Draft Global Strategy on Public Health, Innovation and Intellectual Property

The context

1. In resolution WHA59.24 the World Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important to ensure that the increasing prevalence of noncommunicable diseases in those countries is recognized and addressed.

2. There are 4.8 billion people living in developing countries (80% of the world population). Of this amount, 2.7 billion live on less than US$ 2 a day (56,25% of the world population). Communicable diseases account for 50% of the developing countries burden of disease. On the other hand, non-communicable diseases have an increasing impact on the burden of disease of developing countries. Furthermore, poverty directly affects the acquisition of health products, especially in developing countries.

3. Governments, the pharmaceutical industry, charitable foundations and nongovernmental organizations have made progress in recent years by funding initiatives to develop new products against diseases affecting developing countries and to increase access to existing products. However, these initiatives have proved inadequate to surmount the challenges of ensuring both access and innovation for needed medical technologies. Much more must be done in relation to the scale of avoidable suffering and mortality.

4. In resolution WHA60.30 the World Health Assembly encouraged the development of proposals for health-needs driven research and development that include a range of incentive mechanisms, including those that address the relation between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products and a method for tailoring the optimal mix of incentives to a particular condition or product.

5. Advances in biomedical science have provided opportunities to develop new, affordable health products, and in particular to meet public health needs in developing countries. These opportunities must be harnessed more effectively and more urgently.

6. In addition, growing criticism has been registered, in developed and developing countries alike, on the barriers posed by proprietary rights over the access to medicines, in particular with regard to anticompetitive practices in the field of patent rights.
7. Although international intellectual property agreements foresee flexibilities that could facilitate increased access to medicines by developing countries, the adequate implementation of these flexibilities is hindered by the scarcity of resources and the lack of production.

The aim

8. The aim of the proposed Global Strategy on Public Health, Innovation and Intellectual Property is to provide a medium-term framework based on the recommendations of the CIPIH and the relevant WHA resolutions. The Strategy seeks to address the urgent need to take action to ensure access to medicines for all, and also to secure an enhanced and sustainable basis for needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries.

9. The elements of the Global Strategy that are designed to promote innovation, build capacity and improve access, will:

(a) establish a research and development agenda that covers the health needs of developing countries;
(b) propose mechanisms to carry out the above research and development agenda, including strengthening worldwide capacity for research and development, particularly in developing countries, into diseases, conditions and problems affecting those countries;
(c) secure financing for the activities resulting from the research and development agenda, including exploring innovative financial mechanisms;
(d) seek to increase the availability, accessibility and uptake of health products (in particular, medicines, vaccines and diagnostics) in developing countries. To sum up, the Global Strategy and Plan of Action shall include a medium-term framework of reference for needs-driven R&D, relevant to diseases conditions and problems that disproportionately affect developing countries. The need to redirect R&D is hereby recognized.

The focus

10. The focus of the strategy will be on access to health care technologies relevant to all diseases, conditions or problems, as well as on research and development for areas diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable.

11. The eight elements agreed by the Intergovernmental Working Group at its first meeting provide the organizing principle for the plan of action.
The principles

12. The right to health protection is a universal and inalienable right and is the government’s duty to ensure the means for its enforcement.

13. The right to health takes precedence over commercial interests.

14. The right to health implies equitable access to medicines.

15. The promotion of technological innovation and the transfer of technology is a right of all States and should not be restricted by intellectual property rights.

16. The intellectual property rights shall become neither an obstacle to the access to medicines nor to the policies that ensure and protect the public health. The intellectual property rights shall guarantee the economic and social welfare in a balanced manner.

17. Countries have the right to implement all the flexibilities contained in the TRIPS Agreement and reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health and in other international agreements in order to safeguard and ensure the access to medicines and health technologies.

18. International negotiations on issues related to intellectual property rights and health within the various international organizations must maintain coherence with the priorities of public health.

19. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.

20. Developing countries must have the capacity to cooperate on the basis of their shared interests and economic and social needs if they are to benefit from global markets.

21. The research and development of developed countries policies should reflect the health needs of developing countries.

