

SEMINAR REPORT



STRENGTHENING THE GLOBAL R&D SYSTEM: INNOVATION FOR HEALTH NEEDS IN DEVELOPING COUNTRIES

HELD AT THE AUDITORIUM JACQUES-FREYMOND
GENEVA – FRIDAY 4 MAY 2012

INTRODUCTION

The Geneva seminar¹ was held in the context of an important milestone that has been reached in long-standing global efforts to address a critical gap in the development of drugs and other health technologies that meet the health needs of poor and neglected populations:

- The report² of the **WHO Consultative Expert Working Group (CEWG) on Research and Development: Financing and Coordination** was published in April 2012. Building on the work of several earlier WHO initiatives, it makes a number of key recommendations – the most far-reaching of which is for the creation of a binding global Convention for Health R&D.
- The CEWG report was scheduled³ for discussion by Committee A in the 65th World Health Assembly (WHA), 21-26 May 2012.

The seminar brought together a diverse range of stakeholders and experts, including the Nobel Laureate Joseph Stiglitz and representatives of governments, intergovernmental organizations, NGOs, industry, public-private partnerships, journalists and academics. It invited preliminary responses to the CEWG findings; encouraged debate on the needs for and merits and practicalities of a global Convention for Health R&D; and focused attention on key issues that merited consideration for a well-informed debate on the CEWG proposals by the WHA.



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?**

This document summarises the main points presented and discussed in the seminar, as well as some relevant background material that provides salient features of the background to the question of an International

Convention for Health R&D. It provides an accompaniment to the Brief for Policy-Makers⁴ which has been prepared by the seminar co-sponsors for circulation at the 65th WHA.

WELCOME

Opening the seminar, **Philippe Burrin** (Director, GIIDS) highlighted the important work of the Institute's Global Health Programme. Also welcoming the participants, **Gaudenz Silberschmidt**, (Director, Division of International Affairs and Vice-Director, Swiss Federal Office of Public Health) congratulated the CEWG for its thorough analysis and recommendations, including for a possible R&D Convention. Noting the importance that Switzerland and other countries attached to policy coherence in global health, he observed that it would be vital to get all relevant sectors on board through national dialogue before it could be decided what position would be taken on the question of an R&D Convention and it would be advisable to allow time for this. **Ilona Kickbusch**, Director of the GIIDS Global Health Programme, thanked all her team for their work to organize the seminar and pointed to the growing recognition of the need for better governance for global public goods (GPGs) such as health in the 21st century. Adding her own welcome, the moderator **Sigrun Møgedal** (Special Adviser, Norwegian Knowledge Centre for the Health Services) observed that new opportunities were arising in these times of change and that global financing of development was moving from charity to shared responsibility.



**John-Arne Røttingen, Sigrun Møgedal,
Joseph Stiglitz**

MAIN FEATURES OF THE CEWG REPORT

Summarizing the report, CEWG Chair **John-Arne Røttingen** (Professor of Health Policy, Institute for Health and Society, University of Oslo) emphasized the conclusions that addressing the market failure requires delinking of R&D costs and prices of products and that such R&D is a global public good where there is need for collective action and agreed financing contributions. He focused particularly on the need to implement the recommendations in a manner securing a systematic and sustainable solution, which an R&D Convention would provide; and noted that there was broad support for this, citing:

- The results of a recent expert Dephi survey⁵, which had concluded that “a regulatory instrument would be a desirable and feasible measure to promote R&D for neglected diseases”.
- The conclusions⁶ of the EU Foreign Affairs Council meeting of 27 Foreign Ministers on the EU role in global health, which included the need for **working towards a global framework** for R&D that addresses the priority health needs of developing countries and prioritizes pertinent research actions to tackle global health challenges; exploring models that dissociate the cost of R&D and the prices of medicines; ensuring public investments in health research secure access to the knowledge and tools generated as a global public good and help generate socially essential medical products at affordable prices; and promoting dialogue and joint action with key global players and stakeholders.

