Conference Report

International meeting on a Global Framework For Supporting Health Research and Development (R&D) In Areas of Market and Public Policy Failure

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International Conference Center of Geneva (CICG)

An international meeting on a global framework for supporting health research and development (R&D) in areas of market and public policy failure was held in Geneva on 29 April 2003. The meeting was jointly organised by The Consumer Project on Technology, Médecins Sans Frontières, Health Action International, Oxfam, and the Third World Network. Over 150 people attended from various disciplines, ranging from the WHO, WTO and other UN agencies, industry, academia, and non-governmental organisations. The following brings together the main comments made during the presentations and discussions.

Opening Remarks

"You shouldn't defend the indefensible, but some people are" began Sir John Sulston, Founding Director of the Wellcome Trust Sanger Institute, and current holder of the Nobel Prize for Medicine. "The patent ethos cannot solve all our problems."

"There is currently an excessively regulated system with too much central control," he said, which pushes prices up. "The high cost of development includes a huge framework of testing and marketing, which will not apply to life-saving drugs developed by public research."

His opening remarks concluded with a call to wealthy countries to do more. "The rich G8 countries are in a tremendous phase of war building at the moment. Why are we doing this? It is through sharing, making the world more even, that there will be more markets and wealth. And health is an issue of security."

Prioritising Need over Profit

"Among the large number of new chemical entities developed between 1970 and 1999 only 16 for tropical diseases and tuberculosis" began Dr Bernard Pécoul, director of MSF's Access to Medicines Campaign. "Half of these were the product of animal research. And the pipeline is empty.

Dr Pécoul said that there is a lot of basic research, but this new knowledge is not moved into the R&D process. "Interesting compounds do not necessarily enter development; even if they do, there is no assurance they will be adapted and available to people in the developing world."

Worldwide spending on health R&D has never been so high – estimated at US$ 70-75 billion for 2002 – but this spending does not equate to health needs.

Dr Pécoul indicated that market incentives can still play a role – for example for malaria and TB – but "the most neglected diseases are totally out of the game. They affect a lot of people but they are all in developing countries." He said that these diseases are neglected because "the international community has agreed to leave it up to the private sector and consider medicines as commodities. This system has failed to respond to the needs of 80% of the world's population. The global pharmaceutical market ignores neglected diseases."

Dr Pécoul said the global rules needed changing to prioritise people's need over profit. "This means creating a global non-for-profit pharmaceutical industry. If we just repeat the strategy we use in rich countries to tackle the immense problem we have in Africa we will fail."

Dr Jonathan Quick from WHO-EDM outlined the current gaps. "The 20th century was the century of medicines and vaccines. We started the century with 1 synthetic medicine and a couple of vaccines. We went into this century with a large range of medicines for many therapeutic groups and a couple of dozen vaccines – except there is a big gap."

He broke the problem down into six fundamental questions: who sets the priorities, who does it, who pays, who produces it, how do we ensure access, and how do we co-ordinate these activities.

"The question of who sets priorities, and how, is based on a number of considerations, including: mortality and morbidity, disease trends, cost to society, limitations of existing products, alternatives, scientific feasibility, and current industry engagement. These questions are more political than technical. The question of who does the R&D is getting more answers. We have seen several studies that show the market itself doesn't deliver."

The question of who pays leads to other questions. "What is the political feasibility, predictability, and sustainability, fairness in who benefits, and how much independence will we have? Some money comes with more strings attached than others. A successful strategy depends on solid analysis of all options and on building effective alliances."

Dr Quick said there is a lot more knowledge and players today than 5 years ago. "The question of who pays is one of the key blocks right now. Who produces the resulting product is key but, probably the most important thing is predictable demand. There is a great need for co-ordination."

To solve the problem we need at least two types of information, said Louis Currat, executive secretary of the Global Forum for Health Research. The first is institutional – those actors and factors that determine health status of population. The second is economic – the magnitude of problem, its determinants, knowledge today, cost effectiveness, and current levels of investments. "This information will guide decision-makers to priority areas. These will be different for different institutions and countries, but will form a coherent goal. The aim is to enhance synergies, with the objective of influencing thousands of decisions. More information and transparency is needed."

