

RESOLUTIONS

WHA61.1 Poliomyelitis: mechanism for management of potential risks to eradication

The Sixty-first World Health Assembly,

Having considered the report on poliomyelitis: mechanism for management of potential risks to eradication;¹

Recalling resolution WHA60.14, which urged Member States in which wild poliovirus is still present, especially the four countries in which poliomyelitis is endemic, to intensify poliomyelitis eradication activities in order rapidly to interrupt all remaining transmission of wild poliovirus;

Recognizing the need to make rapidly available the necessary financial resources to eradicate poliomyelitis;

Recognizing the need to minimize the long-term risks of inadvertent reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission;

Recognizing the need for international coordination of the strategies to minimize and manage the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission globally;

Noting that planning for such international consensus must begin now in order to be ready for implementation of coordinated strategies without delay after transmission of wild poliovirus is interrupted globally,

1. **URGES** all remaining poliomyelitis-affected Member States to engage all levels of political and civil society in order to ensure that every child is consistently reached and vaccinated during every supplementary immunization activity against poliomyelitis, so that all remaining transmission of wild poliovirus is interrupted rapidly;
2. **URGES** Nigeria to reduce the risk of international spread of poliovirus by quickly stopping the outbreak in northern Nigeria through intensified eradication activities that ensure all children are vaccinated with oral poliomyelitis vaccine;
3. **URGES** Afghanistan, India and Pakistan to implement the large-scale mop-up activities now needed to interrupt their final chains of poliovirus transmission, given the very low levels of type 1 poliovirus now present in these countries;

¹ Document A61/5.

4. URGES all Member States:

- (1) to achieve and maintain routine immunization coverage against poliomyelitis at a level greater than 80% of the childhood population and set country-specific target dates;
- (2) to strengthen active surveillance of acute flaccid paralysis in order to detect and identify promptly any circulating poliovirus and prepare for certification of poliomyelitis eradication;
- (3) to complete the activities outlined in phase I of the WHO global action plan for laboratory containment of wild polioviruses¹ and prepare to implement appropriate long-term safeguards and biocontainment conditions for remaining wild polioviruses within 6 to 12 months after detection of the last case of poliomyelitis caused by a circulating wild virus;
- (4) to make available rapidly the necessary financial resources to eradicate poliomyelitis and minimize the risks of reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission;

5. REQUESTS the Director-General:

- (1) to continue to provide technical support to the remaining countries affected by poliomyelitis in their efforts to interrupt the final chains of transmission of wild poliovirus;
- (2) to assist in mobilizing the financial resources necessary for full implementation of the intensified eradication effort and for ensuring that the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis are minimized;
- (3) to undertake the necessary research to characterize fully the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis, to develop appropriate strategies and products for managing these risks, including safer processes for production of inactivated poliovirus vaccine and affordable strategies for its use, and to set, if and when appropriate, a date for the eventual cessation of use of oral poliomyelitis vaccine use in routine immunization programmes;
- (4) to develop a new strategy to reinvigorate the fight to eradicate poliomyelitis from the remaining affected countries, drawing on experience from regions where poliomyelitis is eradicated and on operations research in order to determine the most efficient and cost-effective interventions;
- (5) to report to the Health Assembly when she determines that transmission of wild poliovirus type 1 is likely to have been interrupted globally, and to submit with that report a proposal or proposals for review by the Executive Board for a mechanism to mitigate the risk of the reintroduction of poliovirus that does not involve amending the International Health Regulations (2005) or developing another binding instrument.

(Seventh plenary meeting, 23 May 2008 –
Committee A, first report)

¹ Second edition, document WHO/V&B/03.11.

WHA61.2 Implementation of the International Health Regulations (2005)

The Sixty-first World Health Assembly,

Having considered the report on implementation of the International Health Regulations (2005);¹

Recalling resolution WHA58.3 on revision of the International Health Regulations, which decided that the Sixty-first World Health Assembly would consider the schedule for the submission of further reports by States Parties and the Director-General on the implementation of the International Health Regulations (2005) and the first review of their functioning, pursuant to paragraphs 1 and 2 of Article 54 of the Regulations;

Underscoring the importance of establishing a schedule to review and evaluate the functioning of Annex 2, pursuant to paragraph 3 of Article 54 of the International Health Regulations (2005);

