
Draft global strategy and plan of action on public health, innovation and intellectual property

Public–private partnerships for health-care product development: benefits, challenges and products

Report by the Secretariat

1. The Commission on Intellectual Property Rights, Innovation and Public Health issued a report in 2006,¹ highlighting the urgent need for appropriate new products – including vaccines, diagnostics and treatments – in order to tackle the health needs of poor people more effectively.
2. The present document examines public–private partnerships for product development in terms of the benefits they provide, the challenges they face and the contribution they are expected to make in the future.
3. There has been a marked growth in the number of partnerships of this kind in the last few years. One analysis² sees this as the result of changes in attitudes and sociopolitical ideology; of a need to find a new approach capable of improving the response of the private and public sectors to international public health challenges; and of a recognition that emerging health problems (of which the advent of HIV/AIDS was an example) require a range of responses that are beyond the capacity of either the public or private sectors operating independently.

BENEFITS

4. On the basis of current evidence, the principal benefits of public–private partnerships for new health-care products include an increase in the number of products in development, greater funding and the potential for lower development costs, a reduced time to market, improved availability of, and access to, the products in question, an improved health impact and higher innovation levels.

¹ Document CIPIH/2006.1.

² Buse K, Walt G. Global public–private partnerships: part I – a new development in health? *Bulletin of the World Health Organization*, 2000; **78**(4): 549–561.

5. The Commission's report notes that "the emergence of public-private partnerships for product development has been a very significant development within the past decade They have significantly increased the number of products in development for diseases and conditions predominantly affecting developing countries."

6. A study issued in 2005 found that public-private partnerships of this type were responsible for three quarters of all identified drug development projects for neglected diseases, and concluded that, of the projects carried out by multinational companies, most either involved partnerships already, or were likely to do so in the near future.¹ The study considered that the increasing use of partnerships is encouraged by advantages that can be obtained in two central areas: funding and skills.

7. Public-private partnerships for product development do not directly develop drugs. They operate by bringing together research partners from academia and the private pharmaceutical and biotechnology sectors, and by securing public-sector funding. Performing what has been termed "virtual" research and development,² these partnerships' main functions are: the integration and coordination of multiple partners and contractors throughout the course of drug development; the allocation of philanthropic and public funds to appropriate research projects; and the management of portfolios of research and development projects in the area of neglected diseases.¹ The latter function has been seen as critical to the success of such partnerships, allowing them to spread risks.

8. It is possible for a candidate product to come under the influence of a public-private partnership in a variety of ways and at any point in the continuum from research to access via development. The Commission's report notes that companies can set up relatively inexpensive programmes by focusing on the early stages of research and development, which require a significantly smaller investment, on the basis that the expensive clinical trials phase (and some of the early-stage research) can be subsidized by a public-private partnership or through other public or non-profit funding.

9. The Commission's report concluded that public-private partnerships may have the potential to develop products at much lower costs than the pharmaceutical industry. One study noted mounting evidence of the effectiveness and efficiency of direct research funding channelled through public-private partnerships for product development in the neglected disease sector.³

10. The same study also described broader benefits. Recognizing that empirical evidence is currently limited as many such partnerships have only recently come into existence, the study nevertheless argued that in the area of neglected diseases, the products of these partnerships have proven to be of value in terms of their time to market, health impact and degree of innovation. Such partnerships are likely to yield improved product efficacy, access, and acceptability thanks to their ability to bring together the best mix of technical, scientific and clinical expertise in the area of neglected diseases; to enable access to facilities that multinational companies may not have; to apply knowledge of product profiles, markets, and processes in developing countries; and to give consideration from the outset to issues relating to access and use.

¹ Moran et al. *The new landscape of neglected disease drug development*, London School of Economics and Political Science and the Wellcome Trust, London, 2005.

² Widdus R, White K. *Combating diseases associated with poverty: financing strategies for product development and the potential role of public-private partnerships*, The Initiative on Public-Private Partnerships for Health, Global Forum for Health Research, 2004.