Linking R&D to Access

AIDS is a disease that disproportionately affects the developing world, but also has a market in the West. The debate in recent years has focused on the high price of AIDS drugs, but lessons can also be learnt from the R&D of AIDS drugs.

"AIDS is one of the success stories", said Dr Gill Samuels, vice-president at Pfizer. "In '87 we had one medicine. By 1999 there were more than 60, and more than 102 in 2001. It proves it can be done if the need is there."

Bob Huff from Gay Men's Health Crisis said that although "The R&D situation for HIV drugs is not as crucial as for other illnesses," the drugs aren't perfect. "Efficacy not optimal, toxicity can be worrisome, tolerability is a problem, costs are significant. We need better drugs."

R&D gaps remain, he said. "Drug development is well supported and industry is able to do this work. However, the research on cheap diagnostics and how the drugs are best used is woefully under-supported"

At the International AIDS Vaccine Initiative, linking R&D and access is crucial. “If we scale everything up now, we will still have around 1.5 million infections a year” said Saul Walker. “It [vaccine development] is too urgent a problem to do in a serial fashion – we need several things in the pipeline at once. This increases investment risks - you are trying to invest large amounts of money before all the data is in. Flexibility is important, as is the willingness to take risks.

“Business as usual will not deliver,” he said. “Widespread access in countries most affected will need suitable products, significant supply capacity, rapid regulatory approval, delivery infrastructure, social mobilisation, and financing.”

Partnerships: Different Motivations But A Shared Objective

Joelle Tanguy, director of advocacy and public policy, Global Alliance for TB Drug Development, agreed that “affordability and accessibility must be a priority from the start.” She outlined the urgent need for new TB drugs, stating there had been no novel TB drug for 30 years, because although the disease kills 2 million people every year, they mostly occur in the developing world, making TB an unattractive market for the private sector.

Miss Tanguy said that GATB’s estimates for developing a new drug are much less than the standards industry estimate, at “$US 115 million for the development of a lead compound from preclinical to registration, including the cost of failure.”

The Global Alliance is one of many public-private partnerships currently in existence. “Today there are over 30 public-private partnerships, for prevention, treatment and diagnosis,” said Dr Quick. “You cannot stereotype how these new initiatives work as they are all very different.”

The private, public, and NGO sector interact in complicated ways, said Dr Roy Widdus, of the Initiative on Public-Private Partnerships for Health. “Successful collaboration will depend on a shared objective – although motivations may differ, shared risk taking, shared decision-making, a contribution from each partner, and benefits – some of which will be good PR.”

He said that each of these partnerships is predicated on a win-win proposition. “Different contributions are made by different participants, and each of them get something in return.” The lesson from public-private partnerships, he said, is that “dedicated individuals and initiatives can lead to changes where governments and markets fail. Collaboration is necessary, and I don't regard it as a necessary evil. But true collaboration is hard work.”

Moving R&D into the Public Domain

Speaking from his experience of the Human Genome Project, Dr Tim Hubbard, of the Wellcome Trust Sanger Institute said that “large scale projects delivering high quality, complete products can be conducted in the public domain if the management is right.”

The Human Genome Project was a six-nation collaboration, with a strong structure of line-management, which operated through co-operation and competition: “you want to be ahead of the others – you certainly don't want to be behind – but you share all your information.” He pointed out that the sequencing of the human genome sequence was achieved early, under budget and at a higher quality than originally planned, yet with no profit motive.

“All the data was released in real time, which is very different from how scientific research is normally published. Openness has benefits – it is less hassle, drives progress forwards, and exposes errors,” he said. “Biology is too complicated for any organisation to have a monopoly. The more people who look at a piece of data, the more valuable it is. This fits in with models in other areas such as open source software, Pubmed and Napster, all of which are part of a movement that recognises that openness is worthwhile.”