22. The Global Strategy and the Action Plan should also secure that the products needed by developing countries that will result form research and development are: (i) available at sufficient quantities; (iii) effective and of quality; (iv) affordable for public or individual users;

The elements

Element 1: Prioritizing research and development needs

23. Health research and development policies of developed countries need to adequately reflect the health needs of developing countries. Gaps and difficulties in research relating to the public health needs of developing countries need to be identified urgently. A better
understanding of the developing countries health needs, and their determinants, is essential to drive sustainable research and development on new and existing products.

24. The actions to be taken to prioritize research and development needs are as follows:

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

(a) develop methodologies or mechanisms to identify gaps in research relating to public health needs

(b) disseminate identified gaps, and evaluate their consequences on public health

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

(a) provide an assessment of identified gaps at different levels – national, regional and international - to initiate research in affordable and therapeutically sound products to meet public health needs.

(b) promote accessibility to compound libraries for identification of compounds with potential activity against the above-mentioned public health needs.

(c) provide technical support to developing countries in order to create libraries of new compounds at both national and regional levels, in partnership with universities, research institutes and other stakeholders as appropriate.

(d) identify IP-related provisions at different levels – national, regional and international - that might negatively affect increased research on public health, and suggest ways to facilitate access to research results and research tools

(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 and regional levels

(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments
(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs in developing countries

(c) include research and development needs for traditional and alternative medicines especially in developing countries as deemed appropriate.

(d) promote the creation and development of fully accessible public health libraries in order to enhance availability and use of relevant databases by universities, institutes and technical centers, especially in developing countries;

(e) ensure the leadership and commitment of governments, regional and international organizations in determining priorities for R&D according to public health needs;

(f) increase overall R&D efforts on health problems that predominantly affect developing countries, leading to the development of quality products adapted to public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability);

(g) build capacity in health R&D and local production within developing countries through strategies that: promote access to knowledge, tools, and the technology necessary for innovation; ensure effective coordination and building of networks; ensure appropriate and sustainable financing; and training of human resources necessary to build the appropriate regulatory capacity in developing countries.

Element 2: Promoting research and development.

25. There are many determinants of innovation capacity within developing countries. Political, economic and social institutions in each country should participate in the development of health research policy, taking into consideration their own realities and needs. The range of measures to promote, coordinate and finance public and private research in public health needs must be substantially enhanced. Greater investment, in both developed and developing countries, is required.

26. The actions to be taken to promote research and development oriented public health needs are as follows:

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

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

(b) promote public access to the results of government funded research, through requirements that all investigators make available the results of their research.
(2.2) supporting governments in improving national health research programmes and establishing strategic research networks to facilitate 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

(2.3) promoting upstream research and product development in developing countries
(a) promote discovery science, including but not limited to open-source methods, not to be protected by patent, in order to develop a sustainable portfolio of new products
(c) promote basic and applied scientific research on public health needs
(d) promote early-stage drug research and development in developing countries
(e) increase funding for expanding clinical trials for medicines, technologies and treatments to be applied to diseases that disproportionately affect developing countries.

(2.4) improving global cooperation, coordination and financing of medical research and development
(a) stimulate global cooperation, coordination and financing, using systematic reviews and needs assessment amongst others;
(b) set up a forum, or enhance existing ones, through WHO’s endeavours, in order to improve the coordination of research and development activities and sharing of information in order to address health needs of developing countries.
(c) Support further discussion on a medical research and development treaty that considers the establishment of research priorities, the identification of funding needs, and sustainable funding mechanisms to meet those needs amongst others, taking into account the specific needs and abilities of developing countries to support such research. The discussion should also address incentives to accept obligations to fund research, including but not limited to the possibility that countries that achieve norms for funding research be given additional flexibility in terms of obligations to enforce intellectual property rights on medical inventions.

(2.5) Ensuring access to knowledge and technology relevant to meet public health needs of developing countries
(a) put in place measures that safeguard the public domain.
(b) promote public access to the results of government funded research, through requirements that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts.
(c) support the creation of open databases and compound libraries, including
unrestricted access to drug leads identified through the screening of compound libraries,

d) encourage developed countries, universities and donors to require that publicly or
donor funded medical inventions and know-how be made available through open
licensing for use in developing countries on reasonable and affordable non-
discriminatory terms.

e) consider the incorporation of research exemptions in legislation of developing
countries to address public health needs, consistent with their obligations, if any,
under the Agreement on Trade-Related Aspects of Intellectual Property Rights and
the Doha Declaration on TRIPS and Public Health.