Mindful of the request to the Director-General in resolution WHA59.2 on application of the International Health Regulations (2005) to report to the Sixtieth World Health Assembly and annually thereafter on progress achieved in providing support to Member States on compliance with, and implementation of, the International Health Regulations (2005);

Recognizing the need to rationalize reporting on all aspects of implementation of the International Health Regulations (2005) in order to facilitate the work of the Health Assembly,

1. REAFFIRMS its commitment to implement fully the International Health Regulations (2005) in accordance with the purpose and scope set out in Article 2 and the principles embodied in Article 3 of the Regulations;

2. DECIDES:

(1) in accordance with paragraph 1 of Article 54 of the International Health Regulations (2005), that States Parties and the Director-General shall report to the Health Assembly on the implementation of the Regulations annually, with the next report to be submitted to the Sixty-second World Health Assembly;

(2) in accordance with paragraph 2 of Article 54 of the International Health Regulations (2005), that the first review of the functioning of the Regulations shall be made by the Sixty-third World Health Assembly;

(3) in accordance with paragraph 3 of Article 54 of the International Health Regulations (2005), that the first review and evaluation of the functioning of Annex 2 shall be submitted to the Sixty-second World Health Assembly for its consideration;

3. URGES Member States:

(1) to ensure that the contact details of the centre that has been designated as the National IHR Focal Point are complete and up to date and to encourage relevant staff within the centre to access and use the Event Information Site on the WHO web site;

¹ Documents A61/7 and A61/7 Corr.1.

(2) to take steps to ensure that the national core capacity requirements specified in Annex 1 to the Regulations are developed, strengthened and maintained, in accordance with Articles 5 and 13 of the International Health Regulations (2005);

(3) to designate an expert, if they have not already done so, for the IHR Roster of Experts, in accordance with Article 47 of the International Health Regulations (2005);

(4) to continue to support each other and collaborate with WHO in the implementation of the International Health Regulations (2005), in accordance with resolution WHA58.3 and relevant provisions of those Regulations;

4. REQUESTS the Director-General:

(1) to submit every year a single report, including information provided by States Parties and about the Secretariat's activities, to the Health Assembly for its consideration, pursuant to paragraph 1 of Article 54 of the International Health Regulations (2005);

(2) to provide support to Member States with the most vulnerable health systems in strengthening core capacity requirements for surveillance and response at airports, ports and ground crossings, paying special attention to the sub-Saharan Africa laboratory network;

(3) to encourage efforts to ensure effective communication between National IHR focal points concomitant with the communications with WHO IHR contact points and encourage the sharing of information on the state of actual outbreaks in order to facilitate alert and appropriate response activities for the prevention and control of infectious diseases across borders.

(Seventh plenary meeting, 23 May 2008 –
Committee A, first report)

WHA61.3 Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan

The Sixty-first World Health Assembly,

Mindful of the basic principle established in the Constitution of WHO, which affirms that the health of all peoples is fundamental to the attainment of peace and security;

Recalling all its previous resolutions on health conditions in the occupied Arab territories;

Taking note of the report of the Director-General on the health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan;¹

Stressing the essential role of UNRWA in providing crucial health and education services in the occupied Palestinian territory particularly in addressing the emergency needs in the Gaza Strip;

¹ Document A61/18 Rev.1.

Expressing its concern at the deterioration of economic and health conditions as well as the humanitarian crisis resulting from the continued occupation and the severe restrictions imposed by Israel, the occupying power;

Expressing its concern also at the health crisis and rising levels of food insecurity in the occupied Palestinian territory, particularly in the Gaza Strip;

Affirming the need for guaranteeing universal coverage of health services and for preserving the functions of the public health services in the occupied Palestinian territory;

Recognizing that the acute shortage of financial and medical resources in the Palestinian Ministry of Health, which is responsible for running and financing public health services, jeopardizes the access of the Palestinian population to curative and preventive services;

Affirming the right of Palestinian patients and medical staff to have access to the Palestinian health institutions in occupied east Jerusalem;

Deploring the incidents involving lack of respect and protection for Palestinian ambulances and medical personnel by the Israeli army, which led to casualties among Palestinian medical personnel, as well as the restrictions on movement imposed on them by Israel, the occupying power, in violation of international humanitarian law;