³ Grace C. *Developing new technologies to address neglected diseases: the role of product development partnerships and advanced market commitments*, London, DFID Health Resource Centre, 2006.

11. The Commission's report further concluded that public-private partnerships constitute a new, effective and important means of pursuing research and development that is relevant to the health needs of developing countries. They offer the promise of developing products in a cost-effective manner, making use of the diversity of new actors in the field of biomedical research.

CHALLENGES

12. To date, the principal challenges identified for public-private partnerships for product development include ensuring sufficient and sustained funding, and efficient management and organization; and meeting the expectations raised.

13. There is widespread concern, expressed for example in the Commission's report, that insufficient and/or intermittent financing may prevent partnerships from fulfilling their promise. Partnerships of this type rely heavily on private, not-for-profit funding, with governments playing a relatively small role. A study of 24 partnerships, conducted for the Commission,¹ indicated that foundations contributed 75% of the funding. The Bill & Melinda Gates Foundation alone funded 60% of the total, and was the single funding source for nine of the partnerships. Furthermore, the study cited an estimate of the annual funding gap for these partnerships of between US\$ 400 million and US\$ 700 million.

14. The Commission therefore made a number of recommendations in its report.

- Current donors should sustain or increase their funding for research and development to tackle the health problems of developing countries.
- More donors, particularly governments, should contribute to increasing funding and helping to protect public-private partnerships and other research and development sponsors from changes in policy by any major donor.
- Funders should commit funds over longer time frames.
- Public-private partnerships for product development need to continue to demonstrate that they are using their money wisely, that they have transparent and efficient mechanisms for accountability, and that their constituent partners coordinate, collaborate, and continue regularly to monitor and evaluate their activities.
- The pharmaceutical industry should continue to cooperate with these partnerships and increase contributions to their activities.
- Research institutions in developing countries should be increasingly involved in conducting research and trials.

¹ CIPIH study: Ziemba E, *Public-private partnerships for product development: financial, scientific and managerial issues as challenges to future success, SHARED INC*. Accessible online at <http://www.who.int/intellectualproperty/studies/Ziemba.pdf>.

15. A paper published in 2003 concludes that such “virtual” research and development for drugs is effective, but that it poses new management and organizational challenges.¹ It requires experienced management, together with an understanding both of the relevant diseases and the research and development processes for drugs to treat them, and of the different perspectives and needs of all the partners involved. Transparency, teamwork and commitment are of paramount importance to the success of such partnerships.

16. The overriding challenge for public–private partnerships for product development, given sufficient funding, is to respect the demanding specifications and timescales they have set themselves for delivery of new products. Not all candidate products will be successful: for example, the Institute for OneWorld Health terminated work on K777 (a cysteine protease inhibitor for use in Chagas disease) when preclinical studies suggested it was hepatotoxic.

PRODUCTS

17. The Secretariat has identified 18 major public–private partnerships and partnership activities for product development that are currently devoted to products for diseases that predominantly affect developing countries. The following diseases are concerned:

- HIV/AIDS and tuberculosis (Type II diseases)²
- Chagas disease, dengue and dengue haemorrhagic fever, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, and schistosomiasis (Type III diseases).

18. Of the diseases mentioned above, lymphatic filariasis, onchocerciasis and schistosomiasis lack dedicated public–private partnerships for innovative product discovery and development;³ however, they fall within the ambit of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, which, although not a public–private partnership, forms partnerships with both public and private organizations.

19. Over the past 30 years, the development of most products for diseases affecting developing countries has involved some form of partnership between the private and public sectors (notably through the Special Programme, with, in the case of malaria, the additional involvement of the Walter Reed Army Institute of Research of the United States of America, together with Chinese governmental institutes). With the advent of the new range of public–private partnerships, the pace of partnership development is accelerating. Since these partnerships have only been established relatively recently, evidence of outcomes in terms of products developed is necessarily limited. However, the number of products in the pipeline for most Type II and Type III diseases is encouraging. The 18 partnerships and partnership activities referred to above concern the following diseases:

¹ Nwaka S, Ridley R. Virtual drug discovery and development for neglected diseases through public–private partnerships, *Nature Reviews Drug Discovery*, 2003, 2: 919–928.

