POLICY BRIEF

A Global Convention for Health R&D?

BRIEF FOR POLICY-MAKERS[1]

AN IMPORTANT DEBATE

The recently issued report[2] of the **WHO Consultative Expert Working Group (CEWG) on Research and Development: Financing and Coordination** represents an important milestone in a major international effort to address a critical gap in the development of drugs that meet the health needs of poor and neglected populations.

In collaboration with the Harvard Global Health Institute and the Institute for Health and Society at the University of Oslo, the Global Health Programme of the Graduate Institute of International and Development Studies, Geneva held a public seminar on 4 May 2012 on **"Strengthening the Global R&D System: Innovation for Health Needs in Developing Countries"**. The seminar invited preliminary responses to the CEWG findings, in the context of the discussion of the CEWG report in Committee A at the 65th World Health Assembly (WHA), 21-26 May 2012.

This policy brief aims to highlight the global significance of the CEWG report for global health and development and to contribute to a constructive and well-informed debate about its recommendations. Therefore, the main points of discussion and conclusions of the 4 May seminar, together with salient features of the background to the **question of a Global Convention for Health R&D** are outlined in this document.

THE NEED: IGNORANCE IS FATAL

"The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition".[3] but disparities in health between populations have grown dramatically in the last century and are most starkly revealed by differences in life expectancy. Until the end of the 19th century, global average life expectancy remained below about 30 years for both men and women. Subsequently, it has more than doubled, but with the largest gains in high-income countries and the poorest gains in low- and middle- income countries. The 1990 report of the Commission on Health Research for Development[4] concluded that far too little was being spent on R&D for the health needs of LMICs and on strengthening their own R&D capacities (later captured in the **'10/90 gap'** slogan).

The large disparities in life expectancy constitute a massive health inequity because they are avoidable. In a broad sense, they can be attributed to poverty, weak health systems and lack of access to safe, affordable and appropriate medicines and other health technologies. Research and Development (R&D) has played a crucial role: as analysis by economists has highlighted, much of the gains seen in life expectancy during the last 100 years have their origins in technology – i.e. the application and diffusion of the knowledge and products gained from R&D – and a **large part of the health disparities observed globally has been attributed to failures to ensure that LMIC populations benefit from technology**.[5,6] Knowledge generated by research should be seen as a global public good and it is clear that restrictions in knowledge or its application may cost lives: **ignorance is fatal**.[7]

Nobel Laureate Joseph Stiglitz giving his Keynote Address at the seminar in Geneva. He noted that global health and the production of global public goods are among key global issues where one cannot get away from thinking about global governance. In his view, the mission and challenge is clear – **can the international community come together to generate the relatively modest sum of money needed to address the needs of the majority of the world's population?**

ANTECEDENTS TO THE CEWG REPORT

The 2001 report of the Commission on Macroeconomics and Health[8] aggregated evidence that investment in health is essential for development; contributed to arguing for increasing contributions to health aid, partly through global pooled mechanisms like GAVI, GFATM and UNITAID; and made the case for a large new fund to support health R&D for the needs of LMICs given the market failures and lack of incentives for private investments. Three types of diseases were distinguished:

- **Type I diseases** are incident in both rich and poor countries, with large numbers of vulnerable population in each. This includes typically the large burden of NCDs.
- **Type II diseases** are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. These are mainly infectious diseases like HIV/AIDS and tuberculosis.
- **Type III diseases** are those that are overwhelmingly or exclusively incident in LMICs. These are the neglected tropical diseases, such as sleeping sickness, kala azar, or Chagas disease.

The 2006 report of the Commission on Intellectual Property Rights, Innovation and Public Health (established in 2003)[9] recommended that *"WHO should develop a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries."* resulting in the establishment of an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property[10] in 2006.

In 2008, a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA-PHI)[11] was adopted designed to promote innovation, build capacity, improve access and mobilize resources. One critical element was left incomplete: how would the necessary finances be generated and managed?

An Expert Working Group (EWG) on Research and Development: Financing and Coordination[12] examined this issue but its 2010 report – despite some progress made - did not attract widespread support. Later in the year, the WHA called for a further Consultative Expert Working Group on Research and Development: Financing and Coordination, whose report was issued in April 2012. The scope of CEWG mandate included two aspects relevant here:

- Focus on financing and coordination of R&D for health products and technologies related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases.
- Centre on GSPA-PHI elements 2: Promoting research and development and 7: Promoting sustainable financing mechanisms.

MAIN FEATURES OF THE CEWG REPORT

Overall, the CEWG report concludes that a global framework is needed and should encompass three critical elements: ensuring financing of R&D; coordinating the global efforts; and providing an observatory function to inform the process. It sees potential for an R&D Convention to cover areas beyond Types II and III diseases. In particular, there is widespread concern about the lack of incentives for the development of new antibiotics. The CEWG recommendations can be classified into four main types:

1. PRINCIPLES:

- Affordable products can best be achieved through free open market competition.
- Ensuring access to affordable products requires delinking of R&D costs and prices of products.
- R&D is a global public good with a need for collective action and agreed financing contributions to avoid free riding and aggregate under-investment.

