Executive Summary

Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination


World Health Organization
Executive summary

The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) was established by the World Health Assembly (WHA) in 2010 by resolution WHA63.28 with the principal task of deepening the analysis and taking forward the work done by the previous Expert Working Group on Research and Development: Coordination and Financing (EWG) which reported in 2010. Underlying both expert groups was the objective set out in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI):

“to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.”

In undertaking our work we were mindful of the request that we “observe scientific integrity and be free from conflict of interest” in our work and we also decided to be as open and transparent as possible by providing an open forum during our first meeting, calling for submissions, providing open briefings after each of our meetings, and publishing as much as possible on our web site.1

Chapter 1: Introduction

We describe the background to our work beginning with the establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2003 and set out how we interpreted our terms of reference and our approach to our task. Our focus is on the needs of developing countries for new products (including medicines, vaccines and diagnostics), but we recognize the importance of other kinds of health research relating to health systems, operational and implementation research, the effectiveness of interventions and health-related policy issues.

Chapter 2: Setting the scene: the issues

We set out the reasons why action is required to address the fact that current incentive systems fail to generate enough research and development, in either the private or public sectors, to address the health-care needs of developing countries. In the case of developing countries, the market failure which intellectual property rights try to correct is compounded by a lack of reliable demand for the products generated by research and development (R&D). Thus the incentive offered by intellectual property rights fails to be effective in correcting the market failure. There is therefore an economic case, based on market failure, for public

action. There is also a moral case. We have the technical means to provide access to life-saving medicines, and to develop new products needed in developing countries, but yet millions of people suffer and die for lack of access to existing products and to those that do not yet exist. This is also a matter of human rights as articulated, for instance, in WHO’s constitution which states 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”.

We review recent trends in the pharmaceutical industry more generally, including the fall in the approval of new drugs, including those with new therapeutic effect, while, until recently, R&D expenditures have continued to rise and many existing top-selling medicines are going out of patent. We note the responses of the pharmaceutical industry, including a spate of mergers and acquisitions, a greater focus on emerging markets, and the search for new and better models of innovation often characterized as “open innovation” and involving more open collaboration with external partners. We compare these with the approaches we analyse in Chapter 3.

We review the evidence on health R&D relevant to developing countries, beginning with the pioneering work of the Commission on Health Research and Development (CHRD) in 1990 and subsequent estimates by the 1996 Ad Hoc Committee on Health Research, the Global Forum on Health Research, and latterly the estimates produced by G-Finder. We also review the evidence relating to new product development in the last decade, including products developed by public–private partnerships for product development. We note the importance of linking research strategies to access considerations and, in that context, the relevance of delinking the costs of R&D from the price of products.

We then review in outline the issues relating to financing and coordination of R&D. In respect of financing we note the various recommendations that have previously been made for increased financing of R&D, notably the call of the CHRD for 2% of health expenditures and 5% of development assistance for health to be devoted to health R&D. We also note the four innovative sources of financing reviewed by the EWG, and other proposals, such as the Financial Transactions Tax, which have been proposed as a source of finance for development, including health. As regards coordination, we note the diversity and complexity of the current R&D landscape and also previous recommendations regarding the need for better coordination, including improved priority-setting, coherence and efficiency.

Chapter 3: Review of proposals

We focus here on the assessment of the proposals contained in the EWG report, combined with other proposals submitted to us as a result of our call for submissions, which we consolidated into 15 grouped proposals. Annex 2 sets out our understanding of the EWG process and how we established our own grouped proposals. We then provide an assessment of each of our grouped proposals based
on criteria we established, drawing on the more detailed reviews contained in Annex 3, which are summarized under the headings of public health impact, and technical, financial and implementation feasibility. We also take into account the results of consultations held in five of WHO’s regions.

We conclude that the following proposals met our criteria less well: Tax breaks for companies, Orphan drug legislation, Green intellectual property, Priority review voucher, Transferable intellectual property rights, Health Impact Fund and Purchase or procurement agreements.

This does not necessarily mean that countries or the international community should not adopt such measures, nor that it might not be in their interest to do so. Indeed several of these proposals (e.g. orphan drug legislation or procurement agreements) are already in existence and regarded by many as successful in achieving their objectives. It simply means that, in relation to our terms of reference, we do not think they do, or will, perform well in stimulating R&D needed by developing countries for health-care products for Type I, II and III diseases.

