

[Global framework on]essential health research and development

Proposed text	EC position	Fallback
[Title]	Delete [Global framework on].	
The Fifty-ninth World Health Assembly,		
1. Recalling resolutions WHA52.19, WHA53.14, WHA54.10, WHA56.27, and WHA57.14;	Acceptable.	
2. Considering the need to develop safe and affordable new medicines for such communicable diseases as AIDS, malaria and tuberculosis, and for other diseases or illnesses that primarily affect the world’s poorest people;	Acceptable.	
3. Recognizing the importance of providing support for the development of treatments for diseases that have small client populations;	Acceptable.	
4. Recognizing the importance of making global health and medicines a strategic sector;	Delete.	Prefer to reword – what does it mean? What is ‘a strategic sector’? But acceptable if necessary.
5. Concerned about the need for appropriate, effective and safe health tools for patients living in resource-poor settings;	Acceptable.	
6. [Mindful that more than 70% of new drug approvals are for medicines that do not provide incremental benefits over existing ones; ¹]	Prefer to delete; our focus should be on developing new medicines, not criticising the licensing and approvals process, and this figure is in any case based on flawed methodology.	Acceptable if necessary.
7. Considering the urgency of developing new medicines to address emerging health threats such as multidrug-resistant tuberculosis, and other infectious diseases of relevance to developing countries;	Acceptable (though greater clarity over what exactly this addresses would be welcome.	
8. Aware of the need for additional funding for research and development for new vaccines, diagnostics, and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries;	Acceptable.	

9. [Recognizing the importance of global public undertakings such as the Human Genome Project, and the increasing relevance of open and accessible public research in advancing science and the transfer of technology;	Delete “increasing” – if anything, it is privately-funded research that is increasingly relevant.	Acceptable if necessary.
10. [Further aware of the promise of new, open models for the development of medical science, enhanced participation in, and access to, scientific advances, and increased knowledge;	Delete.	Acceptable if clarified.
11. [Recognizing the importance of public/private partnerships devoted to the development of new essential drugs and research tools, but concerned about the need for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives;	<ol style="list-style-type: none"> 1. Replace ‘Recognising’ with ‘Note’ 2. Replace “concerned about” with “and”; this implies that governments do not set such a priority agenda, which most do. 3. Split into two recitals at the first comma. 	Acceptable if necessary.
12. [Recognizing the importance of public and private investment in the development of new medical technologies;]	Acceptable and important.	
13. Considering that a number of developing countries have been strengthening their research and development capacity in new health technologies, and that their role will be increasingly critical, and recognizing the need for continued support for research in and by developing countries;	Acceptable and important.	
14. Recognizing that intellectual property rights are one of several important tools to promote innovation, creativity, and the transfer of technology;	Acceptable and important.	
15. [Recognizing at the same time the importance of providing for a 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 fundamental right of every human being to the enjoyment of the highest attainable standard of health and the promotion of follow-on innovation;]	<ol style="list-style-type: none"> 1. Delete “proper”. 2. Replace with: “Recognizing at the same time the important of providing a balance between intellectual property rights and the public domain, noting the role that 	Acceptable if necessary.

	intellectual property rights play in bringing knowledge into the public domain in order to promote follow-on innovation.	
16. Taking into account Article 7 of the TRIPS agreement that states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”;	Acceptable.	
17. Stressing that the Universal Declaration of Human Rights provides that “everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”;	Acceptable.	
18. [Considering that it is imperative to reconcile the public interest in accessing the products derived from new knowledge, with the public interest in stimulating invention;]	Prefer to delete as repeated recital 15.	Acceptable if necessary.
19. [Concerned about the impact of high prices of medicines on access to treatment, and the need to implement intellectual property laws in a manner that reconciles incentives for development of new medicines with the need to promote access to all, consistent with paragraphs 4, 5 and 7 of the Doha Declaration on TRIPS and Public Health;]	Split into two recitals at the first comma, in order to less immediately link IPR to prices.	Acceptable if necessary.
20. Aware of the need for [a new global framework (mechanism) to provide] adequate and sustainable levels of financial support for public health needs-driven research, including in particular for priority medical research;[including the possibility of exploring a new global	Original text acceptable; text in brackets not.	Seek alternative text focusing on the outcome of sufficient investment, rather than the process of new frameworks.