2. FUNCTIONS/OPERATIONAL:

- There is need to increase public investments to at least US$6 billion annually (double the current total investments).
- All countries should commit to spend at least 0.01% of GDP on government-funded R&D.
- 20-50% of funds should be channelled through international pooled mechanisms to improve efficiency and coordination
- There should be more efficient and collaborative R&D processes through sharing of results: *Open Knowledge Innovation*: precompetitive research and development platforms, open source and open access schemes, and the utilization of prizes, in particular milestone prizes, equitable licensing and patent pools.
- Strengthening R&D capacity in and technology transfer to LMICs is required.
- Establish a Global Health R&D Observatory and relevant advisory mechanisms under the auspices of WHO. The Observatory would need to collect and analyse data, including in the areas of financial flows to R&D; the R&D pipeline; and learning lessons. Advisory mechanisms could involve a Network of Research Institutions and Funders and could be based on the current Advisory Committee on Health Research (ACHR) and the ACHRs of the WHO regions, with suitably revised terms of reference and ways of operation.

3. IMPLEMENTATION INSTRUMENT:

- There is need for an agreed *global framework*.
- A global legally binding instrument would be most effective
- CEWG proposes an international Convention on Global Health R&D (utilizing Article 19 of the WHO Constitution)
- This would be the first global regulatory instrument for a global public good within health.

4. PROCESS/NEXT STEPS:

- A resolution at 65th WHA
- Establish a working group (WG) or technical committee composed of two Member States from each WHO region to undertake preparatory work on the elements of a draft agreement.
- Provide for the establishment of an intergovernmental negotiating body open to all Member States, to be established under Rule 40 to draft and negotiate the proposed R&D convention following on from the report of the proposed WG.

SEMINAR ON "STRENGTHENING THE GLOBAL R&D SYSTEM: INNOVATION FOR HEALTH NEEDS IN DEVELOPING COUNTRIES" HELD ON 4 MAY 2012 AT THE GRADUATE INSTITUTE, GENEVA

The seminar opened with remarks from **Philippe Burrin** (Director, the Graduate Institute), **Gaudenz Silberschmidt**, (Ambassador and Head, Division of International Affairs, Swiss Federal Office of Public Health) and **Ilona Kickbusch** (Director, Global Health Programme, the Graduate Institute). **John-Arne Røttingen** (Professor of Health Policy, Department of Health Management and Health Economics, Institute for Health and Society, University of Oslo), chairperson of the CEWG, introduced the CEWG report and its conclusions. **Sigrun Møgedal** (Special Adviser, Norwegian Knowledge Centre for the Health Services) moderated the keynote address of Nobel Laureate **Joseph Stiglitz** (Professor, Columbia University). A panel discussion then followed, moderated by **Ilona Kickbusch**, involving **Suerie Moon** (Research Director, Forum on Global Governance for Health, Harvard Global Health Institute), **Liu Zhenmin** (Ambassador and Permanent Representative of China, Geneva), **Tom Mboya Okeyo** (Ambassador and Permanent Representative of Kenya, Geneva), **Sally Davies** (Chief Medical Officer, UK), **Timothy Wells** (Chief Scientific Officer, Medicines for Malaria Venture) and **James Love** (Executive Director, Knowledge Ecology International).

Following the recommendations of the CEWG report, the discussion of the seminar can be classified into four main types:

1. PRINCIPLES:

- A political choice needed to be made regarding the use of knowledge as a global public good and the value base is very important, with the highest attainable standard of health acknowledged as a human right.
- New opportunities are arising: global financing of development is moving **from charity to shared responsibility.**
- The CEWG report is a milestone, offering a promising path towards improving the governance of the global R&D system so that medicines can be made accessible to all the world's population, 80% of whom live in LMICs. It is modest in scope, avoiding some contentious areas but in tune with the objective of establishing **a framework for improving health and not just creating R&D for medicines**. The issue is about neglected people and not just neglected diseases.

2. FUNCTIONS/OPERATIONAL:

- This report offers WHO an important opportunity to exert leadership on a critical global health issue, applying its unique role as a norm-setting institution and an arena where all countries can come together to negotiate rules and standards.
- **Why do we need a global set of rules for R&D?** The world is growing increasingly interdependent when it comes to health and is becoming more multi-polar with the growing economic and political power of the MICs. This has important implications for medicines R&D: now be seen to be of global benefit as well as meeting LMIC needs.
- **Are binding legal norms needed?** Experience of the past two decades demonstrates that soft norms are not enough. For medicines, patients have had to rely on soft norms for access, while patent-holders could count on binding international law in the form of the TRIPS Agreement to protect their interests. Binding norms (hard law) can be difficult to negotiate, but if health matters enough to governments, binding norms can be reached. Coherence to a set of rules is needed to avoid some countries free-riding on the open access research outputs of others and then privatizing that knowledge.
- The proposed new instrument will operate in parallel with, not instead of, the current system that rewards innovation with monopoly. "Intellectual property is more about responsibility than rights".
- The new financing proposals could be adopted within the framework of the agreed GSPoA-PHI.

