The Ministry of Health of the Republic of Uzbekistan has reviewed the draft global strategy and plan of action on public health, innovation and intellectual property.

The Ministry of Health herewith submits its comments and suggestions concerning the draft.

Annex on 12 pages.

A. Ikramov
First Deputy Minister
We agree with paragraphs 11-14.

Paragraph 14 (e) currently reads:

(e) Encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to [health products]/[medicines] for all, as well as explore and implement, where appropriate, [innovative]/[alternative] incentive schemes for R&D [to complement the existing ones].

We propose the following:
Encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, innovative incentive schemes for R&D to complement the existing ones.

Proposed text of paragraph 18:
The right to health takes precedence over commercial interests.

We agree with paragraphs 27 and 28 (a) and (c).
Paragraph 28.1.3 should read:
1.3 prioritizing research and development in traditional medicine and knowledge in accordance with the relevant provisions of international instruments of making consultation with the right holders in agreement with the national legislation of the party to the relevant provisions of international instruments referring to the rights of indigenous peoples and local communities.

We agree with paragraph 30.2.1 (a).

Paragraph 30.2.2 (a) should read:
(a) support discovery science, including, where feasible and appropriate, open-source methods, in order to develop a sustainable portfolio of new products.

(b) facilitate upstream research and improve accessibility to compound libraries including provide technical support to developing countries in order to create libraries at both national and regional levels and promote access to drug leads identified through the screening of compound libraries.

We agree with (c).

(g) promote new knowledge to facilitate the development of new products to tackle the health problems of developing countries.

Paragraph 2.4 (c) should read:
support the creation of open databases and compound libraries, including promoting access to drug leads identified through the screening of compound libraries.

Delete (d) and (e).

In paragraph 32, 3.2 (c) should read:
encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries and provide developing countries and their institutions with support to alleviate the negative impact of health workforce migration taking into account the work of WHO and other relevant organizations.

We agree with 3.4 (a).

3.4 (b) should read:
encourage and promote national and international policies on traditional medicine to facilitate prior art for patent regimes and disclosure and benefits sharing.

3.4 (c) should read:
(c) encourage all countries to ensure high standards of safety and efficacy for traditional medicine and promote and fund research for standardization of traditional medicine systems.

In paragraph 34, 4.1 should read:
(a) make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for research and development, particularly in developing countries.

(b) devise a list of technologies related to research and local production of health products relevant to developing countries.

(d) promote the dissemination of technological and other information contained in patents and published patent applications, as well as published information related to patent status, oppositions, revocations and nullifications.

Paragraph 34, 4.2:
(b) make arrangements to promote technology transfer for therapeutic use.

Paragraph 34
4.3 developing mechanisms to manage intellectual property in order to promote transfer of and access to key technologies, including sharing of patent databases
(a) examine the feasibility of patent pools of upstream and downstream technologies to promote innovation and access to health products and medical devices for diseases affecting developing countries
(b) consider additional effective, sustainable and complementary mechanisms including appropriate patenting and licensing policies to promote innovation of and access to products of relevance to public health needs of developing countries.

Move subparagraph (c) to element 5.

Paragraph 36, 5.1:
(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries.

(e) to strengthen education and training in the granting, application and management of intellectual property from a public health perspective including use of flexibilities contained in the TRIPS Agreement.

(f) WHO to encourage Member States to use traditional knowledge digital libraries for their patent examination procedures in order to prevent misappropriation of traditional knowledge.

(g) 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.

(h) establish measures to avoid unethical experiments involving human beings as a requirement for registration of medicines and technologies.

(i) to create a Coordination Committee among WHO, WIPO and WTO for looking at solutions on the issue of public health and intellectual property.

(5.2) upon request, WHO, in collaboration with WTO, to provide support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) WHA 56.27 paragraph 1 (2).

(b) to consider, whenever necessary, adapting national legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other international agreements, by means including the dissemination of best practices in collaboration with WIPO.

(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.
(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) and the WTO decision of 30th August 2003.
and identify ways and means to fully implement the flexibilities contained in the TRIPS Agreement and the Doha Ministerial Declaration with a view to ensure access to medicines and 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 and 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 the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health.

Paragraph 36, 5.3 examining and promoting alternative incentive schemes for research and development

(a) explore and implement complementary incentive schemes for research and development that address the linkage between the cost of research and development and price of health products.

instead of

(c) assess the impact of data-exclusivity and data protection on access to medicines regulations in countries wherever it is provided.

(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.

(e) examine and devise 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.

(f) 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 the Doha Declaration on TRIPS and public health.

(g) avoid restrictions for the use of or reliance on undisclosed test data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.
2.3(f) WHO in collaboration with WTO and WIPO to provide assistance to developing countries in drafting legislation that is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights relating to research exemptions.

Encourage developing countries to work with the appropriate international organizations when implementing legislation relating to health-related research exemptions.

3.2(d) enhance capacity building in intellectual property rights in developing countries to promote local exploitation of intellectual property systems specially oriented to public health needs.

