EU actions on Access To medicines

- an MSF perspective

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ACCESS CAMPAIGN
MEDECINS SANS FRONTIERES

Médecins Sans Frontières (MSF)

- MSF is an international medical humanitarian organisation which provides impartial medical assistance to those affected by armed conflict, epidemics, natural disasters, or exclusion from health care.

- Today, MSF carries out this work in 70 countries worldwide, while also using our voice to raise awareness on neglected crises and advocating for improved medical care, tools and protocols.

Where can EU actions have the biggest impact on improving access to medicines?

- R&D: ensuring *affordability* and *suitability*
- Quality standards
- Ensuring policy coherence trade and development policies
- Tiered pricing
- GAVI cooperation

EU funding for global health R&D:

- The EU R&D funding should be needs driven and seek to fund areas of research where industry does not invest/under-invest - this is where added value of public funding is the greatest.

- Public funding should be preferential in its support to development of drugs, vaccines and diagnostics that will be both suitable and affordable.

    - Ex: vaccines free of cold chain, fixed dose combination treatments, shorter treatments with less side effects, point of care diagnostics

Affordability: Public funding and IP

- Opening up publicly funded R&D: MSF welcomes the open access requirements for scientific publications in Horizon 2020 and the new EMA policy to proactively publish clinical study reports supported by the new Clinical trials regulation.

- More ambition needed: Where public money has partly or fully funded the research, affordability of end products should be assured (this is not the case for EDCTP2 or IMI2)

- EU funded research for global health should ensure generic competition upon marketing approval, production guarantees, and registration requirement of drugs for endemic countries.

Policy coherence between trade, customs and development policies

- The EU should stop pushing developing countries to accept TRIPS+ measures in bilateral trade agreements
  - This is the one single policy that undermines almost *all other positive measures* by limiting partner countries ability to make use of trips flexibilities to meet public health needs
- The EU should improve investments in partner countries that ensure oversight of the quality, safety and efficacy of medicines.
  - not use IP enforcement by customs authorities on goods in transit as a way to address quality and safety concerns -> disrupts the supply flow of legitimate generics.

Tiered pricing not the solution

- Competition should be the default option for achieving affordability - it has proven to be superior to tiered pricing for reliably achieving the lowest sustainable prices.

- Tiered pricing is a commercial strategy based on how much a market is able to pay (often based on the high-income segment). Starting point is not ensuring access to medicines for all.

- The tiered pricing regulation

- The EU should work against further integration of tiered pricing policies - both in EU legislation and in international organisations such as GAVI and the Global Fund.

EU cooperation with GAVI

- GAVI graduating countries: need for better graduation plan (losing subsidies and access to GAVI prices)

- GAVI's eligibility criteria: needs a major overhaul and needs to be more public health determined/driven (28 countries have never been eligible for GAVI support have a GNI that is lower than the higher GNI graduating countries).

Promoting the role and engagement of European industry

- The EU should incentivise harmonisation across member states of quality standards of medicines produced in the EU and meant for export outside the EU to low resource countries in order to avoid double standard policies

Specific support to the strengthening of national ATM policies and capacities

- Outcomes of European Medicines Agencies regulatory assessments should be made more broadly available
- Should develop a similar system to the collaborative registration project of WHO Prequalification Programme (fast track registration in 90 days of WHO prequalified medicines, without jeopardising confidentiality agreements with manufacturers)
- Current access to certain parts of the Common Technical Documents is too limited as a form of cooperation.

Recommendations

- R&D: Not just a question about more money, but money better spent - no more blank checks! We need conditions to better guide and ensure suitable and affordable drugs, vaccines and diagnostics

- Ensure that EU trade policies doesn't undermine its other ATM policies and efforts - developing countries should not be forced to accept TRIPS+ provisions

- Tiered pricing does not ensure access for all - it is simply a way of maximising profits in different markets leaving big populations in MICs behind.

- EU should push for better graduation plans for GAVI graduating countries.

Recommendations

- The EU Should develop a similar system to the collaborative registration project of WHO Prequalification Programme

- And put in place incentives for harmonisation of quality standards of medicines produced in the EU for export.

Thank you!