Expressing deep concern at the grave implication of the wall on the accessibility and quality of medical services received by the Palestinian population in the occupied Palestinian territory, including east Jerusalem;

Expressing deep concern also at the serious implications for pregnant women and patients of Israeli restriction of movement imposed on Palestinian ambulances and medical personnel,

1. DEMANDS that Israel, the occupying power:

- (1) lift immediately the closure in the occupied Palestinian territory, particularly the closure of the crossing points of the occupied Gaza Strip that are causing the serious shortage of medicines and medical supplies therein, and comply in this regard with the provisions of the Israeli-Palestinian Agreement on Movement and Access of November 2005;
- (2) reverse its policies and measures that have led to the prevailing dire health conditions and severe food and fuel shortages in the Gaza Strip;
- (3) comply with the advisory opinion rendered on 9 July 2004 by the International Court of Justice on the wall which, inter alia, has grave implications on the accessibility and quality of medical services received by the Palestinian population in the occupied Palestinian territory, including east Jerusalem;
- (4) facilitate the access of Palestinian patients and medical staff to the Palestinian health institutions in occupied east Jerusalem and abroad;
- (5) pay the Palestinian Authority all its remaining customs and health insurance revenues, regularly and without delay, in order to enable it to fulfil its responsibilities with respect to basic human needs, including health services;

(6) ensure unhindered and safe passage for Palestinian ambulances as well as respect and protection of medical personnel, in compliance with international humanitarian law;

(7) improve the living and medical conditions of Palestinian detainees, particularly children, women and patients;

(8) facilitate the transit and entry of medicine and medical equipment to the occupied Palestinian territory;

(9) shoulder its responsibility towards the humanitarian needs of the Palestinian people and their daily access to humanitarian aid, including food and medicine, in compliance with international humanitarian law;

(10) halt immediately all its practices, policies and plans, including its policy of closure, that seriously affect the health conditions of civilians under occupation;

(11) facilitate the work of UNRWA and other international organizations and ensure the free movement of their staff and aid provisions;

2. URGES Member States and intergovernmental and nongovernmental organizations:

(1) to help overcome the health crisis in the occupied Palestinian territory by providing assistance to the Palestinian people;

(2) to help lift the restrictions and obstacles imposed on the Palestinian people in the occupied Palestinian territory;

(3) to remind Israel, the occupying power, to abide by the Fourth Geneva Convention relative to the Protection of Civilian Persons in Time of War of 1949;

(4) to support and assist the Palestinian Ministry of Health in carrying out its duties including running and financing public health services;

(5) to provide financial and technical support to the Palestinian public health and veterinary services;

3. EXPRESSES its deep appreciation to the Director-General for the efforts to provide necessary assistance to the Palestinian people in the occupied Palestinian territory, including east Jerusalem, and to the Syrian population in the occupied Syrian Golan;

4. REQUESTS the Director-General:

(1) to provide support to the Palestinian health and veterinary services including capacity building;

(2) to submit a fact-finding report on the health and economic situation in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan;

(3) to support the establishment of medical facilities and provide health-related technical assistance for the Syrian population in the occupied Syrian Golan;

- (4) to continue providing necessary technical assistance in order to meet the health needs of the Palestinian people, including the handicapped and injured;
- (5) to support the development of the health system in Palestine, including development of human resources;
- (6) to report on implementation of this resolution to the Sixty-second World Health Assembly.

(Seventh plenary meeting, 23 May 2008 –
Committee B, first report)

WHA61.4 Strategies to reduce the harmful use of alcohol¹

The Sixty-first World Health Assembly,

Having considered the report on strategies to reduce the harmful use of alcohol² and the further guidance on strategies and policy element options therein;

Reaffirming resolutions WHA32.40 on development of the WHO programme on alcohol-related problems, WHA36.12 on alcohol consumption and alcohol-related problems, development of national policies and programmes, WHA42.20 on prevention and control of drug and alcohol abuse and WHA57.16 on health promotion and healthy lifestyles;

Recalling resolution WHA58.26 on public-health problems caused by harmful use of alcohol and decision WHA60(10);

Noting the report by the Secretariat presented to the Sixtieth World Health Assembly on evidence-based strategies and interventions to reduce alcohol-related harm, including the addendum on a global assessment of public health problems caused by harmful use of alcohol;³