Røttingen also noted that there was 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. Røttingen quoted Richard Bergström, head of the European Federation of Pharmaceutical Industries and Associations⁷: “**A variety of incentives probably have to be applied, but having all in common that the financial return has to be separated from the use of the product**”.

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 processes.**

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 where there is 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
- Open Knowledge Innovation: There should be more efficient and collaborative R&D processes through sharing of results through measures such as: 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 research and development 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 to provide inputs to an Advisory Committee, which could be based on the current Advisory Committee on Health Research (ACHR) and also the ACHRs of the WHO regions, with suitably revised terms of reference and methods 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:

- 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.

THE KEYNOTE ADDRESS

In his keynote address, the Nobel Laureate Joseph Stiglitz (Professor, Columbia University) said that a Convention providing for the financing of research, particularly for medicines for LMICs, had been needed for a very long time to solve the problem of how to combine incentives for R&D with ensuring access to drugs at the lowest marginal cost. He thought that the CEWG's approach does this well and called the report a 'milestone'. Recalling the recognition of knowledge as a global public good (GPG), he reflected on the limitations to innovation

of R&D systems driven exclusively by intellectual property rights and patenting which impose impediments to advancing knowledge. R&D for neglected diseases must be funded in a globally efficient way and he saw the need for a Convention committing finances as essential to address two critical issues: avoiding the problem of 'free riding' and achieving delinking of research costs and product pricing. Stiglitz commended the CEWG report as modest in scope, avoiding a number of contentious areas but in tune with the objective of establishing a framework for improving health by building a sustainable system for health R&D. Importantly, he saw it bringing 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 medicines for HICs. Finally, Stiglitz highlighted the need for global collective action and for balancing between the urgency of addressing avoidable deaths while taking the time to develop consensus for an agreement.



Joseph Stiglitz

THE PANEL DISCUSSION

Introducing the Panel Discussion, **Ilona Kickbusch** (Global Health Programme, Graduate Institute, Geneva)



Ilona Kickbusch

critical it was to break through the barrier of dealing with the problem of Types I and II diseases, which must be recognised as a global issue.

Suerie Moon (Harvard Global Health Institute, Harvard University) welcomed the recommendations



Suerie Moon

specifically, lies with governments – not with industry, civil society, foundations, the UN system or

observed that a political choice needed to be made regarding the use of knowledge as a GPG. She reminded participants that there are established mechanisms to produce GPGs but that sometimes the collective action of WHO was undervalued. She also stressed that the value base was very important, with the highest attainable standard of health acknowledged (WHO Constitution) as a human right. Recalling Stiglitz's description of the proposal for an R&D convention as 'modest', she emphasized how

of the CEWG – particularly on a binding R&D convention – as 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. She focused on four areas:

1. Who is ultimately responsible for ensuring access to medicines? The primary responsibility for ensuring the protection and promotion of human rights in general, and the right to health

public-private partnerships, although each of these other actors of course has a role to play. The CEWG has posed a challenge for governments – are they ready to fulfil their responsibility to build a global system to meet the health needs of their populations? In particular, it is a challenge to the governments of middle-income countries, including but not limited to the BRICS.

2. At a time when WHO is in budgetary crisis and its credibility as the leading global health authority has been challenged, is WHO in any shape to take on the difficult task of hosting treaty negotiations? Especially when it has been difficult for WHO to respond forcefully to the potentially negative effects of trade on health in general, and intellectual property rules in particular? In all of the debates on how WHO should be reformed or re-invented to better meet the needs of today's interdependent world, the one area where there seems to be consensus is regarding WHO's unique role as a norm-setting institution and an arena where all countries can come together to negotiate rules and standards. This report offers WHO an important opportunity to re-exert leadership on a critical global health issue.

