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### **Background Document for Proposed Resolution on Global Framework on Essential Health Research and Development**

1. This resolution is a response to a growing concern over the inadequacy of the current global system for supporting innovation in new medicines and other health technologies, as well as concern about the impact of an increasing percentage of people without access to essential medicines and other technologies for health care, both in terms of their financial affordability and availability.
2. The resolution seeks the establishment of a global framework for supporting essential medical research and development predicated upon the principle of equitable sharing of the costs of research and development, and incentives to invest in useful research and development in the areas of patients' need and public interest. The process to carry this forward include the creation of a working group of interested Member-States that would submit a progress report to the Sixtieth World Health Assembly (May 2008) and a final report with concrete proposals to the Executive Board at its 121st session (January 2009). As the lead global agency on health needs, WHO plays a crucial role in priority setting and the development of policy recommendations on how priority research can be carried out.
3. Member States are also asked to make global health and medicines a strategic sector and take determined action to ensure that R&D efforts address the areas of priority for patient needs, especially for those living in resource-poor settings, to harness collaborative R&D initiatives involving disease-endemic countries, and to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – and that such systems work to ensure that essential medicines are rapidly delivered to people, with special attention to those living in poverty.
4. Global trade agreements that focus solely on drug patents or drug prices do not provide sufficient incentives for development of priority medicines, including but not limited to medicines that are essential to treat and cure diseases that primarily affect patients living in poverty, or many of the public goods that are essential for the development of new medical technologies. High drug prices constitute increasing barriers to access in all countries. There are also inadequate mechanisms to enhance the capacity of all countries to contribute and participate in medical innovation efforts.
5. While the shortcomings of the current system are important everywhere, the impact on those living in poverty is particularly harsh. Every day over 35,000 people die from infectious diseases such as AIDS, malaria, tuberculosis, and other neglected diseases such as Leishmaniasis, Chagas disease and sleeping sickness. These diseases affect hundreds of millions of persons, yet we lack safe, affordable, effective, field-adapted vaccines, diagnostics, and drugs to tackle them.
6. In cases where medicines are needed where significant numbers of patients have higher incomes, there is disproportionate emphasis on products that do not provide incremental benefits over existing ones. A breakdown of the 1,035 new drugs approved by the US FDA (Federal Drug Administration) between 1989 and 2000 revealed that more than 3/4 are classed as having no therapeutic benefit over existing products, so-called 'me too' drugs (NIHCM 2002). At the same time it was noted that less than 1% addressed diseases that primarily afflict the poor and for which new treatments would have the greatest effect on world healthcare (WHO 2003).
7. There is a growing need to develop new medicines to address emerging health threats such as multi-drugs resistant TB, SARS, avian flu, and other infectious diseases. Basic science about infectious diseases exists

and biomedicine is developing extremely fast, but there exist inadequate sustainable mechanisms and incentives to turn such knowledge into useful products. There is continued need for new antibiotics, in the race between society and the pathogen, where each new drug provides only a temporary breathing space. The current systems of incentives do not provide sufficient support for the pre-emptive development of new drugs for resistant strains of disease since there is no market until resistance is widespread. Growing resistance of bacteria to existing antibiotics is already a global concern as few new treatments are being developed. The public needs to develop more effective treatments for potential health pandemics, like SARS or avian flu, before such pandemics occur, and to utilize business models for drug development that ensure that treatments are effective and accessible in resource poor settings, and benefit everyone, including persons living in poverty.

8. There is insufficient funding for research and development for new vaccines for AIDS and other illnesses. Most of the 3.1 million persons who died of AIDS related illnesses in 2005 were living in poverty. The development of such vaccines is a global public good, and requires a multilateral strategy for widespread access. Existing market incentives are apparently insufficient to encourage the development of many vaccines, and while some research has been successfully completed outside the commercial sector, new mechanisms are required to support the costs of vaccine development and production.

9. Global public goods such as the Human Genome Project (HGP) and other open and accessible public research projects advance science knowledge, and also facilitate access to that knowledge, and the transfer of technology. It is accepted that health research has been accelerated through immediate free access to the sequence of the human genome and other related genomic datasets. This success can be seen as part of a larger shift in public policy towards requiring research data to be openly accessible (Arzberger et al. 2004) through recognition of the additional benefit it brings. The creation of global public goods relevant to health research could be further incentivised through recognition of each countries support for them.

10. As well as allowing easy data sharing, the Internet has dramatically lowered the cost of collaboration, thereby proving the potential to substantially improve health research productivity. As a result, open collaborative models for research and development are now proving a competitive alternative to traditional closed proprietary models, such as open source software development. These models have the potential to be extended to the development of medical science (Economist, 2004). Open access business models for scientific publishing are also proving successful, as a result of the low cost of disseminating information through the Internet. It has been recognised that their widespread adoption has huge advantages for the dissemination of knowledge and transfer of technology as well as being sustainable (Wellcome Trust 2003).

