

Global Health Policy Forum , 28 June 2012

Rue de la Science 15/NYERERE, 1049 Brussels.

- Summary of Discussions –

Executive summary and key recommendations:

On 28 June, 37 stakeholders from Civil Society, the pharmaceutical industry, academia, WHO with the participation of Marie-Paule Kieny, assistant DG, and different Commission DGs participated in the quarterly Global Health Policy Forum chaired by DEVCO D4 (see participants list annexed).

Under the heading "R&D and Global Health", the aim was to debate on the recommendations from the Consultative Expert Working Group on R&D (CEWG) report in the context of the resolution of the last World Health Assembly and to jointly explore opportunities for rapid follow-up action. To ensure internal policy coherence, the Commission was represented by different DEVCO units, DG SANCO as well as DG RTD in the panel.

During the debate on presentations made by four experts on the topic, participants recognized the importance of the CEWG recommendations for global health R&D and called for concrete steps in order to implement them – notably by looking at opportunities in the context of the current decision-making process around Horizon 2020.

In general, participants recommended that instead of putting too much weight to the question on whether we need a binding or non-binding instrument, one should rather look at concrete steps that can already be made to take existing recommendations forward, such as, for example:

- The set up of a Global health R&D observatory, with two key functions: to collect fragmented information and data and to bring WHO back as a leading organisation in the process. Also: collect best-practices on de-linking prices of medicine from research costs.
- The adoption of new sustainable financing proposals for global health R&D, for example through a Financial Transaction Tax. Ensure that upfront public financing for R&D is available in order to make delinking from the prices of products possible.
- Higher priority needs to be given to R&D on neglected diseases within Horizon 2020 and the EDCTP – a compromise should and can be found between EU market interests and developing country needs, eg through promoting private-public partnerships.
- Delinking prices of medicines from R&D costs: Lessons learnt from successful Product Development Partnerships (PDPs) should be taken into account.
- The 0.01% of GDP target should be part of global social protection system to correct "market failures".
- Promoting a truly open innovation model based on more systematic and efficient information-sharing by all stakeholders, including the pharmaceutical industry.
- R&D priorities should be set and co-financed by disease-endemic countries, in line with Busan principles and the "beyond aid" agenda.
- On the donor side, EU should play leading role in taking forward CEWG recommendations. EU Member states and developed countries in general should avoid where possible slowing down a process where developing countries have shown good will for progress and for taking the lead.

- Many different sectors need to be involved in CEWG report implementation, both at global and country level – eg. cross-ministry collaboration, private sector and civil society involvement etc. Next opportunity for involvement in process: Open consultations in the context of this year's WHO EURO Regional Committee in Malta (10-13 September).
- Public sensitization efforts are needed to increase public pressure and demand from a wider audience for more funding for R&D on neglected diseases. Also: support Commissioner Piebalgs' proposal on funding for development assistance.

Next GHPF:

- **20 September 2012:** Follow-up of consultation process in view of Programme for Action on global health.
- **6 December 2012:** Private Sector involvement in healthcare delivery.

Full report:

1) Update on general issues and introduction by the present European Commission DGs

SANCO:

- May-Nov: Follow-up discussions around WHA resolution options.
- The CEWG resolution was the most difficult issue on this year's WHA agenda

Save The Children (STC - Frazer Goodwin):

- Would be good to get an update on European Commission planned Global Health Programme for Action
- Please include Frazer Goodwin in participants' list.

Walter Seidel (DEVCO D4):

- Decision on which shape the Programme of Action on global Health 2013 will take is still pending – DEVCO aims at a Communication, but to be confirmed.