He concluded with a call for a global R&D fund that would push R&D in the public domain. “A global research & development trade agreement would ensure that each country is committed

to spending a minimum percentage of GDP on healthcare related R&D. This would build national research capacity. Countries would have some ability to target funding to health care issues relevant to its populations. The fruits of research funded by this R&D fund could be required to be open to all signatories to the agreement."

The European Commission has played an active role in shaping public policy in Europe, said Tomas Niklasson of DG Development at the European Commission. "We cannot afford to be satisfied with what has been achieved but we can recognise that some changes have been made. Further action is needed to develop global public goods.

"We think industry has a role to play, and can be guided by an appropriate mix of regulation and incentives," he said. "There is obviously a need to put in place strict conditions and rules – sticks as well as carrots. This is about making the market operate better, and making market operators behave differently. It is not about giving them a free lunch or a windfall." The point was made more forcefully by Dr Mary Moran of MSF: "I want us to be cautious about giving more incentives to a system that we know is expensive and difficult to control."

While overall spending on health research in the private sector ($45 billion) and public sector ($40 billion) are about the same, only 4% of this is spent in developing countries. Charles Clift of the UK Department for International Development (DFID) compared this to spending on agriculture research, where twice as much is spent in the public sector ($22 billion) compared to the private sector ($ 11.5 billion), and 34% of this is spent in developing countries.

"Among the reasons for this are a strong tradition of public sector research, and an only recent application of IP protection relevant to plant breeding," he said. He noted, however, that "there is a danger that public sector research will increasingly be driven by market forces as patenting is embraced by public sector research institutions. Like agriculture, the patenting of intermediate technologies in biomedical research, by both the public and private sectors, may be inhibiting research."

Enhancing Technological Capacity in the Developing World

Priscilla Nyakundi, principle research officer, Kenya Medical Research Institute, gave an overview of the problems faced by poor countries in doing research. "Lack of funding is a result of low GDP, which in sub-Saharan Africa is about US$ 300." Less than 1% of this is allocated to research.

She said there is a need for research funding to motivate scientists. "We have a brain drain because researchers are poorly paid. Those who remain may not be able to compete for funding." Poor communications systems also limit the ability to research and write proposals, she said.

"We need to collaborate through regional and international networks to facilitate research. Transfer of appropriate technology is essential," she said, adding that her institute was able to manufacture drugs. "All we need is a little bit of transfer of technology and some funding. We need technology transfer for diagnostics. Some of us have the technology but are unable to make use of it. We would like to collaborate also in vaccine development. We have the political will, it is an outside boost that is lacking."

"One of the assumptions of TRIPS is that IP will facilitate technology transfer," said Pedro Roffe at UNCTAD. He indicated that a large percentage of exchanges take place within corporate structures. "International firms should ensure that their activities fit into the scientific and technological policies of host countries and contribute to the development of national scientific and technological capacities, including their capacity to innovate."

"The challenge for developing countries" said Sisule Musungu of the South Centre, " is to enlarge the capacity to benefit from science and technology. This implies increased investment in basic sciences, R&D and technological innovation. It is only when each country clearly understands the issues and develops a national capacity that we can hope for developing countries playing their proper role in R&D agenda setting.

He said “developing countries should have the long-term intention to work at technology development as opposed to transfer. Simple transfer implies a continued dependency on the West. It is only when indigenous technological capacity is built that we will hope in the long run to have an effect on R&D for neglected diseases.”

Effective global health research is anchored and based in strong national health research systems, said Tikki Pang from WHO’s Research Policy & Cooperation. “Whether or not knowledge is global, the use of knowledge is local. This is a very important reality.”

Charles Clift reminded everyone that health is about development. Improved health requires not just R&D on health but rising living standards, and better service provision for poor people more generally. The more successful developing countries developed an indigenous capacity for scientific and technological innovation. Health R&D in developing countries depends on contributions from a multiplicity of scientific disciplines.

Do Patents Help or Hinder Research?