framework]		
21. [Considering the global appeal on research and development on neglected diseases launched on 8 June 2005 with the support of 18 Nobel Laureates, over 2500 scientists and health experts, academics, nongovernmental organizations, public research institutes, governments officials and members of parliament, calling for [Noting the need for] new policy [rules] [approaches] to stimulate essential research and development in health, especially for the most neglected diseases;]	Prefer to delete.	Acceptable if necessary.
22. Aware of the need to promote new thinking on the mechanisms that support innovation;	Acceptable.	
23. Recognizing the importance of strengthening capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts,	Acceptable.	
1. URGES Member States:	Amend to refer also to “regional economic integration organisations, where appropriate,”.	
(1) to make global health and medicines a strategic sector, to take determined action to emphasize priorities in research and development addressed to the needs of patients, especially those in resource-poor settings, and to harness collaborative research and development initiatives involving disease-endemic countries;	Delete “to make global health and medicines a strategic sector” – this is not clear (although it may have been clarified in the related recital above);	
(2) [taking into account [the results of the Commission on Intellectual Property Rights, Innovation and Public Health and] existing frameworks, to take an active part, in cooperation with WHO and other international actors, [in the establishment of a framework for defining global health priorities] in supporting essential medical research and development [based on the principle of equitable sharing of the costs of research and development by all those who benefit from it] and incentives to invest in useful research and development in the areas of patients’ need and public interest;]	Acceptable, except: 1. Delete [in the establishment of a framework for defining global health priorities] – no new structures are needed. 2. Delete “[based on the principle of equitable sharing of the costs of research and development by all those who benefit from it]”.	
(3) to ensure that progress in basic	Add “to <u>work to</u> ensure	Acceptable if necessary.

science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients’ and clients’ needs, especially those living in poverty, taking into account the critical role of gender and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people;	that..”	
[(4) to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;]	Delete “bilateral”.	
[(5) to ensure that the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health is included on the agendas of WHO’s regional committees in 2006;]	Acceptable.	
2. REQUESTS the Director-General:		
(1) to establish an open-ended working group of interested Member States to consider proposals to [establish a global framework for supporting][strengthen incentives and mechanisms for] needs-driven research, consistent with appropriate public interest issues [and [taking note of the work][building on the analysis] of the WHO Commission on Intellectual Property Rights, Innovation and Public Health];	<ol style="list-style-type: none"> 1. Delete “open-ended”. 2. Delete “of interested Member States” 3. Delete [establish a global framework for supporting] – accept [strengthen incentives and mechanisms for]. 4. Either reference to the CIPRIPH is acceptable, but it must be clear that this report and only this report is the basis for the working group’s work (possibly linked to the IPR resolution working group, which could be combined with this one). 	Add “..Member States <u>and regional economic integration organisations</u> to consider”.
[(2) to submit an annual progress report on the working group of interested Member States [to] beginning with the [Sixtieth] World Health Assembly [(May 2007), and, if possible], a final report	<ol style="list-style-type: none"> 1. Delete annual; there should be only two reports, the first to the 60th WHA and the second and last 	

<p>[with concrete proposals] through the Executive Board at its 121st session (January 2008) to the Sixty-first World Health Assembly (May 2008)[and to suggest alternative simplified systems for protection of intellectual property, with a view to enhancing accessibility to health innovations and building capacity for product development, uptake and delivery in developed and developing countries.]]</p>	<p>to the 61st.</p> <ol style="list-style-type: none"> 2. Delete “of interested Member States”. 3. Delete [and to suggest alternative simplified .. developed and developing countries] – this is outside the WHO’s competence. 	
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