A second category consists of proposals that, irrespective of their other merits, are not principally contributing to improved financing or coordination of research and development. In that category we place Regulatory harmonization and Removal of data exclusivity.

The third category consists of proposals that we felt best met our criteria: Global Framework on Research and Development, Open approaches to research and development and innovation,2 Pooled funds, Direct grants to companies, Milestone prizes and end prizes and Patent pools.

It would be possible to pursue each of these proposals individually but we see them as part of a wider package of measures that will promote R&D in ways that can also help address access issues. Delinking should be a fundamental principle underpinning open approaches to research and development and innovation. An absolutely necessary condition for implementing these approaches will be a sustainable source of funding.

Chapter 4: Strengthening global financing of health research and development

We review the four sources of financing assessed in the EWG report: A new indirect tax, Voluntary contributions from businesses and consumers, Taxation of repatriated pharmaceutical industry profits and New donor funds for health research and development. Having reviewed the four proposals against the available evidence, we reach the view that some form of taxation is the most fruitful avenue to explore in the search for new and sustainable sources of funding.

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2 Includes, inter alia, precompetitive research and development platforms, open source, open access and equitable licensing.
However, it would be unrealistic, given the multifaceted nature of development needs, to think that one specific new source that would generate very significant amounts of money on a global scale would or should be devoted to the particular field of health R&D of relevance to developing countries. Rather we argue that from any new source of funding that might emerge a portion should be related to the improvement of health as an acknowledged development priority, and that another portion also should be devoted to currently underfunded R&D areas, including those within the CEWG mandate.

We then consider the evidence concerning different forms of taxation that might be suitable as the basis for raising taxes, including for health R&D. In looking at the various tax options we support the principle that taxes should be progressive, bearing more proportionately on the rich than the poor, particularly for sources unrelated to public health (e.g. an airline tax). On the other hand we recognize that particular forms of indirect taxation relevant to public health, such as “sin” taxes related to reducing lifestyle risks, are regressive in nature and that in these cases the public health benefits, particularly for the poor, should outweigh the possible adverse impact on income distribution. At the same time it is important that tax and benefit policies are looked at as a whole; in principle regressive impacts could be offset by changes in other taxes.

We look at the evidence for taxes on fat, sugar and tobacco and their potential for raising revenue. We examine various national examples where countries raise taxes specifically to fund health or health R&D. We consider various proposals for taxes that might raise finance for global purposes. We conclude that countries should first consider at national level what tax options might be appropriate to them as a means of raising revenue to devote to health and health R&D. We highlight, in particular, two possible taxes – the Financial Transactions Tax and the Tobacco Solidarity Contribution—that in addition to the airline taxes implemented in some countries could be used to generate funds to be channelled through an international mechanism to supplement national resources. We express our hope that such a tax could be agreed as part of an international commitment to finance global public goods, including for health and health R&D relevant to developing countries.

In the context of the overall funding of R&D by governments, we then review the performance against the various goals and targets that have been proposed for national financing of health and health R&D, such as the Abuja target for health spending of 15% of government expenditure, and the CHRD targets. In this respect, the limitations of current data are noted, particularly for developing countries. However the available evidence suggests that most African countries, as also some other regions of the world, are a long way from meeting the Abuja target and the 2% target for health research. Developed countries, on average, meet or exceed both these targets and spend around 0.15% of gross domestic product (GDP) on health research. By contrast, we calculate that only 2.5% of development assistance for health is channelled to R&D, or 1.5% if we include both bilateral and multilateral assistance.
However, in reality, development agencies fund only 15% of total R&D devoted to Type II and III diseases by developed country governments, as the great majority is channelled through government-funded research organizations. For this reason we favour targets which relate R&D effort to GDP as the best available measure for contribution to global public goods. On this measure the largest public funder of relevant research is the USA at about 0.01% of GDP, but several developing countries are also significant spenders.

We conclude that proportionate targets related to health-related public expenditure or development assistance are not the best means of achieving the objective, principally because the denominator is itself not necessarily at its target level. We therefore propose an approach which sets targets that relate a country’s effort in R&D spending, relevant to our mandate, to its GDP – a concept that is applicable to both developed and developing countries and takes account of the international public good that can be generated by each country’s own R&D spending.

Our principal conclusion is that:

- All countries should commit to spend at least 0.01% of GDP on government-funded R&D devoted to meeting the health needs of developing countries in relation to the types of R&D defined in our mandate.