Element 3: Building and improving innovative capacity.

27. Developing innovative capacity requires an approach that interconnects education,
intellectual property and technology transfer. There is a need to frame and support effective
policies that promote the development of capacities in developing countries related to
health innovation. This would include:

- building innovative capacity in science and technology and traditional medicine;
- rational health orientated intellectual property management;

28. The agenda for this element covers the following:

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

(a) support investment by developing countries in human resources and knowledge
bases, especially in technical training, university and professional education
(b) support existing and new research and development groups in developing
countries.
(c) strengthen public health schools and national institutes of health, with a view to
generate scientific evidence and create a critical mass of specialists in health to
ensure the establishment and support of all public health programs.
(d) train personnel and strengthen health surveillance systems to gather and analyze
strategic information in the public health area.

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

(a) strengthen regulatory capacity in health issues, according to the needs of each
country.
(b) strengthen human resources in R&D in developing countries through the
elaboration and implementation of a long-term capacity building plan
(c) take action to mitigate the negative impact of selective migration policies implemented by developed countries that result in the brain-drain of human resources from developing countries in health related areas.

(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries.
   (a) develop successful models in developing innovative capacity
   (b) intensify North–South and South–South partnerships and networks to support capacity building.

(3.4) supporting the policies of developing countries in promoting innovation and development of traditional medicines, ensuring compliance with the principles of the Convention on Biological Diversity.

Element 4: Transfer of technology

29. North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. 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.

30. The actions to be taken in relation to this element are as follows:

   (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 technical support and strengthening of innovative capacity in developing countries
      (b) promote transfer of technology and production of health products in developing countries through investment and capacity building provided by developed countries.
      (c) encourage the dissemination of technological and other information contained in patents and patent applications, as well as information related to patent status, oppositions, revocations and nullifications.

   (4.2) supporting improved collaboration and coordination of technology transfer
      (a) encourage North–South and South–South cooperation, and collaboration between institutions in developing countries and the pharmaceutical industry, in order to encourage and support regional networks in R&D for health related technologies and product innovation.
(b) support technology transfer related to research and development on natural products for medical use
(c) facilitate local and regional networks for collaboration on research and development
(d) urge developed countries to comply with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights.
(e) promote the necessary training to increase absorptive capacity for technology transfer.

(4.3) developing mechanisms to manage intellectual property in a rational and health-oriented manner in order to promote transfer of and access to key technologies

(a) promote patent pools of upstream and downstream technologies to promote innovation of and access to products for priority diseases in developing countries and the evaluation of its practical application
(b) develop other effective and sustainable mechanisms to promote innovation of and access to products for priority diseases in developing countries
(c) encourage the use of intellectual property flexibilities to access health technologies.


31. The provisions in the Doha Declaration on TRIPS and Public Health that relate to access to medicines should be applied to any and all trade, investment or intellectual property agreements, as follows:

- intellectual property rights agreements do not and should not prevent countries from taking measures to protect public health.
- intellectual property rights agreements and laws can and should be interpreted and implemented in order supportive of a countries' right to protect public health and, in particular, to promote access to medicines for all.

In this context, countries have the right to fully use the provisions in such Agreements and laws, which provide flexibility for this purpose.

32. Intellectual Property, investment or trade agreements should not prevent a country from adopting measures necessary to prevent anti-competitive practices that may result from the abuse of intellectual property rights.

33. Intellectual property rights have an important role to play in stimulating innovation in health care products in countries where financial and technological capacities exist, and in relation to products for which profitable markets exists. In developing countries, the fact that a patent can be obtained may contribute nothing or little to innovation if the market is too small or scientific and technological capability is inadequate. The monopoly costs associated with patents can limit the affordability of patented health care products.
34 Other incentive schemes for research and development addressing public health needs, must be explored and implemented. There is a crucial need to strengthen capacities in developing countries to manage intellectual property issues in a rational and public health oriented manner. It is important to take into account the proposals and decisions of the WIPO Provisional Committee on Development Agenda.