² Type II diseases are incident in both rich and poor countries, but with a substantial proportion of cases occurring in poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries.

³ Nwaka S, Hudson S. Innovative lead discovery strategies for tropical diseases. *Nature Reviews Drug Discovery*, 2006, 5: 941–955.

- HIV/AIDS

- (a) The Contraceptive Research and Development (CONRAD) Program – with two additional subprogrammes established by CONRAD:

- (i) Consortium for Industrial Collaboration in Contraceptive Research

- (ii) Global Microbicide Project

- (b) HIV Vaccines Trials Network

- (c) International AIDS Vaccine Initiative – several vaccine candidates with nearly 30 clinical trials under way

- (d) South African AIDS Vaccine Initiative – several projects, including a number of clinical trials

- (e) International Partnership for Microbicides

- (f) Microbicides Development Programme

- Tuberculosis

- (a) Global Alliance for TB Drug Development – eight candidate drugs in discovery phase, four in development phase

- (b) Aeras Global TB Vaccine Foundation – some vaccine candidates in clinical trials

- (c) Foundation for Innovative New Diagnostics – several development projects for tuberculosis diagnostics

- (d) UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases – one drug in development phase

- Malaria

- (a) Medicines for Malaria Venture – 20 candidate drugs in discovery phase (including preclinical development), six in development phase

- (b) Drugs for Neglected Diseases initiative – one drug in development phase, one in post development

- (c) Institute for OneWorld Health – one project in discovery phase

- (d) Malaria Vaccine Initiative – nine vaccine development projects

- (e) European Malaria Vaccine Initiative – several projects under way

- (f) Foundation for Innovative New Diagnostics – activity initiated

(g) UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases – several candidate drugs in early discovery phase prior to feeding into the public–private partnership pipeline; two in development phase.

- Type III neglected diseases

(a) Drugs for Neglected Diseases initiative – nine candidate drugs in discovery phase, three in preclinical development, and four in development phase for Chagas disease, human African trypanosomiasis and visceral leishmaniasis

(b) Institute for OneWorld Health – one project in post-development phase for leishmaniasis

(c) Dengue Vaccine Project

(d) Foundation for Innovative New Diagnostics – human African trypanosomiasis

(e) Pediatric Dengue Vaccine Initiative

(f) UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases – several network-driven drug projects in early discovery phase for kinetoplastids (Chagas disease, human African trypanosomiasis and leishmaniasis) to feed into the public–private partnership pipeline; four in discovery phase through the Helminth Drug Initiative (filariasis, onchocerciasis and schistosomiasis); one in development for onchocerciasis; and one in post-development phase for leishmaniasis.

CONCLUSION

20. Public–private partnerships have been shown to enable individual projects to produce innovative products for neglected diseases.

21. The recent growth in not-for-profit organizations dedicated to the development of products for specific types of neglected diseases has encouraged strong portfolios of projects and provided greater opportunities for making new products available to treat, diagnose and prevent neglected diseases. It has also meant that portfolios can be managed collectively on a larger scale and in a more professional manner than was previously the case.

22. In order to sustain these improvements, efforts will need to be made to maintain or increase the level and diversity of funding, and to continue or improve the professionalism of activities to realize the promise of new products.

23. Consideration needs to be given to ways to meet the strategic challenge of ensuring that the multiple portfolios of activities continue to be aligned to public health needs without inhibiting innovation; that new products are effectively evaluated and, once they become available, made accessible for delivery and use, within the context of public health policy; and that globally the involvement of stakeholders in discovery, development and delivery of new products for neglected diseases is appropriately spread in order to include both developing and developed countries.

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