3. Are binding legal norms needed? The experience of the past two decades demonstrates that soft norms are not enough. When it comes to 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, or hard law, can be difficult to negotiate, but if health matters enough to governments, binding norms can be reached. Coherence is needed because if only some countries encourage an open access approach, other countries can free-ride on those research outputs and then privatize that knowledge. The system won't work unless enough countries agree to play by a set of rules.

4. Why do we need a global set of rules for R&D? The world is changing in two critical ways: we are all growing increasingly interdependent when it comes to health (as demonstrated by the challenge of the H1N1 flu virus in 2009) and the world is becoming more multipolar with the growing economic and political power of the middle-income countries. These two changes have important implications for medicines R&D, which can now be seen to be of global benefit as well as meeting LMIC needs.

Liu Zhenmin (Permanent Representative of China, Geneva) welcomed the CEWG recommendations as



Liu Zhenmin

an innovative effort to address market failure and provide R&D for diseases of the developing world, ensuring affordability of medicines. He emphasised the human rights dimension espoused in the WHO Constitution. Noting that financing was the most difficult aspect, he recommended sufficient time for consideration of the CEWG proposals by governments and also called for the private sector to assume its responsibilities and adopt a long-term vision, sharing innovation, benefits and

risks. He also noted that coordination is of paramount importance, in the context of changing global architectures and the need for a strong leadership role by WHO, focusing on its capacities to identify priorities, set standards and provide a normative role. There is a need for a global convention that must be member-state driven and ensure enforcement.

Tom Mboya Okeyo (Permanent Representative of Kenya, Geneva) focused his remarks on the future



Tom Mboya Okeyo

and how to move to the next steps. The proposed R&D Convention represented the final stages of a long marathon in which Kenya and Brazil had played a key role in 2006 through a resolution in the WHA and which now would put in place new mechanisms to address the health of 5.65 billion people in LMICs. He felt that no more Working Groups or parallel institutions were needed, but rather that the new financing proposals could be adopted within the

framework of the agreed GSPoA. In the face of the global financial crisis, it would be important to strongly market the case for investment in R&D. Kenya's Minister for Public Health would convene a ministerial group during the WHA to discuss action. ANDI, which Kenya had supported and now co-chaired with South Africa, provided a model for cooperation. Action should be taken quickly, building on what was already in place.

Dame Sally Davies (Chief Medical Officer, UK)

stressed the importance of adopting a social rather than medical model of health and recognizing that high global death rates were not only due to infectious diseases but to hypertension, tobacco use, obesity and sedentary behaviour. Research was needed to deliver evidence not only on biomedical aspects but also on social, environmental aspects, the role of infection, etc. She welcomed the CEWG report as an important step in moving the debate forward by highlighting failings and the need for new mechanism. She recognised the need for a careful,



Sally Davies

considered approach and supported the view that this would require some time – in the case of the EU, both to develop a national position and to engage in alignment within the EU. In seeking areas that would help to bring parties together, she felt that the area of infections was one that would provide incentives for everyone to join in constructively.

Timothy Wells (Chief Scientific Officer, Medicines for Malaria Venture) reflected on trends in the



Timothy Wells

pharmaceutical industry during the last 30 years. Over the period, there had been little change in the rate at which new molecular entities emerged as drugs, while R&D costs per drug had risen steeply. There was now an increasing focus on drugs for orphan diseases. PDPs like MMV had been set up to fill the gap of discovery and development of drugs for disease where there had been a market failure and had successfully generated a pipeline of new products. But now there was a need for a global fund to support R&D to ensure a better supply of medicines and to improve health, with every country playing a role. “Intellectual property is more about responsibility than rights”, he observed

James Love (Director, Knowledge Ecology International) welcomed the CEWG report. He stressed



James Love

that the issue was about neglected people and not just neglected diseases. To meet their urgent needs, he focused on the importance of implementation of the report. A set of pooled funding mechanism, additional to any existing obligations, would be best, so that countries could choose which to support and could include those they had a traditional interest in. A range of mechanisms could be used to assist the delinking of R&D from drug costs, including open sourcing, prizes and concessionary

licensing. It would be important to broaden the appeal beyond diseases of the developing world by including some 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.