35. The actions to be taken in relation to this element are as follows:

(5.1) supporting information sharing and capacity building in the management of intellectual property to address public health needs
   (a) promote national and/or regional institutional frameworks in order to build capacity and rational health oriented management of intellectual property especially oriented to public health access necessities and priorities of developing countries.
   (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) ensure that developed countries do not impose restrictions for the use of or reliance on clinical test data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS and other trade agreements.
   (e) require WHO to coordinate with WTO and WIPO to improve dissemination of relevant information at the international level on patents that might be relevant to address specific public health needs.
   (f) urge active and effective participation of health representatives in IP-related negotiations in order to ensure that the outcomes of such negotiations incorporate all the flexibilities important to address public health needs.
   (g) Establish measures to avoid unethical experiments involving human beings as a requirement for registration of medicines and technologies.

(5.2) Encouraging WHO to provide as appropriate, upon request, in collaboration with other competent international organizations, 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 other international agreements in order to promote access to health products, and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments;
   (a) promote legislative and regulatory measures to incorporate flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, affirmed by 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.

(5.3) examining and promoting alternative 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.

(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

Element 6: Improving Delivery, Access and Rational Use

36. Support for health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Mechanisms to regulate the safety, quality and efficacy of medicines and other
health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system.

37. Implementation and impact of international and bilateral agreements that may have a negative impact on access to health products in developing countries need to be regularly monitored. National authorities are encouraged to use and should consider using flexibilities available if any in such agreements in order to improve access to health products in the light of the circumstances in their countries.

38. Countries that have signed any agreement that may impede access to medicines and other health products shall continue surveillance of the implementation and evaluate the impact of such agreements on their people and their health needs. Countries should also establish plans that ensure continuous supply and availability of medicines.

39. The actions to be taken to improve delivery and access are as follows:

(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 medicines, making full use of the transitional period until 2016 or such later period determined by the WTO

(c) prioritize health care in national agendas.

(d) encourage national health authorities to improve national management capacities in order to guarantee delivery and access to medicines and other health products with quality, efficacy and safety

(e) encourage countries to develop strategies to promote rational use of medicines

(6.2) Establishing and strengthening 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 services, and prioritize the regulatory approval of strategic products for national public health programs

(b) promote operational studies to maximize the therapeutical value and use of new and existing products and treatments in health systems

(c) implement national and international disease-control policies that make use of innovative medicines based on scientific evidence of efficacy, safety and comparative costs with regard to therapeutical and economical advantages offered by existing products that are used rationally for such diseases.

(d) encourage compliance with good manufacturing practices

(6.3) promoting competition and pricing of medicines consistent with public health needs
(a) support the production and introduction of generic versions of essential medicines in developing countries, including national legislation to encourage their entry.
(b) frame policies emphasizing essential medicines at affordable prices
(c) recommend that countries evaluate the reduction of tariffs, taxes and other costs on health products as a means to decrease final prices and to increase access;
(d) urge pharmaceutical companies to adopt transparent, consistent and equitable pricing policies that increase access to quality, safe and affordable medicines by developing countries
(e) stimulate the development of policies to monitor pricing by developing countries, to reduce costs and strengthen WHO’s work on pharmaceutical pricing
(f) reinforce and encourage the use of the Bolar Exception to stimulate entry into market of generics as soon as the patent expires.
(g) stimulate the immediate entry of generic products into the market, supported by the WHO and other UN bodies
(h) develop specific measures to enable fast and efficient entry of generic medicines particularly in developing countries.
(i) support regional fora to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines approval concerning diseases that affect developing countries.
(j) strengthen the endeavors of the WHO’s assurance programme, in particular the WHO prequalification programme, and promote its effectiveness in assessing the safety, quality and efficacy of public health products.

Element 7: Ensuring sustainable financing mechanisms.

40. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional donor financing has also been secured for research and development activities relevant for the control and treatment of the diseases covered by this strategy. Nonetheless, further funding on a sustainable basis is essential to support a long-term research and development effort for products to meet the health needs of developing countries. The most serious gaps in donor financing for health products and research and development covered by this strategy need to be identified and analyzed.

