key global initiatives such as the Global Alliance for Vaccines and Immunisations (GAVI) and the Global Fund to Fight AIDS, Tuberculosis and Malaria should be scaled up. Health should always be included among ACP countries' priority sectors. The structured participation of civil society in the dialogue on global health financing should be encouraged.

Horizon 2020, the EU's current Framework Programme for Research and Innovation for the years 2014-2020 (EUR 77 028 billion), allocates EUR 7 472 billion to the 'Health, demographic change and wellbeing' challenge, which, among other initiatives, will fund global health R&D. The Commission publishes a work programme every two years, which outlines specific calls for proposals for Horizon 2020. A major initiative for global health R&D under Horizon 2020 is the extension of the European and Developing Countries Clinical Trials Partnership (EDCTP), a partnership between the EU, some of its Member States and countries in sub-Saharan Africa (SSA), to support clinical research and trials covering HIV/AIDS, tuberculosis, malaria and other poverty-related and neglected diseases disproportionally affecting SSA. The Commission will contribute up to EUR 683 million to this initiative to match cash and in-kind contributions from Member States. The Innovative Medicines Initiative (IMI) has also been extended under Horizon 2020. This public-private partnership between the Commission and the pharmaceutical industry aims to finance pre-competitive pharmaceutical research and development. Although the Commission has made the largest contribution to the IMI's EUR 3 billion budget, priority setting is sometimes driven by private actors, in addition to the Commission itself. While the industry makes choices based on future markets and profit opportunities, addressing existing public health needs both at EU level and globally requires enhanced EU political leadership and steering. The same applies to the EDCTP: despite being publicly financed by the EU, the Partnership retains no ownership or say over the intellectual property generated in its programmes and does not do enough to ensure that all products that have benefited from this public funding during crucial stages of the development process are either accessible or affordable.

The Commission should therefore ensure openness and transparency in the management of the EDCTP and the IMI, and introduce access and affordability conditions to ensure the accessibility of products that have been developed using public resources.

In the midst of Europe's economic and financial crisis, EU donors are struggling to meet commitments and globally agreed targets for poverty reduction and global health, most notably the 0.7 % ODA/GNI target and the allocation of 20% of EU ODA to social inclusion and human development. Although innovative financing mechanisms cannot replace traditional development aid, they can complement it by ensuring a greater amount of resources are invested in global public goods.

Policy Coherence for Development (PCD) is firmly enshrined as an EU international cooperation principle. It means that EU policies should not harm development and individual rights, but should instead contribute to achieving the agreed development objectives. In this regard, it is important to:

- Apply the PCD coherently in legislative and policy-making issues that affect global health in developing countries;
- Ensure that intellectual property, investment and other chapters in FTAs do not include measures beyond TRIPS nor measures that limit governments' policy space to protect public health and ensure access to medicines.

Putting in place an effective mechanism to monitor and control the prices of medicines, which are often artificially inflated by up to thousand times, is extremely important. Either price control or competition law should be considered as possible solutions. In this connection, the pharmaceutical industry should disclose the real costs it has incurred in developing new substances by disaggregating R&D data. A much greater effort should be made to supplement the existing market-driven system by investing in new funding mechanisms and innovation models that delink the costs of R&D from the end prices of health technologies.

Finally, a global effort to address public health priorities is necessary to ensure the efficient distribution of scarce health resources, substantially improve the health status of populations and enhance global preparedness for future health crises. Greater and more sustainable financial commitments are required from both the public and private sector and should be coordinated to achieve maximum utility and effect.