In the final discussion, several participants in the seminar returned to the theme of pressing forward while allowing time for Member States to settle their negotiating positions. Suggestions included:

- Briefings and preparatory processes for delegations in Geneva
- Strategically choosing 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 to TypeII/III diseases
- A deliberative process was essential, which would 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.

In his closing remarks, Professor Stiglitz noted that there are a few key global issues where one cannot get away from thinking about global governance: global health is one of those and the production of GPGs is another. 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?

In line with the above discussions, the co-sponsors of the seminar subsequently prepared a policy briefing for delegates to the 65th WHA, summarising the key issues.⁴

BACKGROUND: HISTORY AND CONTEXT

The Need: Ignorance is Fatal

The WHO Constitution⁸ establishes that “**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**”. But disparities in health between populations around the world have grown dramatically during 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 seen in high-income countries (HICs: life expectancies now typically over 80 years), and the poorest gains seen in low- and middle- income countries (LMICs: life expectancies can be as low as 40 years or less).⁹

The large disparities in life expectancy constitute a massive health inequity because they are avoidable. In a broad sense, they can be attributed to factors such as 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 very important 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 technologies like effective medicines**.^{10, 11} 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**.¹²

Our understanding of the range of factors that contribute to health has greatly expanded in recent years. New knowledge and new tools that are relevant to the particular health problems of populations in LMICs are now seen to encompass:

- **Neglected diseases:** With the creation of PDPs and global funds such as GFATM and GAVI, some of the hitherto ‘neglected’ diseases (especially those specified in the MDGs) began to receive increased (though still less than sufficient) resources, while others (e.g. dengue and a range of tropical parasitic and helminth infections) have remained ‘very neglected’.¹³
- **Neglected health systems:** Efforts to create and implement better treatments for hitherto neglected diseases have highlighted the weaknesses and inefficiencies of many health systems. This problem has been greatly compounded by the massive increase in non-communicable diseases (NCDs such as cancer, diabetes heart disease, stroke, mental and neurological conditions and chronic obstructive pulmonary diseases) in all countries in recent decades.
- **Neglected people:** The distribution of ill-health and high mortality reveals people whose health is seriously impaired as a result of location, poverty and inequities and social biases based on ability, class/caste, ethnicity, gender, race or religion.
- **Neglected health:** The WHO Constitution, Ottawa Charter on Health Promotion, the “Health in All Policies” initiatives within the European Union and, most recently, the work of the Commission on Social Determinants of Health have all recognized that good health is not merely the absence of disease but the result of a range of factors and processes that often originate outside the health sector, including economic, environmental, political and social as well as biological determinants,

With the growing appreciation of the range and complexity of factors beyond the health sector that impact on health, the widening scope of the research agenda required is becoming evident. Increasingly, this agenda is being described as “**research for health**” rather than “health research”.¹⁴

History of Responses

Evolving initiatives

WHO's attention to research began in 1959 with the establishment of the Advisory Committee on Medical (later Health) Research. Two Special Programmes were created at WHO in the 1970s, in human reproduction¹⁵ and tropical diseases¹⁶ as the first global initiatives to pool resources and coordinate international efforts to address unmet needs in services and in the development and delivery of effective, safe, affordable and locally applicable drugs, diagnostics and tools. But the scale of effort remained limited. The 1990 report of the Commission on Health Research for Development¹⁷ concluded that far too little was being spent on R&D for the health needs of LMICs and to strengthen their own R&D capacities to contribute to the solutions. By and large, industry remained reluctant to engage in drug development for health problems specific to LMICs, although Merck's donation of ivermectin (Mectizan) for the eradication of onchocerciasis (river blindness) set a model for a number of other drug donation programmes by the pharmaceutical industry.