11. New public private partnerships (PPPs) devoted to the development of new essential drugs and research tools are important, but there is a need for sustainable sources of funding for such initiatives. Recently some encouraging initiatives to accelerate the development and delivery of health tools for the poor have emerged. Not-for-profit partnerships in the field of infectious and tropical diseases have been established, and are beginning to build a pipeline for projects, in response to the needs of neglected patients (Moran 2005). However, the sustainability of PPPs is in question, as the majority are mainly funded by philanthropic actors. It is particularly unclear where the resources to finance the very expensive later stages of development and clinical trials will come from. Moreover, the response of PPPs remains very limited compared to the global needs. The WHO Special Programme for Research and Training in Tropical Diseases (WHO/TDR) has contributed significantly to the development of new products to be safely used in developing countries, especially in country disease-control programmes, but its health performance has suffered from increasingly severe funding constraints. Redirecting today's knowledge and scientific expertise to realistically address essential health needs will mean a substantial shift in the way health products are valued, financed and made available.

12. A number of developing countries have been strengthening their capacity for new health technologies, and their role in performing and directing health care research will be increasingly critical. New models and financial mechanisms must be pursued in order to create a better environment for health innovation. Technology transfer and research capacity strengthening in disease endemic countries should be at the heart of the endeavour, by making full and appropriate use of the scientific knowledge and resources that already exist in developing countries. International cooperation on R&D should be encouraged, so as to promote scientific

training in all developing countries and their increasing involvement in R&D efforts that respond to public health problems.

13. Intellectual property rights are one of several important tools to promote innovation, creativity activity and the transfer of technology. At the same time, it is important to recognize the need for the proper balance between intellectual property rights and the public domain, and the need to implement intellectual property rules in a manner that is consistent with the basic human right to health, and the promotion of follow-on innovation. Stronger intellectual property rights do create incentives to invest in some types of medical innovation, although in some cases, at a cost of reduced access. It is also well recognized that in some areas, intellectual property rights are not an effective or appropriate tool to stimulate innovation. It is important that the global framework for supporting medical innovation recognise all mechanisms that stimulate and incentivise R&D, including public sector funding of R&D, or new business models for stimulating private investments, such as innovation prizes. There are increasing worries that in some cases R&D is slowed by the complexities of dealing with large numbers of patents (CIPRGPRI, 2005). A recent survey has quantified how serious the situation is, showing that more than 20% of human genes are patented, some as many as 20 times (Jensen and Murray 2005). Patent thickets can make licensing difficult and inhibit follow on innovation. A balanced framework for medical innovation does not rely upon a single incentive mechanism to stimulate innovation, but rather considers a wide range of mechanisms, each with its own strengths and weakness, within different institutional, cultural and social settings.

14. Awareness that the current system for driving innovation requires serious examination was reflected in the establishment by WHO of the Commission on Intellectual Property, Innovation and Public Health to "produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries." It has also led to a number of private calls for a new global framework to support medical innovation, including for example a 24 February 2005 request from 162 scientists, public health experts, law professors, economists, government officials, members of parliaments, NGOs and others asking the WHA Executive Board for an evaluation of proposals for a new global trade framework on medical R&D, and a "Global Appeal on R&D for Neglected Diseases" launched on 8th June 2005 with the support of 18 Nobel Laureates, and the support of over 2500 scientists and health experts, academics, NGOs, public research institutes, governments officials and members of parliament, calling for new policy rules to stimulate essential health R&D, especially for the most neglected patients. There are also many other more narrowly targeted calls for increasing R&D funding for vaccines or microbicides to prevent the spread of AIDS (IAVI, 2005), new treatments for TB, hepatitis, and other areas where safe, affordable, and effective treatments are needed.

15. Other UN bodies are also considering aspects of these issues in a serious and determined manner: in 2004, the World Intellectual Property Organization (WIPO) began a debate on a new "Development Agenda," which includes discussions of how to fashion intellectual property systems in order to promote both innovation and access. Parallel to the UN agencies, the World Trade Organization (WTO) adopted the Doha Declaration on TRIPS and Public Health in 2001, which asked Members to implement intellectual property laws in a manner "to promote access to medicine for all."

16. It is now timely and appropriate to create a forum where WHO Member-States can evaluate various proposals to create sustainable mechanisms for the support of needs drive medical R&D, that are consistent with the need for the development of and access to essential medicines for all, including those living in poverty.

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