Noting the second report of the WHO Expert Committee on Problems Related to Alcohol Consumption⁴ and acknowledging that effective strategies and interventions that target the general population, vulnerable groups, individuals and specific problems are available and should be optimally combined in order to reduce alcohol-related harm;

Mindful that such strategies and interventions must be implemented in a way that takes into account different national, religious and cultural contexts, including national public health problems, needs and priorities, and differences in Member States' resources, capacities and capabilities;

Deeply concerned by the extent of public health problems associated with harmful use of alcohol, including injuries and violence, and possible links to certain communicable diseases, thereby adding to the disease burden, in both developing and developed countries;

¹ See Annex 4 for the financial and administrative implications for the Secretariat of the resolution.

² Document A61/13.

³ Documents A60/14 and A60/14 Add.1.

⁴ WHO Technical Report Series, No. 944, 2007.

Mindful that international cooperation in reducing public health problems caused by the harmful use of alcohol is intensifying, and of the need to mobilize the necessary support at global and regional levels,

1. URGES Member States:

- (1) to collaborate with the Secretariat in developing a draft global strategy on harmful use of alcohol based on all evidence and best practices, in order to support and complement public health policies in Member States, with special emphasis on an integrated approach to protect at-risk populations, young people and those affected by harmful drinking of others;
- (2) to develop, in interaction with relevant stakeholders, national systems for monitoring alcohol consumption, its health and social consequences and the policy responses, and to report regularly to WHO's regional and global information systems;
- (3) to consider strengthening national responses, as appropriate and where necessary, to public health problems caused by harmful use of alcohol, on the basis of evidence on effectiveness and cost-effectiveness of strategies and interventions to reduce alcohol-related harm generated in different contexts;

2. REQUESTS the Director-General:

- (1) to prepare a draft global strategy to reduce harmful use of alcohol that is based on all available evidence and existing best practices and that addresses relevant policy options, taking into account different national, religious and cultural contexts, including national public health problems, needs and priorities, and differences in Member States' resources, capacities and capabilities;
- (2) to ensure that the draft global strategy will include a set of proposed measures recommended for States to implement at the national level, taking into account the national circumstances of each country;
- (3) to include full details of ongoing and emerging regional, subregional and national processes as vital contributions to a global strategy;
- (4) to collaborate and consult with Member States, as well as consult with intergovernmental organizations, health professionals, nongovernmental organizations and economic operators on ways they could contribute to reducing harmful use of alcohol;
- (5) to submit to the Sixty-third World Health Assembly, through the Executive Board, a draft global strategy to reduce harmful use of alcohol.

(Eighth plenary meeting, 24 May 2008 –
Committee A, second report)

WHA61.5 Financial report and audited financial statements for the period 1 January 2006 – 31 December 2007

The Sixty-first World Health Assembly,

Having examined the Financial report and audited financial statements for the period 1 January 2006 – 31 December 2007;¹

Having noted the second report of the Programme, Budget and Administration Committee of the Executive Board to the Sixty-first World Health Assembly,²

ACCEPTS the Director-General's Financial report and audited financial statements for the period 1 January 2006 – 31 December 2007.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.6 Miscellaneous Income 2006–2007 and financing gap for strategic objectives 12 and 13

The Sixty-first World Health Assembly,

Recalling the appropriation resolution for the financial period 2008–2009 (resolution WHA60.12);

Aware of the forecast financing gap in respect of meeting the approved total effective budget for appropriation sections 12 and 13 of, respectively, US\$ 214 million and US\$ 543 million;³

Considering the exceptional surplus in Miscellaneous Income realized in 2006–2007,

1. RESOLVES to appropriate an additional amount of US\$ 15 million from Miscellaneous Income in order to finance appropriation sections 12 and 13 of the Programme budget 2008–2009;
2. REQUESTS the Director-General to report to the Sixty-second World Health Assembly on the status of the Miscellaneous Income account.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

¹ Documents A61/20 and A61/20 Add.1.

² Document A61/22.

³ Document A61/41.