At the World Health Organization/Special Programme for Research and Training in Tropical Diseases (WHO-TDR) current R&D for neglected diseases has been focused on opportunities emerging from non-patent protected products, said Dr Janis Lazdins. But making use of patent-protected technologies will be necessary. “Developing drugs for NDs will require tapping into opportunities arising from profitable markets such as signal transduction and transplantation [for malaria], anti-mycotics [for Chagas], animal health [for onchoceriasis], and biological modifiers such as interferons,” he said.

“Intellectual property rights secure a territory, and exclude others from doing R&D. This includes, by default, R&D for neglected diseases,” he said. He explained that “the most difficult thing is to have access to compound libraries, because these libraries are proprietary. Of course you can generate money to buy libraries but this is not the most effective way.”

A mechanism of sharing needs to be promoted. “This is not a paper exercise, it is a physical need – until you send me the substance there is nothing I can do. Most people are reluctant to share such information,” said Dr Lazdins.

Funding R&D for neglected diseases is being increasingly recognized as one of the major challenges facing the international community today, said Dr Jayashree Watal of the WTO Secretariat. “The intellectual property system itself may not be sufficient to provide incentives for research and development into the diseases which mainly afflict the poor in developing countries.”

Dr Watal went on to recall that “TRIPS represents an effort to find an appropriate balance between the need to promote research and development and the need to ensure affordable access to the fruits of these activities.”

Eric Noehrenberg of the IFPMA said that IPR should be looked at as an incentive. “In India, there are over 5 million people with HIV, there are thousands of generic companies, but there is no work being done on AIDS, and only 2,000 people are getting structured treatment**.”** Jeffrey Kemprecos from Merck added that “ TRIPS is the best framework we have ever had. The biotech industry in India is asking for IP. And people who take on our technology turn into the most robust defenders of IP**.”**

Jean-Paul Moatti of ANRS objected. “The fact that not everybody is getting access to antiretrovirals in India does not at all mean that IP is not a barrier for access.” Philippa Saunders from Oxfam added that “India has never had an equitable public health policy; there has been no serious move to introduce one since the Hathi Committee report more than twenty years ago. The blame for inequity of access to medicines cannot therefore be laid at the door of the generics companies.”

Sir John Sulston called for a winding back of the current situation regarding TRIPS. “The TRIPS Agreement should not be implemented until the developing countries are ready for it. People are not taking advantages of safeguards in TRIPS - this is because bilateral agreements by US and EU are being used to bully countries not to use them.”

TRIPS is a social contract, ensuring profits in return for R&D, said Dr Moran. However, the profits were not all going back into R&D. “Some goes into R&D, more goes to shareholder, more again to marketing, making the process more and more expensive. We have privatised the development of our medicines, it is a very expensive way of doing R&D, there is no guarantee that developing country needs will be met , we get a lot of me-too drugs,” she said.

Dr Hubbard agreed. “R&D is paid for by sales; this in turn leads to IP and marketing, which pushes costs up and limits access. This would not happen under a different model.”

The current model was not only expensive, it was also inefficient, said Jorge Bermudez, Director, National School of Public Health/ FIOCRUZ, Rio de Janeiro. “We are shifting to less innovation, and more incremental technology – modifications of existing drugs.” He cited a recent report by NIHCM, which stated that of a total of 1,035 new drugs approved by the FDA in the USA between 1989 and 2000 only 35% were considered new molecular entities.

Towards a Framework Convention

The WHO constitution mandates WHO to work and promote international agreements between countries to promote public health. It has taken half a century, with the introduction of the Tobacco convention, for that mandate to be executed.

“There are 2 reasons why it took so long for a Tobacco Convention to be established,” said Dr Derek Yack. “The first is the utter conservatism of the public health community and their deep mistrust of legal process. The second is the power of commercial interests. They tend to fight as strongly as they can against legal regulation, and when opposition fails they move to co-option. It was opposed by industry, front groups and other vested interests.”

Dr Yack said that while the first discussion was over a decade ago, it took the appointment of Dr Brundtland, who stood up against industry, to accelerate the process. He stressed the importance of WHO’s involvement. “As a specialised agency we have the right to put out what we think is best.” He said that the process in itself was important. “You cannot underestimate the power of governments coming together over a sustained period of time to discuss an issue.”