41. It is important to expand current initiatives and create new ones, thereby contributing to a flow of resources into innovation and implementation, including product-development partnerships, initiatives by foundations, advance-market commitment mechanisms, prizes and the International Finance Facility for Immunization.

42. The actions to be taken to ensure sustainable financing mechanisms are as follows:

(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, and/or establish a new global funding mechanism as well as propose a governance system for the financial mechanisms 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 and prizes) to accelerate the progress of health-care products from development to delivery
(d) Stimulate the application of prizes for public health products relevant to developing countries under non-exclusive licenses situations or when the patents rights are renounced.

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

(a) document and disseminate best practices in expanding product development partnerships
(b) develop tools to assess performance of product development partnerships
(c) support product development partnerships and other research and development initiatives in developing countries to expand their activities.
(d) propose measures to improve governance of the whole set of donors, with a view to optimize international cooperation in the area of health in accordance with health policies.
(e) adopt policies and principles for the intellectual property related to the new financing mechanisms. These policies and principles should address the issues of whether research and development outputs and health products derived from the outputs are placed in the public domain or patented and if patented, how the patents are managed. Patenting should be the exception rather than the rule and the policies and principles should ensure:
   • access to knowledge and technology
   • the freedom to undertake further research and development into new tools, products or services
   • the affordability and accessibility of products to patients who need them
   • the transfer of technology and know-how to developing countries.

(7.3) increasing resources to organizations in developing countries for public health-oriented research

(a) channel additional funds to health-oriented research organizations of developing countries.
(b) devising and setting up sustainable sources of funding for needs-driven R&D according to criteria of equitable participation and access, adequacy and affordability of health technologies for those who need them.
Element 8: Establishing monitoring and reporting systems

43. Systems should be established to monitor performance and progress of this strategy. Such performance and progress will be submitted to the Health Assembly through the Executive Board every year. A comprehensive evaluation of the strategy will be undertaken every two years.

44. Steps to be taken will include:

(8.1) measuring performance and progress towards objectives contained in the plan of action

(a) establish systems to monitor the implementation of each element of the Global Strategy and Plan of Action and report to WHO’s governing bodies on progress every two years, with effect from end-2009.

(b) the WHO will coordinate with the governments, regional and World meetings to carry out the evaluation and analysis of progress indicators for each element of the Strategy, and inform the outcomes once a year to the executive board of WHO since the end of 2009.

(c) The outcomes of progress indicators will be useful for elaborating, at the World Assembly of Health, measures or recommendations for governments, academia institutions, research foundations, pharmaceutical industry, non-governmental organizations, benefit foundations, WTO, WIPO, and another stakeholder that consider that intellectual property and innovation must be useful for promoting public health.

(d) The WHO will publish biannual progress reports on the Strategy and its impact on public health.

(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 developed and developing countries

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

A global responsibility for action

45. Global responsibility for implementation of the Strategy by 2015 will rest with a range of stakeholders, including WHO’s Member States, the WHO Secretariat, WIPO, WTO, national institutions, development partners, academia, pharmaceutical companies, public–private partnerships, charitable foundations and nongovernmental organizations. Together they can ensure that (i) the development of health products are promoted and funded in a sustainable manner in order to address the health needs of developing countries, and (ii)
health products are accessible and affordable for people and governments in developing countries. Successful implementation will require concerted action.

46. Details of specific collaborative action on implementation are set out in the following draft plan of action, which provides a medium-term framework for stakeholders. It includes progress indicators.

47. The implementation of the plan of action will involve numerous stakeholders at national, regional and global levels. Therefore, realistic costing of the plan will require detailed information on the activities to be undertaken by each stakeholder and at which level. Costs will be reviewed after discussion and agreement on the range of specific actions during this second session of the Working Group. These estimates will include a costing for initial implementation in 2008 and 2009, and a preliminary cost estimate for full implementation. Costing assumptions and estimates for implementation from 2010 should be updated in the biennial review due at the end of 2009 on the basis of predefined monitoring and evaluation data.

48. High prices of medicines contribute to inequitable access to treatment.

49. It is important to strengthen capacity of local public institutions and business in developing countries for participating in research and development efforts.

50. Efforts to develop new products will be of no value if they cannot be made available and accessible to those who need them.