WHA61.7 Members in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution

The Sixty-first World Health Assembly,

Having considered the third report of the Programme, Budget and Administration Committee of the Executive Board to the Sixty-first World Health Assembly on status of collection of assessed contributions, including Members in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution;¹

Noting that, at the time of opening of the Sixty-first World Health Assembly, the voting rights of Argentina, Central African Republic, Cape Verde, Comoros, Dominica, Guinea-Bissau and Somalia were suspended, such suspension to continue until the arrears of the Member concerned have been reduced, at the present or future Health Assemblies, to a level below the amount that would justify invoking Article 7 of the Constitution;

Noting that Democratic Republic of Congo, Gambia, Solomon Islands and Togo were in arrears at the time of the opening of the Sixty-first World Health Assembly to such an extent that it was necessary for the Health Assembly to consider, in accordance with Article 7 of the Constitution, whether or not the voting privileges of those countries should be suspended at the opening of the Sixty-second World Health Assembly,

DECIDES:

- (1) that in accordance with the statement of principles set out in resolution WHA41.7 if, by the time of the opening of the Sixty-second World Health Assembly, Democratic Republic of Congo, Gambia, Solomon Islands and Togo are still in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution, their voting privileges shall be suspended as from the said opening;
- (2) that any suspension that takes effect as aforesaid shall continue at the Sixty-second and subsequent World Health Assemblies, until the arrears of Democratic Republic of Congo, Gambia, Solomon Islands and Togo have been reduced to a level below the amount that would justify invoking Article 7 of the Constitution;
- (3) that this decision shall be without prejudice to the right of any Member to request restoration of its voting privileges in accordance with Article 7 of the Constitution.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

¹ Document A61/35.

WHA61.8 Special arrangements for settlement of arrears: Kyrgyzstan

The Sixty-first World Health Assembly,

Having considered the third report of the Programme, Budget and Administration Committee of the Executive Board to the Sixty-first World Health Assembly on the status of collection of assessed contributions, including Member States in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution, with respect to the request of Kyrgyzstan for the settlement of its outstanding contributions,¹

1. DECIDES to restore the voting privileges of Kyrgyzstan at the Sixty-first World Health Assembly on condition that Kyrgyzstan shall pay its outstanding contributions, totalling US\$ 1 213 895, in 20 annual instalments payable in each of the years 2008 to 2027 as set out below, in addition to its current-year assessment due in the current year:

	US \$
2008	7 350
2009	10 000
2010	15 000
2011	20 000
2012	30 000
2013	30 000
2014	30 000
2015	30 000
2016	30 000
2017	30 000
2018	100 000
2019	100 000
2020	100 000
2021	100 000
2022	100 000
2023	100 000
2024	100 000
2025	100 000
2026	100 000
2027	81 545
Total	1 213 895

2. DECIDES that, in accordance with Article 7 of the Constitution, voting privileges shall be automatically suspended again if Kyrgyzstan does not meet the conditions stipulated at 1 above;

¹ Document A61/35.

3. REQUESTS the Director-General to communicate this resolution to the Government of Kyrgyzstan.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.9 Report of the External Auditor to the Health Assembly

The Sixty-first World Health Assembly,

Having considered the report of the External Auditor to the Health Assembly;¹

Having noted the fourth report of the Programme, Budget and Administration Committee of the Executive Board to the Sixty-first World Health Assembly,²

ACCEPTS the report of the External Auditor to the Health Assembly.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.10 Amendments to the Staff Regulations and Staff Rules

The Sixty-first World Health Assembly,

Noting the recommendations of the Executive Board with regard to remuneration of staff in ungraded posts and of the Director-General,³

1. ESTABLISHES the salaries of Assistant Directors-General and Regional Directors at US\$ 172 546 per annum before staff assessment, resulting in a modified net salary of US\$ 125 155 (dependency rate) or US\$ 113 332 (single rate);

2. ESTABLISHES the salary of the Deputy Director-General at US\$ 189 929 per annum before staff assessment, resulting in a modified net salary of US\$ 136 454 (dependency rate) or US\$ 122 802 (single rate);

3. ESTABLISHES the salary of the Director-General at US\$ 233 720 per annum before staff assessment, resulting in a modified net salary of US\$ 164 918 (dependency rate) or US\$ 146 662 (single rate);

¹ Document A61/23.

² Document A61/24.

³ Document A61/28.