In addition we propose that countries should consider these targets:

- Developing countries with a potential research capacity should aim to commit 0.05–0.1% of GDP to government-funded health research of all kinds
- Developed countries should aim to commit 0.15–0.2% of GDP to government-funded health research of all kinds.

Chapter 5: Strengthening global coordination in health research and development

We examine, in the light of the actions proposed in the GSPA-PHI, the history of coordination efforts in this field, including the Global Forum for Health Research – now part of the Council on Health Research and Development (COHRED) – and, in particular, the important role of WHO, various related initiatives in WHO, including TDR, and the Advisory Committee on Health Research (ACHR). It is also relevant that WHO has recently finalized its research strategy and new terms of reference for the ACHR. We also discuss what might be learned from the experience in international agricultural research of the Consultative Group on International Agricultural Research (CGIAR), noting however the very different construction of the health R&D field.

We conclude that coordination is likely to be most effective where it is associated with a funding mechanism which constitutes a significant part of total R&D funding for the disease areas of concern to us. We also believe, as proposed in Chapter 6, that a binding convention would make coordination more effective. Nevertheless,
there is much that could and should be done to improve coordination within the existing structures and framework. We also think any proposed coordination, and indeed funding, mechanism should, wherever possible, build on existing institutional structures.

There are major challenges for WHO to address the conclusion of the Second World Health Assembly that “research and coordination of research are essential functions of the World Health Organization”. In spite of these challenges, it is our belief that WHO should play a central and stronger role in improving coordination of R&D directed at the health needs of developing countries, and the current WHO reform programme means that this is an opportune time for defining WHO’s appropriate role in relation to the coordination of global R&D. We strongly emphasize the need to consider this task as part of the WHO reform process with consequent action and allocation of resources. A key message is that, to do this properly, WHO requires a critical mass of people and resources. If that critical mass is not reached then the objectives will not be achieved. In addition, coordination policies (e.g. avoiding unnecessary duplication, addressing priorities) need to be effectively implemented through appropriate incentives and other measures. If these conditions are not fulfilled, useful things may be done but they will not amount to coordination as we define it.

The key elements of this coordination function under the auspices of WHO would include:

1) A global health R&D observatory. This would need to collect and analyse data, including in the following areas:
   • financial flows to R&D
   • the R&D pipeline
   • learning lessons.

2) Advisory mechanisms:
   • a network of research institutions and funders that may include specialized sections according to the subject of research (e.g. type of disease), based on an electronic platform supported by WHO, and which may provide inputs to the advisory committee;
   • an advisory committee that could be based on the current ACHR and also the ACHRs of the WHO regions, with suitably revised terms of reference and ways of operation (subcommittees could be established to tackle specific topics and facilitate regional inputs).

Assessing the costs of what we propose would require more detailed work, but would mean only modest allocations with a potentially high impact if R&D coordination is improved. In 2006 the governance and secretariat costs of the CGIAR were estimated at $13.8 million. This was then about 2% of CGIAR spending on R&D. As a proportion of G-Finder estimated health R&D it would be less than 0.05%. For comparison, the costs of G-Finder itself are about US$ 1.5 million annually and, as noted above, the estimated costs of the WHO research strategy US$4 million.
Chapter 6: Implementation: a binding instrument

We first summarize our recommendations on the lines noted above. We then state that it is time to consider new ways forward to achieve the objectives that WHO Member States have been grappling with for so long. There is a need for a coherent global framework that combines the different elements and recommendations into a concerted mechanism.

We look at how conventions have been used to pursue objectives in a number of fields, particularly in relation to the environment, and also in WHO's only convention to date – the Framework Convention on Tobacco Control (FCTC). This includes examination of funding mechanisms associated with conventions or their protocols, including the Multilateral Fund and the recently agreed Green Climate Fund. We also analyse the relative merits of “hard” and “soft” law as a means of meeting our objectives. We look at the various provisions in the WHO constitution for producing agreements, regulations or recommendations and express our preference for recommending a binding agreement based on Article 19 of the WHO constitution.

The content of an agreement would be determined by the outcome of negotiations between Member States, but we set out the principles and objectives which we think should inform the negotiation process and some ideas about the next steps.

The framework for a possible convention has in many ways already been agreed between Member States in paragraph 14 of the GSPA-PHI.