The 1990s saw increasing attention to the issues. Advocacy organizations like the Council on Health Research for Development¹⁸ and the Global Forum for Health Research¹⁹ were established and the '10/90 gap' slogan was popularised.²⁰ There was increasingly seen to be a 'market failure' requiring special measures. This attracted the attention of Foundations (initially Rockefeller and later Gates) which assisted in establishing product development partnerships (PDPs) for some neglected diseases.

The 21st century opened with the setting of the Millennium Development Goals (MDGs), three of which are health-specific (reducing maternal and child mortality and treating infections prominent in LMICs), while all the others are, in some measure, health-determining. The Commission on Macroeconomics and Health, reporting in 2001, aggregated the evidence that investment in health is essential for development, contributing to making the case for the increasing contributions to health aid seen over the last decade²¹ partly through global pooled mechanisms like GAVI, GFATM and UNITAID. However, the Commission also made the case for a

large new fund to support health R&D for the needs of developing countries given the market failures and lack of incentives for private investments.²² The Commission distinguished among three types of diseases:

- **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.

At the same time, the fact that the vast majority of people living with HIV could not afford lifesaving antiretroviral treatment for HIV/AIDS became a political crisis that drew unprecedented attention to the importance of access to medicines as a human rights issue. This culminated in the 2001 WTO Doha Declaration on TRIPS and Public Health, which clearly gave primacy to public health and reiterated the right and responsibility of governments to make full use of flexibilities in intellectual property law to ensure the right to health. The access crisis also highlighted the absence of global governance mechanisms for addressing both innovation and access to medicines in a systematic and sustainable way.²³

However, despite the increased attention to access and affordability, and increased funding and new models of drug development that were emerging, both the scale and scope of efforts to address the underlying problems remained inadequate. In particular:

- The need for greater financing of R&D efforts was growing ever more pressing – partly driven by the increasing success of the PDPs in creating a pipeline of interesting candidates for clinical trials. By mid-decade, the financing requirements for these PDPs alone were moving beyond the capacity of the not-for-profit foundations and the bilateral donors funding them. It was becoming urgent to find additional financing mechanisms and, in some form or another, to attract public resources.
- Industry was engaging an increasingly diverse array of efforts to assist in drug development for health problems of LMICs. But the scale of these efforts was still small compared with the needs and the underlying problem of ‘market failure’ remained. With industry estimating that it costs at least several hundred million dollars to develop a new drug, necessitating high sales prices during the patent-protected period to recoup the investment and show a profit to shareholders, there was little incentive to address the health problems of poor populations. Faced with this weakness in the market mechanism, in which the creation and exclusive use of intellectual property provides the financial driver for innovation, pressure mounted in some quarters for the examination of alternative systems that could separate the incentives for innovation from the prices of medicines – the principle of “de-linkage”.

The WHO response

In an effort to address the underlying problems related to the market failure to provide effective and affordable drugs for the particular health problems of LMICs, in 2003 the World Health Organization established a Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIH). This reported²⁴ in 2006 with some 60 detailed recommendations, the central one being 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.”

In 2006 an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property²⁵ was established and conducted negotiations which led to the adoption in 2008 of a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA-PHI)²⁶ with 8 elements 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 on Research and Development: Financing and Coordination²⁷ was tasked with examining this issue and reported in January 2010. However, despite making some progress, the report of this Expert Working Group did not attract widespread support. Later in 2010, the WHA called for a further Consultative Expert Working Group on Research and Development: Financing and Coordination²⁸, whose report was issued in April 2012. The scope of CEWG mandate included:

- 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 element 2 (Promoting research and development) and element 7 (Promoting sustainable financing mechanisms) of the GSPA-PHI.
- Take forward the work and deepen the analysis of the Expert Working Group
- Examine additional submissions and proposals on R&D financing and coordination.

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