4. DECIDES that those adjustments in remuneration shall take effect from 1 January 2008.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.11 Method of work of the Health Assembly¹

The Sixty-first World Health Assembly,

Having considered the report on method of work of the Health Assembly,²

1. DECIDES to add to the Rules of Procedure of the World Health Assembly a new Rule 12bis, as follows:

Rule 12bis

At each session the provisional agenda and, subject to Rule 12, any proposed supplementary item, together with the report of the General Committee thereon, shall be submitted to the Health Assembly for its adoption as soon as possible after the opening of the session.

2. DECIDES to delete Rules 24 and 25 of the Rules of Procedure of the World Health Assembly;
3. DECIDES to amend Rules 26, 31, 34, 36, 68, and 92 of the Rules of Procedure of the World Health Assembly as follows, on the understanding that the Rules of Procedure shall be renumbered as a consequence of the deletion of Rules 24 and 25:

Rule 26

At each regular session, the Health Assembly shall elect a President and five Vice-Presidents, who shall hold office until their successors are elected.

Rule 31

The General Committee of the Health Assembly shall consist of the President and Vice-Presidents of the Health Assembly, the Chairmen of the main committees of the Health Assembly established under Rule 34 and that number of delegates to be elected by the Health Assembly as shall provide a total of twenty-five members of the General Committee, provided that no delegation may have more than one representative on the Committee. The President of the Health Assembly shall convene, and preside over, meetings of the General Committee.

[...]

Rule 34

[...]

The Chairmen of these main committees shall be elected by the Health Assembly.

¹ See Annex 1.

² Document A61/30.

Rule 36

Each main committee shall elect two Vice-Chairmen and a Rapporteur.

Rule 68

If two or more proposals are moved, the Health Assembly shall, unless it decides otherwise, vote on the proposals in the order in which they have been circulated to all delegations, unless the result of a vote on a proposal makes unnecessary any other voting on the proposal or proposals still outstanding.

Rule 92

Verbatim records of all plenary meetings and summary records of the meetings of the General Committee and of committees and subcommittees shall be made by the Secretariat. Unless otherwise expressly decided by the committee concerned, no record shall be made of the proceedings of the Committee on Credentials other than the report presented by the Committee to the Health Assembly.

4. DECIDES that the Health Assembly shall continue to follow its current practice concerning equitable geographical representation in the nomination of candidates for elected positions in the Health Assembly and its subsidiary bodies, with a view to such nominations being received by the Director-General no later than the opening of each session of the Health Assembly.

5. FURTHER DECIDES that the foregoing changes to its Rules of Procedure shall take effect from the closure of its Sixty-first session.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.12 Multilingualism: implementation of action plan

The Sixty-first World Health Assembly,

Convinced of the relevance of the recommendations made in the report of the Joint Inspection Unit¹ entitled Multilingualism and access to information: case study on the World Health Organization, which was submitted to the Programme, Budget and Administration Committee of the Executive Board at its first meeting;

Recalling the provisions relating to multilingualism contained in the Medium-term strategic plan 2008–2013 (resolution WHA60.11);

Also recalling the resolutions and rules relating to language use in WHO, and in particular resolution WHA50.32 on respect for equality among the official languages, resolution WHA51.30 concerning the availability of governing body documents on the Internet and resolution EB105.R6 on the use of languages in WHO;

¹ Document JIU/REP/2003/4.

Considering that the universality of the organizations of the United Nations system is based on, among other things, language diversity and equality among the official and working languages chosen by the Member States;

Welcoming in this regard the resolution on multilingualism (61/266) adopted by the United Nations General Assembly in May 2007;

Commending the report by the Secretariat entitled “Multilingualism: plan of action”¹ submitted to the Executive Board at its 121st session in May 2007,

1. REQUESTS the Director-General to implement, as rapidly as possible, the plan of action contained in the Secretariat’s report,¹ and in particular the following points:

(1) preparation, before the 124th session of the Executive Board, of a timetable for implementation of the plan of action and a table showing the financial implications globally fitting within the framework of the Medium-term strategic plan 2008–2013;

(2) preparation of a strategy to set translation priorities, associating Member States by means of a mechanism of informal consultations to be defined;

2. ALSO REQUESTS the Director-General to ensure:

(1) equal respect for linguistic diversity at WHO headquarters, regional offices and country offices;

(2) establishment of a database to make it possible to determine in which official languages of the Organization members of WHO staff belonging to the professional category are fluent;

(3) that health-care background is taken into account when recruiting WHO language-services staff;

(4) encouragement of and promotion of access to, high-quality language training for all the Organization’s staff;

3. FURTHER REQUESTS the Director-General to report to the Sixty-second World Health Assembly on the implementation of this resolution, and to report biennially thereon.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.13 International Agency for Research on Cancer: amendments to Statute²

The Sixty-first World Health Assembly,

Considering the amendments to Article VI of the Statute of the International Agency for Research on Cancer adopted by the Governing Council at its Fiftieth Session;³

¹ Documents EB121/6 and EB121/6 Corr.1.