The proposed convention aims at providing effective financing and coordination mechanisms to promote R&D. We see a convention not as a replacement for the existing intellectual property rights system but as a supplementary instrument where the current system does not function. R&D under the convention should focus on the development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries related to Type I diseases.

We take it as granted that our suggestions are set in the context of a broader framework for health research and that the proposed financing mechanisms and the convention should: i) be supportive of health research in general, including on public health and health systems, ii) not imply resource shifts from other important areas of health research or iii) limit scope for financing of R&D on health needs in developing countries only to particular technologies or options.

To strengthen R&D capacity in, and technology transfer to, developing countries, we see the need for support to:

- Capacity building and technology transfer to developing countries.
- The promotion of partnerships and collaborations based on joint agendas and priority setting related to developing country health needs and national plans for essential health research.
• The development and retention of human resources and expertise.
• Institutional and infrastructure development.
• Sustainable medium/long-term collaborations.

We suggest that the following proposals be considered as part of the framework for a negotiation process for a convention:

Objectives
• Implementing states’ obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.
• Promoting R&D for developing new health technologies addressing the global challenges constituted by the health needs of developing countries by means which secure access and affordability through delinking R&D costs and the prices of the products.
• Securing sustainable funding to address identified R&D priorities in developing countries.
• Improving the coordination of public and private R&D.
• Enhancing the innovative capacity in developing countries and technology transfer to these countries.
• Generating R&D outcomes as public goods, freely available for further research and production.
• Improving priority-setting based on the public health needs of developing countries, and decision-making relying on governance structures which are transparent and giving developing countries a strong voice.
• Core elements under the convention should focus on development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries related to Type I diseases.

Financing
• All countries should aim to achieve specified levels of public funding on health R&D relevant to the needs of developing countries.
• Countries could fulfil their financial commitment through contributions to a financing mechanism established under the convention, in combination with domestic spending on R&D undertaken to attain the convention’s objectives, or through development assistance where applicable.
• 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.
• Such financing may be generated from existing taxpayer resources, from new national revenue-raising measures, or by channelling a portion of the resources raised from any new international mechanism to this purpose. Voluntary additional public, private and philanthropic contributions to a pooled funding mechanism can also be envisaged.
• The convention and its financing mechanisms for the more defined objectives of R&D need to be supportive of the broader context of overall allocation of public financing to health research and the sustainability of financing in other areas of health research.

• The convention should define which research entities in the public and private sectors, in public–private partnerships, and in developed or developing countries, should be eligible for funding.

• Funding should be directed so as to promote cost-effective R&D in ways that will also promote subsequent access to technologies in developing countries, in particular using the tools identified in our report which best meet these criteria, such as open knowledge innovation.

• Funding should also be directed in ways that promote capacity-building and technology transfer to the public and private sectors in developing countries.

Coordination

• A coordination mechanism, which would help to promote, in particular, the objectives in Element 2.3 of the GSPA-PHI (“improving cooperation, participation and coordination of health and biomedical research and development”), and could be based on the ideas we put forward in Chapter 5.

• The coordination mechanism would need to improve the measurement of the volume, type and distribution of relevant R&D and the evaluation of R&D outcomes, in particular so that progress against commitments and compliance could be measured. This will depend in part on data and reports provided by parties to the convention.

Compliance mechanisms also need to be devised, including through cooperation of the parties to the convention.

Next steps

The issues that will need to be addressed in a negotiation of a binding agreement are many and complex. One of the reasons that the negotiations on the GSPA-PHI took so long was that there was very little preparatory work. We suggest therefore that the World Health Assembly should consider, first, establishing a working group or technical committee composed of two members from each WHO region to undertake preparatory work on the elements of a draft agreement, soliciting inputs as necessary from other Member States, relevant intergovernmental organizations, funders, researchers, the private sector, civil society and academics as necessary. Alternatively, as was done with the FCTC, an open-ended intergovernmental working group could be established with appropriate technical support. The WHA should also provide for the establishment of an intergovernmental negotiating body open to all Member States to be established under Rule 40 of the World Health Assembly’s rules and procedure to draft and negotiate the proposed R&D agreement following on from the report of the proposed working group.
The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) was established by the World Health Assembly in 2010 with the principal task of deepening the analysis and work done by the previous Expert Working Group on Research and Development: Coordination and Financing (EWG) that reported in 2010. Underlying both expert groups was the objective set out in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property:

“...to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.”