Dr Yack pointed to a number of effective treatises relating to air pollution, marine life, and biodiversity, all of which have had measurable outcomes. David Hohman added that “there are a couple of models behind tobacco. Look at the cloning convention and the convention of the rights of people with disabilities. Both of these started out with committees composed of Member State members.”

A clear set of goals was essential said Dr Yack. “For Tobacco we had a simple set of problems, clear commitment, clear scientific solutions. What you are doing is much more complex but that doesn't mean that you shouldn't start now and this meeting is an excellent starting point for it.” He added that it was important to be very clear about the objectives. “There are many health R&D needs ranging from vaccines, treatment, diagnostics, research into infrastructure, health systems, to prevention and health promotion.” He ended with the caveat that “the idea of a global fund for R&D will get a lot of support from developing countries but it will probably fall apart at the last minute because rich countries won't put the money in.”

Charles Clift of DFID was questioned why an R&D treaty was the best approach, both theoretically and politically. “Very few, if any, governments will commit themselves to long term funding increases via an international treaty. Is an R&D treaty best negotiated around health, or around increasing the scientific and technological capability of developing countries more generally?”

Jamie Love said we already have an R&D treaty. “Its called the TRIPS agreement. But TRIPS is a limited and problematic framework for addressing global R&D.” Love argued that R&D could be annexed to the WTO agreements. “The WTO got over the promises without action scenario, and maybe that's why we want to tag on to it.”

One of the problems with the current system is that the R&D process is paid for by sales, which limits access. “If a medicine is free, whoever wants it gets it. But if you have to get the people who buy the product to pay for R&D then the cost goes up. If you then ask them to pay for marketing then the price goes up even more and even less people get treated.” He said “This relates to people in developing countries but increasingly also people in the US and Europe. Even for a relatively wealthy country, the requirement that high price pays for R&D leads to these scenarios. So there are competing goals between access and paying for R&D.”

“Private benefits” he said “are not equal to social benefits.”

Rémi Parmentier, of ASH and Greenpeace, said that “experience shows that treatises and conventions work only if NGOs act as a very active watchdog and remind governments to meet their legal obligation and duty and put their words into action.”

What needs to happen

- define a needs-driven international R&D priority agenda
- commit all countries to contribute to R&D for health
- outline an agreement and clear rationale for sharing the burden of the cost of this R&D
- define appropriate funding and incentive mechanisms for governments to fulfil their commitments to public sector involvement in R&D
- establish and strengthen international mechanisms for exchanging and transferring research results, knowledge, and technology
- ensure that developing country involvement in public R&D is central, including through North-South and South-South collaboration, and through the conduct of such R&D in disease-endemic countries.

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Ellen ‘t Hoen said she thought that “on the issue of R&D we are making progress. People no longer say there is no longer a problem. I remember three years ago people from industry and WHO and so on would come to these meetings and say that they were doing lots of wonderful things, we've got it all under control. Those days are gone.” Dr Quick added that “The fact there were people here from four different diseases clusters is significant. You are on a critical point and we are here to respond to that.”

Sisule Musungu said “I think dealing with this within the international framework is important. This cannot be an issue of G8 countries deciding what to do. I am convinced that only through multilateral processes will we be able to deal with the challenge.”

Concluding Remarks

Some concluding remarks were made by Sir John Sulston. His concern was that “We are building barriers in our collective societies, most by the rich against the poor. The fundamental issue is redistribution of wealth.”

“Remember the old adage - if you give them a fish you feed them for a day. If you give them a fishing rod then they can feed themselves for a lifetime and other generations get fed too.” He said. “I'm not beating up on industry; industry is doing exactly what it is set up to do, and one of those things is to defend their products at all costs. It is up to our governments. In that way you are making the fishing lines. This means the G8 giving away some of their wealth.”

Sir Sulston concluded with a warning against the profit motive. “The rich societies have been more and more clearly trying to put a price on everything. But as we do go down this road of trying to put a price on anything including our own ideas, we are throwing our own goodwill out the window.”