Discussions during the consultation focused on the sub-elements, specific actions, stakeholders and indicators. The proposed changes are listed below in track changes (for the elements and actions) or as comments (for stakeholders and indicators).

**Element 1. Prioritizing research and development needs**

(1.1) identifying gaps in research on diseases that disproportionately affect developing countries

(a) develop methodologies to identify gaps in research on Type II and Type III diseases and on developing countries’ needs in relation to Type I diseases

(b) provide an initial assessment of identified gaps.

(1.2) facilitating upstream research on new and existing products for diseases that disproportionately affect developing countries

(a) improve accessibility to compound libraries for identification of compounds with potential activity against the above-mentioned diseases, by means including public–private collaboration

(b) provide technical support to developing countries in order to create libraries of new compounds at both national and regional levels.

(1.3) coordinating research activities between developed and developing countries

(a) coordinate international efforts in research and development in order to optimize resources, especially for developing countries

(b) support developing countries in building technological capacity.

(c) promote the active participation of developing countries in the innovation process.

(1.4) formulating explicit prioritized strategies for research and development at country level

(a) developing countries to set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments

Comment [t1]: The initial assessment should subsequently be expanded to include other diseases.

Comment [t2]: Change indicator (iii) to: “No. of patents generated or co-generated by local scientists working in developing countries”. A similar change would be required in indicator (ii).
(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products to combat diseases in developing countries (including Type I diseases)

(c) include research and development needs for traditional medicines in a prioritized strategy.

**Element 2. Promoting research and development**

(2.1) increasing funding for research and development that focuses on the health needs of developing countries

(a) developed countries to devote a larger proportion of their health research and development budgets to the health needs of developing countries.

(2.2) supporting governments in improving national health research programmes and facilitating better coordination of stakeholders in this area

(a) promote cooperation between private and public sectors on research and development

(b) provide support for national health research programmes in developing countries through political action and long-term funding

(c) develop and implement systems for supporting health-related innovation in developing countries (including intellectual property management).

(2.3) promoting upstream research and product development in developing countries

(a) promote discovery science, including through open-source methods, in order to develop a sustainable portfolio of new products

(b) promote access to drug leads identified through the screening of compound libraries

(c) promote basic and applied scientific research

(d) promote early-stage drug research and development in developing countries

(e) developing countries to consider legislation that is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights relating to research exemptions

(f) promote public funding for clinical trials and other mechanisms for stimulating local innovation

Comment [t3]: Add the following stakeholders: WHO, private sector.

Comment [t4]: Indicator (iv) will have to be modified accordingly.

Deleted: on Type II and Type III diseases
(2.4) improving global coordination and financing of medical research and development

(a) improve global coordination and financing, using systematic reviews and needs assessment

(b) set up a forum, or enhance existing ones, in order to improve the coordination of research and development activities and sharing of information

(c) support further discussion of a medical research and development treaty.

Element 3. Building and improving innovative capacity

(3.1) building capacity of developing countries to meet research and development needs for new health products

(a) support investment by developing countries in human resources and knowledge bases, especially in tertiary education

(b) support existing and new research and development groups in developing countries.

(3.2) framing and supporting effective policies that promote the development of capacities for health innovation

(a) strengthen product regulatory capacity in developing countries

(b) strengthen human resources in research and development in developing countries through a long-term plan for human resources

(c) address appropriate training and retention of researchers and health professionals, including issues relating to migration.

(3.3) providing support for innovation capacity building in developing countries, including in areas such as science and technology, regulation, clinical trials, the transfer of technology, traditional medicine and intellectual property

(a) document and disseminate best practices in innovation

(b) promote successful models in developing innovative capacity

(c) intensify North–South and South–South partnerships and networks to support capacity building.
developing and implementing policies that will promote innovation based on traditional medicine

(a) develop and promote traditional medicine within an evidence-based framework

(b) promote documentation of traditional knowledge and natural genetics resources

(c) encourage developing countries to ensure high standards of safety and efficacy for traditional medicines

(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicines.

Element 4. Transfer of technology

(4.1) promoting transfer of technology and the production of health products in developing countries

(a) devise a mechanism, or make better use of existing ones, to facilitate transfer of technology and technical support

(b) promote transfer of technology and production of health products in developing countries through investment and capacity building.

(4.2) supporting improved collaboration and coordination of technology transfer

(a) encourage North–South and South–South collaboration, and collaboration between institutions in developing countries and the pharmaceutical industry

(b) support technology transfer related to research and development on natural products

(c) facilitate local and regional networks for collaboration on research and development

(d) promote compliance with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(4.3) developing mechanisms to manage intellectual property in order to promote transfer of and access to key technologies

(a) promote patent pools of upstream and downstream technologies

(b) develop other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries
(c) examine best practices in areas such as competition, transparency and proper remuneration for patent holders.

**Element 5. Management of intellectual property**

(5.1) supporting information sharing and capacity building in the management of intellectual property with public health orientation

(a) promote national and/or regional institutional frameworks in order to build capacity and rational health oriented management of intellectual property with public health orientation

(b) compile and maintain national databases on patent status of relevant health-related products and promote exchange of information between relevant government departments to strengthen capacities of analysis and the quality of the patents

(c) stimulate cooperation between pertinent national institutions in order to promote the quality of patents relevant to public health needs

(d) WHO, in collaboration with WIPO, UNCTAD and WTO, to strengthen education and training in the management of intellectual property, including but not limited to pharmaceutical and genetic patentability and examination.

(5.2) Upon request, provide as appropriate, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on TRIPS and Public Health, and with other international agreements related to health.

