

## **WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: Draft Global Strategy and Plan of Action**

### **Comments by the Wellcome Trust**

**September 2007**

#### **Introduction**

1. The Wellcome Trust is pleased to have this opportunity to comment on the WHO Intergovernmental Working Group's (IGWG) Draft Global Strategy and Plan of Action on public health, innovation and intellectual property. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £500 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. The Trust devotes a substantial portion of its funding to research on health problems that disproportionately affect developing countries. We agree that there is an urgent need for global cooperation to enhance the development of, and access to, health products for these countries. We commend the WHO and the IGWG for taking on the task of creating a strategy to achieve this. However, the current draft must be made more focused and more specific if it is to provide a workable framework for action. Below we have elaborated on four issues that we consider essential for the IGWG to address:
  - Sustainable funding for product development public private partnerships (PDPs);
  - Coordination and increased funding for health research capacity strengthening;
  - Prioritising global R&D needs for neglected health products and sharing information on who is filling those needs; and
  - Management of publicly funded IP to promote its application to developing country needs.

#### **Sustainable funding for product development public private partnerships (PDPs)**

3. The strategy and plan of action needs to include long-term commitments from national and multilateral donors to increase funding for PDPs. The PDP model has proven very effective at combining the strengths of R&D capacity in the public and private sectors, in the North and the South.<sup>1</sup> A strong array of PDPs will be one of the best ways of taking forward the development of new products for low income markets.
4. There is now a real deficit in funding the PDPs as they move into large-scale clinical trials. Furthermore, with about half of PDP funding coming from just one source (the Gates Foundation) there is an urgent need to diversify their funding base. Ideally, national and multilateral donors who currently do not play a major role in this area could commit during the IGWG negotiation process to provide more funding.

<sup>1</sup> As demonstrated in Mary Moran et. al. (2005) "The New Landscape of Neglected Disease Drug Development" <http://www.wellcome.ac.uk/assets/wtx026592.pdf>

5. Some pharmaceutical companies are to be applauded for their in-kind support to PDPs but it is important to foster strong commitments from more companies. WHO may be able to catalyse this through more engagement with the industry leaders and industry associations, and by convening pharmaceutical companies, funders and PDPs.
6. To deliver top quality PDP clinical trials in developing countries, more training of individuals and more funding for developing country clinical trial sites must be provided. The INDEPTH network currently provides an important base for malaria trials but more clinical trials infrastructure is required. There is also a crucial need to provide career pathways for key individuals involved in clinical trials – including between trials – otherwise teams are lost and expertise dissipates. Personnel exchanges between PDPs and pharmaceutical companies could be key tools in this type of capacity building.

### **Coordination and increased funding for health research capacity strengthening**

7. Donors and research institutions in the South and North should coordinate their efforts to strengthen health research capacity. We believe that there is a particular need to strengthen the ability of African research institutions to build their capacity. In April 2007, the Trust sponsored a meeting in Kilifi, Kenya to convene leaders of African research institutions and funders to discuss how the groups could better collaborate to achieve this aim. Some recommendations that came out of the meeting were:
  - Health *service* capacity strengthening is often a prerequisite to health *research* capacity strengthening, because academic medical centres can otherwise be overwhelmed by the need to provide health services and be unable to find time for research;
  - In supporting health research capacity in the UK and developing countries, the Trust takes the approach of developing people and supporting them throughout their careers. This is no less important in building and sustaining research capacity in developing countries. It needs to start early, with well-trained school teachers, strong school science education and research experience opportunities for undergraduates. For those who go on to a PhD, there must be job opportunities at different levels of seniority, with some degree of competition but not to the extent that good scientists are forced to abandon a research career due to lack of job opportunities. To avoid “brain drain”, internationally competitive researchers must be given adequate opportunities and incentives to remain in, or to return to, their home countries. Girls and women need to be recruited and encouraged into this pipeline from the beginning.
  - Supporting senior scientists should be a priority, in order to strengthen the cadre of leaders and role models. This can be done by nurturing junior researchers, attracting senior scientists back from abroad, and nurturing those already in post.
  - Research institutions need support for organisational and management processes.
  - Northern institutions should be encouraged to establish long-term partnerships with institutions in the South, rather than short term projects or visits. South-South partnerships should also be encouraged and supported. Southern institutions need support to build negotiation skills so that they can more effectively negotiate with funders and Northern partners.

### **Prioritising global R&D needs for neglected health products and sharing information on who is filling those needs**

8. The WHO should convene health experts from the South and North to prioritise health problems of developing countries that are in need of better technical solutions. The 14 conditions identified in the draft strategy are a good starting point – we are especially pleased to see the attention to type I, type II and type III diseases – but the prioritisation of health

problems must be explicitly supported by evidence, and must be able to change according to the evolving understanding of global needs. For example, the need for developing country-specific research on chronic diseases has been recognised only relatively recently, and new infectious agents are continually evolving. Likewise, research priorities must be able to change based on the progress of R&D for specific health conditions: as the basic understanding of diseases advances, R&D priorities must be able to take advantage of new opportunities, or abandon dead ends.

9. The WHO should also provide a forum for research sponsors in the public sector and the private sector to share information on what R&D they are supporting that has relevance to priority health problems. Even within the public sectors in individual countries, research funders are still working out the best ways to coordinate their activities to achieve common goals. In the UK, the newly established UK Collaborative on Development Sciences is bringing together the key government and philanthropic research funders, including the Wellcome Trust, to coordinate support for research that directly or indirectly relates to international development. Progress on coordinating public sector activity on a global scale is still far behind where it needs to be.
10. Engaging the private sector in this process will be more of a challenge, due to the need to protect commercially sensitive information. Information sharing arrangements for industry partners will need to be designed to respect these requirements.

#### **Management of publicly funded IP to promote its application to developing country needs**

11. Universities and public sector research institutes, with encouragement from public and charitable research funders, should take IP management decisions with a view to maximising opportunities for the inventions to be used to benefit poor populations in developing countries. When licensing IP to commercial partners, this may mean including terms that preserve access to the technologies to address needs of developing countries, particularly if the primary licensee does not intend to serve those markets. The IGWG strategy should encourage these practices.
12. Oftentimes, IP that could be developed to serve neglected health conditions does not attract interest from commercial licensees or investors. Therefore, what is required is a commitment from technology transfer offices at universities or public research institutes to invest time and effort to seek other translation opportunities for these inventions. This may involve making contact with PDPs or other non-commercial partners, or identifying public or charitable sources of translational funding to further develop the technology. Doing this requires university leaders and technology transfer offices to be committed to translating research results to produce global public benefit, rather than narrowly focusing on translation as a means to achieve financial returns.
13. In some countries, including the UK, there is currently a lack of clarity on whether the driving force of a university technology transfer should be making money for the university, or exploiting technology for societal benefit in line with the university's charitable mission. Governments and research funders need to make it clear that the function of technology transfer in public institutions is to deliver the benefits of technology to the global public.