1. The European Union takes the opportunity of this public hearing to build on the positions developed during the Finnish and the German EU Presidencies since 2006. We would like to thank the WHO for their preparations of the final meeting of the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property, in November 2007.

2. Specifically, we are grateful to the WHO IGWG Secretariat for their improved draft global strategy and plan of action (GSPA) and for providing background documents defining key terms and mapping current activities, as previously requested by the EU. While not exhaustive, the mapping exercise started with the background documents published on 28 August, is particularly helpful in building a common level of understanding for the November meeting. We would be grateful if the secretariat could continue this effort and provide overviews of existing “R&D groups”, research for existing funding mechanisms and existing PPPs in this field. This will give the IGWG a better understanding of what has already been achieved, and what gaps remain for the IGWG process to address.

3. The European Union is committed to improving medicine availability, affordability, acceptability and access for those in need, particularly for the poor in developing countries. EU Member States and the Commission have played a constructive role in the IGWG process so far, which Dr. Margaret Chan recognised in
September 2007, in her speech to the Regional Committee for Europe. The EU held a stakeholder workshop on public health, innovation, and intellectual property in Brussels in April, and we remain active in preparing for the November IGWG – the European Commission held a civil society dialogue in Brussels this September\(^1\). We also very much appreciate the efforts of WHO and other Member States in organising several regional consultation meetings since the first IGWG.

4. The new draft global strategy and plan of action, presented late July, is generally better balanced and structured than previous documents. The EU supports the overall aim of providing a medium-term framework for needs-driven research and development relevant to diseases that disproportionately affect developing countries’ populations. The draft strategy addresses the research and research capacity needs of developing countries concerning these diseases. We welcome in particular the emphasis put on the need to increase the availability, accessibility and uptake of health products specifically in poor resource settings. The driving force, both for innovation and access, is a functioning, strengthened and adequately funded health system which provides equitable access to prevention, care and treatment services.

5. The current draft strategy takes into account most of the EU comments made in the process so far, and represents a good basis for discussion in November. However, we think that within the strategy there is considerable duplication and that proposed actions are too unspecific. The appropriate actors and targets should be more clearly identified. The strategy should be simplified, avoiding current overlaps and allowing increased focus of the IGWG process on achieving the objectives defined by the World Health Assembly. The EU is currently studying the document in this respect.

6. The GSPA should aim to improve prioritisation and coordination in research and development, in particular, on diseases that disproportionately affect developing countries. It should help to clarify the research and development needs in each of the proposed types of diseases which may differ widely. The mechanisms and the

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incentives to encourage research and development on particular types of disease will differ accordingly. The first task should be systematic mapping and tracking of existing research and development efforts. Priorities should be based on a focus on key areas of research, such as those addressing common determinants for the diseases or common solutions for various diseases. Global actions should be prioritised. One important priority is to secure adequate and sustainable financing and institutional mechanisms to foster innovation and access to vaccines, medicines and diagnostics to address diseases that disproportionately affect poor people in developing countries. Existing successfully approaches must be supported, including public private partnerships and existing forms of coordination like TDR (Special Programme for Research and Training in Tropical Diseases). The EU has supported the Global Fund to fight against AIDS, TB and Malaria, and welcomed innovative financing mechanisms, such as the International Financing Facility for Immunisation (IFFIm) AMC (Advance Market Commitment) and UNITAID.

7. The number of actions and related indicators should be reduced. The strategy contains 80 actions and twice as many progress indicators. This might be too challenging, both for the negotiation in November 2007 and for the proposed follow-up. Too many of the proposed progress indicators are not directly relevant; those which remain need to be more specific, measurable and feasible so that progress against the plan can be monitored in practice.

8. Responsibilities and the division of labour should be better defined. To ensure effective implementation and monitoring, the final global strategy and plan of action must be clear on who is responsible for doing what and by when. The primary focus should be on specific actions within the remit of WHO where Member States and WHO can take the lead. Specific actions falling outside the remit of WHO, which require the cooperation and involvement of other stakeholders and international organisations, should take account of their respective competences and strengthen the synergy of activities.

9. Responsibilities should have a clearer overall timeframe and intermediate steps and targets where appropriate, distinguishing between short term, medium term and long term actions.
The EU will continue to participate in the work of IGWG and of international organisations, such as WTO and WIPO. This includes support to developing countries in intellectual property management, in accordance with the Doha ministerial declaration.

10. In our view, the quality, safety and rational use of medicines, and supporting regulatory capacities to combat substandard drugs and counterfeiting need a higher profile in the strategy. The EU, in particular, puts a lot of energies and resources in ensuring that the medicines that are delivered to its own population are of verified quality, and thinks there cannot be double standards when new drugs are developed for or delivered to people living outside the EU.

11. The document also needs to contain stronger, more explicit references to the Millennium Development Goals and to previous political commitments on health policies made at global level. We also like to draw attention to the Noordwijk Medicines Agenda of 21 June 2007 that identified specific actions for accelerating innovation and access to medicines for diseases that disproportionately affect developing countries.

12. In addition, we would like to see more clear references to the existing WHO framework for access to essential medicines, which consists of four logical elements: rational selection, affordable prices, sustainable financing and reliable systems. The strengthening of health systems should be more prominent in the strategy. Delivery and access depends largely on the capacity of the health systems in countries and this should be emphasised. Although the relationship between public health, innovation and intellectual property rights is important, as shown by the proposed actions under various elements, improving public health outcomes depends also on many other factors.