(a) promote legislative and regulatory measures to incorporate flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on TRIPS and Public Health, and with other international agreements related to health.

(b) avoid the incorporation of TRIPS plus measures in any trade agreements and in national legislation, that may have negative impact on access to health products or treatments in developing countries.

(d) identify ways and means to fully implement the flexibilities contained provided for in the TRIPS Agreement and the Doha Ministerial Declaration with a view to ensure access to medicines.
(e) recommend the participation of health authorities in intellectual property negotiations with a view to reaffirm all the flexibilities and safeguards related to public health and to prevent decisions that may negatively affect access.

(f) take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing with the aim of facilitating access to medicines consistent with Agreement on Trade Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health.

(g) effectiveness of the WTO Decision on Implementation of Paragraph 6 of the Doha Declaration in relation to export to countries with insufficient or no manufacturing capacity should be kept under review and appropriate changes considered to achieve a workable solution, if necessary.

(h) request WHO to provide information to Members on all mechanisms and flexibilities in the TRIPS Agreement that can be used for the export of medicines manufactured without the permission of the patent owner, including the Decision of the WTO of 30 August 2003.

(f) take necessary legislative steps to allow compulsory licensing for export consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health.

(5.3) examining and promoting complementary, alternative and/or additional incentive schemes for research and development

(a) examine and implement alternative incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products including, but not limited to, the prize fund model.

(b) consider the use of the advance market commitment approach if appropriate and affordable, based on participatory approach.

(c) consider measures to ensure the strict application of the patentability criteria in order to obtain the best interpretation for public health as stated in paragraph 4 of Doha Declaration on TRIPS and Public Health.

(d) developing countries should adopt or effectively implement policies in order to prevent or correct anti-competitive practices related to the use of patents for health products, including the use of pro-competitive measures available under the intellectual property law.

Deleted: ¶ (a) promote legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements, by means including the dissemination of best practices.

Deleted: ¶ (b) promote bilateral trade agreements that do not incorporate “TRIPS-plus” protection in ways that might reduce access to medicines in developing countries.

Deleted: ¶ (c) encourage trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health).

Deleted: ¶ (d) expand the advance-market commitment approach.

Deleted: ¶ assess the impact of data-exclusivity regulations.

Comment [t5]: Add World Bank as one of the stakeholders.
(e) Avoid restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.

**Element 6. Improving delivery and access**

(6.1) encouraging governments to invest in the health-delivery infrastructure

(a) invest in developing health-delivery infrastructure and ensure financing of health products

(b) develop effective and sustainable mechanisms in least-developed countries in order to increase access to existing medicines, making full use of the transitional period until 2016

(c) prioritize health care in national agendas.

(6.2) instituting mechanisms to regulate the quality, safety and efficacy of medicines and other health products

(a) strengthen capacity to monitor the quality, safety and efficacy of health products, and accelerate the regulatory approval of products with potential utility

(b) conduct operational studies to maximize the value and use of new products in high disease-burden settings with inadequate health services

(c) implement national and international disease-control policies that are based on evidence that use of new and existing products has an impact

(d) encourage compliance with good manufacturing practices in developing countries

(e) minimize the public health consequences of counterfeit and substandard products.

(6.3) promoting competition and ensuring that pricing of medicines is consistent with public health policies

(a) support the production and introduction of generic versions of essential medicines in developing countries, including national legislation to encourage generic entry on patent expiry

(b) frame policies emphasizing essential medicines at affordable prices

(c) remove tariffs and taxes on health-care products and monitor their supply and distribution chain

Deleted: examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use.
(d) take necessary legislative steps in countries with manufacturing and export capacity to allow compulsory licensing for export consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health

(e) encourage pharmaceutical companies to adopt transparent and consistent pricing policies, aiming to reduce prices for developing countries

(f) monitor pricing policies and strengthen WHO’s work on pharmaceutical pricing.

**Element 7. Ensuring sustainable financing mechanisms**

(7.1) securing additional and sustainable financing for research and development in order to address the health needs of developing countries

(a) develop and implement a resource mobilization plan

(b) assess the utility of existing funding mechanisms, or a new global funding mechanism, in order to increase global coordination and sustainable funding of medical research and development

(c) use current and new financing initiatives (such as advance-market commitment schemes, prize fund and global R&D Treaty) to accelerate the progress of health-care products from development to delivery

(7.2) facilitating the expansion of activities in order to develop and deliver affordable products

(a) document and disseminate best practices in expanding public–private partnerships

(b) develop and implement tools to assess performance of public–private partnerships

(c) develop, support and sustain public–private partnerships and other research and development initiatives in developing countries in expanding their activities.

(7.3) increasing resources for research organizations in developing countries

(a) channel additional funds to research organizations in both the private and public sector of developing countries.

**Element 8. Establishing monitoring and reporting systems**

Comment [t6]: In the list of stakeholders, add “(as appropriate)” after pharmaceutical industry.

Comment [t7]: In indicator (i), replace “existing public-private partnerships” with “well-performing public-private partnerships”. Add a footnote that indicator 7.2(b) will be used to identify which public-private partnerships are performing well.
(8.1) measuring performance and progress towards objectives contained in the plan of action

(a) establish systems to monitor performance and report to WHO’s governing bodies on progress every two years, with effect from end-2009.

(8.2) monitoring the impact of intellectual property rights and other factors on innovation and access to medicines and other health-care products

(a) monitor and report periodically to WHO’s governing bodies on the gaps and needs related to health-care products in developing countries

(b) monitor the impact of intellectual property rights and other factors on innovation and access to health-care products

(c) monitor investment in research and development to address the health needs of developing countries.