38. International and bilateral agreements that may have an impact on access to health products in developing countries need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements, and the ones contained in the TRIPS agreement and reaffirmed in the Doha Declaration, that would permit improved access need to be considered for action by national authorities in the light of the circumstances in their countries. The impact of such actions on innovation needs to be monitored.

Paragraph 39, 6.1:
(a) invest in developing health-delivery infrastructure and ensure financing of essential health products.
(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, making full use of the transitional period until 2016.
(d) encourage national health authorities to improve national management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and to develop strategies to promote rational use of medicines.
(g) encourage pooled procurement mechanisms in developing countries.

Paragraph 39, 6.2:
(a) develop and strengthen drugs regulatory authority capacity to monitor the quality, safety and efficacy of health products and services, and prioritize the regulatory approval of life-saving products with potential utility for national public health programs.

(b) conduct operational studies to maximize the therapeutic value and use of new and existing products and treatments in health systems.

(c) develop and 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.

(e) strengthen the WHO pre-qualification programme.
(f) develop legislation and strategy against the public health consequences of counterfeit and substandard spurious products.

(g) initiate a programmed action with ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals. Such harmonizations should take into account the following elements:

- level of socio economic development
- essential and non-essential drugs
- conventional and break-through drugs
- drugs for the treatment of neglected diseases
- the “fair treatment” interpretation of TRIPS article 39.3
- clarification of the working relationship between the drug regulatory authorities and patent offices.

Paragraph 39, 6.3 promoting competition and ensuring that pricing of medicines is consistent with public health needs

(a) support the production and introduction of generic versions of essential medicines in developing countries, including review of national legislation to encourage generic entry on patent expiry and which is consistent with international obligations concerning the protection of intellectual property rights.

(b) frame policies emphasizing developing countries availing essential medicines and treatments available in developed countries at affordable prices.

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

(d) encourage 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, consistent and equitable pricing policies, aiming to reduce prices for developing countries that increase access to quality, safe and affordable medicines by developing countries.

(f) monitor pricing policies and stimulate the development of policies to monitor pricing by developing countries, to reduce costs and strengthen WHO’s work on pharmaceutical pricing.

and

(g) utilize the flexibilities inscribed in the TRIPS Agreement especially on parallel importation (exhaustion of rights) and research exemption.

(h) exploit expired or invalid patents to introduce generics in the market.

(i) promote use of generics in the developing countries.
Paragraph 39, 6.4  Increase awareness among users, doctors and pharmacists regarding generic products

Paragraph 42, 7.1  Endeavour to secure adequate and sustainable financing for research and development in order to address the health needs of developing countries

(a) Establish in 2008 an expert task force to:
• examine current financing, coordination and prioritization of research and development on health products for diseases that disproportionately affect developing countries, building on the work already done.
• identify ways to improve coordination and sustainability of existing financing mechanisms and to expand them as appropriate.
• explore proposals for new and innovative models of financing for health research and development, as needed with contribution from both developed and developing countries, taking into account lessons learned from UNITAID, IFFIm and AMCs.
• 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.
• progress report on process to the 62nd WHA.
• report with concrete recommendations to the 63rd WHA through the Executive Board.

(b) encourage channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness in line with WHA resolution 58.34.

(c) create a database of possible sources of financing for R&D.

(7.3) Setting up a global R&D fund to address the identified R&D gaps in Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.

(a) of this fund, money will be earmarked and provided for research in the form of grants for R&D for these diseases in advance, as well as prize/rewards for path-breaking research after it is accomplished.
(b) of this fund, money will be earmarked and provided to buy out patents to ensure that health products are made available at affordable prices in developing countries.
(c) financing for this fund will come from contributions by countries, donors, industry and taxing of international financial transactions as agreed to by Member States.
(d) an operational mechanism will be set up for this fund as agreed to by Member States.

Text to be considered with Element 7:
(2.1) increasing funding for research and development that focuses on the health needs of developing countries
(a) urge developed countries to devote an appropriate proportion of their health research and development budgets to the health needs.
Increase funding to strengthen clinical trials and regulatory infrastructure in developing countries, in particular in sub-Saharan Africa.

Element 8. Establishing monitoring and reporting systems

Paragraph 44, 8.2 monitoring the impact of intellectual property rights and other factors on innovation and access to medicines and other health-care products.

(b) monitor and report, in collaboration with the WTO and WIPO, the impact of intellectual property rights and other factors on innovation of and access to health-care products in consultation as appropriate with other international organizations competent in intellectual property.

(c) monitor and report the impact of new mechanisms on innovation and access to health products and medical devices.

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

A global responsibility for action

1 Global responsibility for implementation of the strategy by 2015 will rest with a range of actors, 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 discovery and 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.

2. 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.

3. 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.

We endorse the following wording:

4. High prices of medicines contribute to inequitable access to treatment.
5. It is important to strengthen capacity of local public institutions and business in developing countries for participating in research and development efforts.

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