2) CEWG report and WHA resolution: Presentations¹ and comments from participants:

- 1. PRESENTATION - WHO (ZAFAR MIRZA: COORDINATOR; DEPARTMENT OF PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY, INNOVATION, INFORMATION, EVIDENCE WHO): IN THE HYPOTHESIS OF A LONG PERIOD BEFORE AGREEMENTS ON THE RECOMMENDATIONS OF THE REPORT COULD BE APPROVED AND ENDORSED, HOW WOULD YOU CONSIDER AND PRIORITIZE THE OPTIONS PROPOSED IN THE REPORT TO DISSOCIATE THE COST OF R&D AND THE PRICE OF MEDICINES AND THE MECHANISMS TO COORDINATE THE GLOBAL RESEARCH STRATEGY?***
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Interventions/ comments from participants on presentation:

Eric Sattin (DEVCO D4):

- CEWG Report in line with Global Health Communication 2010 recommendations
- Delinking costs of R&D from costs of medicines = key concern
- Mechanisms to coordinate Global research strategy are needed.

¹ To see content of presentations, please refer to annexes.

- Recommendation from CEWG report on 0.01% of GDP to be allocated to research is an independent recommendation – majority of this funding is supposed to be managed by the same countries that allocates it – from national budgets.

Institute for Tropical Medicine Antwerp:

- Rather than identifying the problem as a market failure, should we not see it as a social protection failure?
- The 0.01% of GDP target: should be part of global social protection system to correct market failures.

Barcelona Institute for Global health:

- It was mentioned during the presentation that open knowledge is not the same as open innovation – could we elaborate on that point?
- Recommendation to use part of 0.01% for pooled mechanism² - 20-50% is rather large – why?
- Why are decisions on this being postponed – what is the position of EU here?

International Partnership for Microbicides (IPM) :

- Pooled funding mechanism: how would they work and who would manage them?

STC:

- How are the 10:90 gap and the identified national burden of disease taken into account?
- 0.01% is the equivalent of 10% of health ODA – this is quite a large part of health ODA. Does that match the national burden of disease figures?

Health Action International (HAI)

- Have there been any concrete proposals yet on the way forward?
- Horizon 2020 is a great opportunity – new innovation models being discussed – voted by EP.

WHO speaker – answers to interventions made by participants (above):

- Market failure is the terminology used – little point in questioning it.
- Importance of increasing opportunities for health financing.
- "Open Knowledge Innovation" has new dimension compared to the already known "open knowledge": Openness and sharing of research, incl. (to the extent possible) IP-protected research.
- 20-50% of 0.01% allocated to pooled mechanism is a recommendation from the CEWG group – up to Member States (MS) to see whether to take on this recommendation.
- On the burden of disease question: the linkage with national burden of disease is made in the report.
- It is worth noting that 1 billion people are affected from neglected tropical diseases type III only. This number becomes even larger if type II and I are included.
- Pooled funding: MS are going to discuss who will run it and how.

² CEWG Report recommendation: "A financing mechanism should be established based on contributions by governments. The convention may determine a level of contribution, taking account of countries' own investments in relevant R&D, either domestically or in other countries. We have suggested a contribution of 20-50% of their total funding obligation to a pooled funding mechanism." http://www.who.int/phi/CEWG_Report_5_April_2012.pdf

SANCO:

- The way forward: One of the conclusions of the broad stakeholder discussions held for the elaboration of the report was that more time was needed for wider consultations with relevant stakeholders – including from the private sector - before getting more concrete and having a binding treaty: Notably the US and China pledged for more time, Latin America was divided and Kenya withdrew its initial proposal for a binding treaty. So: in the end, it was a process resolution.
- That said, many concrete things could already been done now on the basis of the preliminary recommendations, whereas coming to an agreement on a binding treaty usually takes time.

RTD:

- Increasing R&D costs also affects developed countries and “their” diseases. We need to look internally at tendencies within European research here as well.
- Provisions already exists on data openness, implying that it should, in principle (by default), be published – unless there are very good reasons for withholding it (justifications).

2. Presentation - Albrecht Jahn (Member of the Consultative Expert Working Group on R&D: Financing and Research; Professor for public Health at the institute of Public Health, University of Heidelberg): How do you see the interaction between a Global framework for R&D and the many existing and very diverse initiatives to support developing countries' health needs?