3. IMPLEMENTATION INSTRUMENT:

- To combine incentives for R&D with ensuring access to drugs at the lowest marginal cost, a Convention committing finances is essential to address two critical issues: avoid the problem of 'free riding' and achieving delinking of research costs and product pricing. The **primary** responsibility for ensuring the right to health lies with governments – not with industry, civil society, foundations, the UN system or public-private partnerships, although each of these other actors has a role to play. The CEWG has posed a challenge for governments (including those of MICs and not limited to the BRICS) – are they ready to fulfil their responsibility to build a global system that will meet the health needs of their populations?
- A global Convention for Health R&D would bring substantial benefits to HICs as well as to LMICs, recognising that health is now a global issue with diseases migrating freely across borders; and with the results of R&D for LMIC health needs also providing insights into medicine in HICs. It will be important to broaden the appeal beyond diseases of LMICs by including concerns of HICs, such as the need for new antibiotics. Pursuing a mixed model with new incentives would help address the lack of sustainability of current drug development models and support the achievement of health for all.
- It is important to adopt a social rather than medical model of health, recognizing that high global death rates are not only due to infectious diseases but to hypertension, tobacco use, obesity and sedentary behaviour. Research is needed to deliver evidence not only on biomedical aspects but also on social, environmental aspects, the role of infection, etc.
- A set of pooled funding mechanisms, additional to any existing obligations, would be best, so that countries could chose which to support and could include those in which they had a traditional interest. A range of mechanisms could be used to assist the delinking of R&D from drug prices, including open sourcing, prizes and concessionary licensing.

4. PROCESS/NEXT STEPS:

- There is need for global collective action and for balancing between recognizing the urgency of addressing avoidable deaths while taking the time to develop consensus for an agreement. It will be vital to get all relevant sectors on board through dialogue nationally and in some cases (e.g. the EU) regionally, before it could be decided what position may be taken on the question of an R&D Convention. A deliberative process is essential, to allow development of a consensus based on a broad understanding of why the CEWG conclusions had been reached and why they were so important for the health of the vast majority of the world's population. It would be valuable to have briefings and preparatory processes for delegations in Geneva and elsewhere; and to strategically choose the best scope and image: a broad approach of "R&D for Health" was seen as important. However, it also poses some challenges compared to the more narrow scope of R&D restricted Type II/III diseases.

KEY ISSUES FOR POLICY MAKERS

There is now very widespread acceptance that the present system of R&D for drug development fails to ensure the right to health and health equity, especially for poorer populations. **The CEWG proposes a solution involving a binding R&D Convention.**

- **Is this the right approach in principle or, if not, what would be a better alternative for securing implementation?**

If an R&D Convention is the best approach for the next 1-2 decades, **what should its overall scope be?**

Should it include:

- **Diseases: Types II and III only; or also Type 1? Or all infectious diseases?**
- **Other health-determining issues that critically depend on research - e.g. research on: health policies and systems; health impacts on climate change; social determinants of health?**

How should it be financed?

- **Agreed and assessed contribution based on a percentage of GDP, or other method?**
- **Whose budgets? Should finance derive from budgets for Science and Technology, Health, Development? Should it be up to states to decide themselves?**
- **A combination of national and international mechanisms is recommended by CEWG, but should there be one international pool or several pools?**

How should it be coordinated?

- **What coordination mechanisms are most appropriate to ensure equitable and effective priority setting, allocation of funding, dealing with both risk assessment and risk management, accountability?**

How should it be monitored?

- **The proposal for a Global Observatory for Health R&D is based on recognising the need to base priorities on health needs; importance of continual supply of information on what R&D effort is currently ongoing, where there are gaps and what are the strategic opportunities; need to monitor and report on compliance with obligations and on effectiveness of efforts and results.**

NEXT STEPS: ACTION FOR POLICY MAKERS

Immediate responses to the CEWG report, as highlighted in the recent Geneva Seminar, have included expressions of impatience for speedy decisions and actions after several years of meetings, commissions and reports; and counselling of a need for political debate at both national and international levels to reach well-considered conclusions that must involve a range of sectors.

These are key questions for debate at the May 2012 WHA.

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More information on the seminar, including footnotes to this document, can be found on http://graduateinstitute.ch/globalhealth/Seminar4May.html

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