Additional or complementing notes on the presentation:

- For incentivizing R&D on poverty-related and neglected diseases, upfront public financing is needed in order to replace rewards linked to prices of medicines.
- Interestingly, the US is already exceeding suggested threshold of 0.01%– US reluctance on treaty is hence not motivated by financial reasons / considerations – other considerations.
- Equally, there is only a small increase needed from EU side, on its current funding, to meet the target.
- pooled funding mechanisms already exist; EDCTP f. Ex.
- EU funded EuropeAid Actions initiated by the European Parliament complement DG Research funding.
- EDCTP: has an open innovation policy
- However, within Horizon 2020, there appears to be a low priority given to the global health priorities as identified in the Council Conclusions on the EU role in Global Health (2010).
- FP7: provided more reference to the CEWG agenda than Horizon 2020.
- Already existing, ongoing initiatives: Unitaid patent pools, airfare taxes etc.
- However, in the long run, reliable collective financing mechanism are needed.
- One should not overrate the question of a binding or non-binding instrument: even a binding treaty is soft-law.

Interventions/ comments from participants on presentation:

DNDI:

- How is affordability ensured?

MsF:

- Proposals are not new.
- EC should explain where further reflection is needed.

Henning:

- Any comments from RTD on Horizon 2020 and opportunities for implementation of recommendations?

WHO:

- This is a global responsibility including from Developing countries.
- Asian economy is booming and the report pushes to go beyond aid – so these countries need more time to find their own financing.
- Market failure issue: limits of social welfare system, even in developed countries.

HAI:

- Horizon 2020 reflects further efforts made by EU – eg. as reflected by rules for participation and regulation of the framework.
- Open access to scientific data in Horizon 2020: this is very new. Exploitation of research results – door opened in a way it was never done before.
- Access to clinical trial data is also a good step forward. However, Clinical trial directive of the EU is pending and EU refuses currently to share information on this.

Albrecht - answers:

- Affordability by EDCTP: I do not think we have a test-case yet for that
- Horizon 2020 (H2020): 2 key elements :
 - o Thematic areas are not yet visible in H2020 document. EDCTP is part of it though.
 - o Issue of joint priority setting – Busan “partnership”. Priorities should be set by disease-endemic countries – should be in the driving seat.
- Not re-inventing the wheel but organizing existing ideas was our mandate.

SANCO:

- WHA: EU MS felt they needed more time before deciding on the various CEWG proposals.

RTD:

- Horizon 2020: suggested increase in budget from FP7 – from 50 to 80 billion EUR.
- Reflects importance of investing in this area.
- First step is to secure this budget – pressure on finance ministers from MS countries is needed.
- H2020 Proposal as it stands now is only general outline for our R&D policy.
- True that there is not much mentioning in the proposal of neglected diseases, maternal health – also NCDs are not specifically mentioned either.

- Nevertheless, EDCTP II is mentioned – under which communicable diseases are addressed – so global health even more prominent than NCDs in the document.

3. Presentation - Brendan Barnes (European Federation of the Pharmaceutical Industries and Associations) *From the pharmaceutical industry perspective what are the most promising models that dissociate the cost of R&D and the prices of medicines and how do you think the models could articulate between themselves?*

Interventions/ comments from participants on presentation:

Institute Barcelona

- Traditionally, R&D cost estimations established by the industry have at times been exaggerated and highly put into doubt by experts (eg. advanced market commitments report)
- Consequence: Some mechanisms might be overpaying R&D costs – higher than real expenditures.
- So, is industry open for sharing real costs with the international community?

IPM:

- Horizon2020: will it also address needs in developing countries, rather than only market needs in Europe, ensuring policy coherence with previous EU global health research commitments?
- Integrated approach to product development, from basic research to market introduction not addressed yet under draft Horizon2020.

Answers to interventions:

Industry:

- R&D costs estimation is still quite a complex exercise, even for industry itself.
- Need for governments to ensure themselves about value for money.
- IMI: we have to declare what we input and EC needs to be comfortable with that.
- For CEWG to fly, geographic and thematic focus important.
- When you eliminate profits on medicines, you gain about 2%. The health systems funding crisis has deeper roots than that.
- Health systems are not ready to absorb some of the costs for innovative research, such as patient-targeted treatment schemes. EU capacity to absorb these innovations?

RTD:

- H2020 is the world's largest public funding mechanism for research
- H2020 not a health nor development research instrument, so there has to be a compromise on how detailed it can be - also needs to address: EU industry and its competitiveness.
- Public-private partnerships is one possible compromise.

4. Presentation - DNDi/HAI (Pascale Boulet, Drugs for Neglected Diseases initiative (DNDi) and Tessel Mellema, Health Action International (HAI) Europe): *How do you see the operationalisation of the recommendations of the report, in a short and medium term perspective.*

Additional notes on presentation:

- PDPs are funded by both public and private financing.
- DNDI position paper was developed, but we did not participate in consultation on CEWG.
- CEWG report addresses 2 key issues of importance:
 - o Sustainability
 - o GLOBAL Public responsibility
- It is puzzling that developed countries, as opposed to developing countries, were slowing the process, despite good will from developing countries to take co-responsibility.
- Delinking: PDPs are doing this. Target product profile: maximum cost based on capacity of government and population to pay – otherwise model is not considered sustainable.
- Non-exclusivity of data also foreseen for very neglected diseases.
- Final product costs should be as close as possible to product development costs.
- Cost of R&D presented in competitive environment very different from figures from non-competitive environment. Eg. DNDI: EUR 400 million allows for up to 13 new treatments by 2018.
- 3 types of measures recommended to take forward – taken from report and GH Council conclusions:
 - o Global health R&D observatory should be set up quickly under WHO – should look at best-practices on de-linking.
 - o New sustainable financing proposals are needed. Following adoption by EP of FTT – portion of that tax would go into global health and of that, into R&D.
 - o Open innovation model: make this sharing more systematic and efficient.
- EU should play leading role in the process.

Interventions/ comments from participants on presentation:

Institute for Tropical Medicine:

- Let's assume there is an extra EUR 1 billion Developing fund for R&D – could that be managed by DNDI?

Institute Barcelona:

- 11% of capital costs as estimation for R&D investment is considered very high.

DNDI - answers:

- We are non-profit so no need to establish levels of capital costs. We use different financing costs.
- EUR 1 billion additional funding does not seem to be enough. Annual 6 billion recommended by CEWG.
- DNDI does not cover all health needs and topics. Wider, more global coordination mechanism needed to for management of all diseases.
- Core lessons learnt from PDPs should be taken into account:
 - o Coordination of R&D with involvement of developing countries.
 - o Open innovation models
 - o Regulatory framework: global regulatory framework and harmonized requirements would help and facilitate R&D.

TB partnership:

- Capital is an important source – how can we blend sources?

WHO:

- CEWG: Regulatory frameworks are important, but not an incentive.
- Universal Coverage very important as underlying concept.

MSF:

- Consultation of EU: will it be broader and widened to more representative public? What will be the process?
- MSF finances a large part of DNDI activities because new diagnostics are needed for MSF field work – regarding vaccines and TB for example.

Albrecht - response:

- Emerging economies should play an increasing role and take responsibility
- References to the "Beyond Aid" agenda should be made.
- Observatory: 2 functions: to collect fragmented information and data. But also: to bring WHO back as a leading organisation in the process.

SANCO - response:

- Invites stakeholders to help the European Commission on how to implement the report.
- Consultations: in context of Regional committee meeting in Autumn this year.
- 10-13 September: WHO EURO Regional Committee in Malta.

DEVCO - response:

- Many different areas / actors / sectors need to be made responsible for CEWG recommendations implementation.
- Cross-Ministry collaboration – at least Ministry of Finance + Ministry of Health – in donor countries: Ministry for Development, foreign affairs etc.
- Complexity of the proposal is as big a deterrent as the financial issues.
- Big sensitization effort needed from public pressure and demand from “non-usual” suspects – wider audience.
- How do you finance research?
- Development Commissioner submitted a much bigger proposal for Development, but it is under discussion.

List of useful documents and annexes:

- CEWG report: <http://www.who.int/phi/news/cewg_2011/en/>
- WHA resolution on the CEWG report – see annex
- EU and its Member States position at the WHA – see annex
- Speaker presentations – see annex
- GHPF Participants list - see annex