² See Annex 2.

³ Document A61/33.

Considering the provisions of Article X of the Statute of the Agency,

ACCEPTS the following amendment to the Statute of the Agency, which shall enter into force forthwith:

Article VI – The Scientific Council

- (1) The Scientific Council shall be composed of highly qualified scientists, selected on the basis of their technical competence in cancer research and allied fields. Members of the Scientific Council are appointed as experts and not as representatives of Participating States.
- (2) Each Participating State may nominate up to two experts for membership in the Scientific Council and, if a Participating State makes such a nomination, the Governing Council shall appoint one of them.
- (3) In identifying experts to be considered for appointment to the Scientific Council, Participating States shall take into account advice to be provided by the Chairperson of the Scientific Council and Director of the Agency concerning the expertise required on the Scientific Council at the time of those appointments.
- (4) Members of the Scientific Council shall serve for a term of four years. Should a member not complete a term, a new appointment shall be made for the remainder of the term to which the member would have been entitled, in accordance with paragraph 5.
- (5) When a vacancy arises on the Scientific Council, the Participating State that nominated the departing member may nominate up to two experts to replace that member in accordance with paragraphs 2 and 3. Any member leaving the Scientific Council, other than a member appointed for a reduced term, may be reappointed only after at least one year has elapsed.
- (6) The Scientific Council shall be responsible for:
 - (a) adopting its own rules of procedure;
 - (b) the periodical evaluation of the activities of the Agency;
 - (c) recommending programmes of permanent activities and preparing special projects for submission to the Governing Council;
 - (d) the periodical evaluation of special projects sponsored by the Agency;
 - (e) reporting to the Governing Council, for consideration at the time that body considers the programme and budget, upon the matters dealt with in subparagraphs (b), (c) and (d) above.

(Eighth plenary meeting, 24 May 2008 –
Committee B, second report)

WHA61.14 Prevention and control of noncommunicable diseases: implementation of the global strategy

The Sixty-first World Health Assembly,

Having considered the report on the prevention and control of noncommunicable diseases: implementation of the global strategy;¹

Recalling resolutions WHA53.17 on the prevention and control of noncommunicable diseases and WHA60.23 on the prevention and control of noncommunicable diseases: implementation of the global strategy;

Reaffirming its commitment to the aim of the global strategy for the prevention and control of noncommunicable diseases² to reduce premature mortality and improve quality of life;

Reaffirming also its commitment to addressing key risk factors for noncommunicable diseases through the implementation of the WHO Framework Convention on Tobacco Control, adopted by the Health Assembly in 2003 (resolution WHA56.1), the global strategy on diet, physical activity and health, endorsed by the Health Assembly in 2004 (resolution WHA57.17), and the evidence-based strategies and interventions to reduce the public health problems caused by the harmful use of alcohol (resolution WHA58.26);

Deeply concerned that the global burden of noncommunicable diseases continues to grow, in particular in low-income and middle-income countries, and convinced that global action is necessary, including by effectively addressing the key risk factors for noncommunicable diseases;

Reaffirming the leadership role of WHO in promoting global action against noncommunicable diseases, and the need for WHO to continue to cooperate with regional and international organizations in order to reduce effectively the impact of noncommunicable diseases,

1. ENDORSES the action plan for the global strategy for the prevention and control of noncommunicable diseases;³
2. URGES Member States:
 - (1) to strengthen national efforts to address the burden of noncommunicable diseases;
 - (2) to consider the proposed actions in the action plan for the prevention and control of noncommunicable diseases and implement relevant actions, in accordance with national priorities;
 - (3) to continue to implement the actions agreed by the Health Assembly in resolution WHA60.23 on the prevention and control of noncommunicable diseases: implementation of the global strategy;

¹ Document A61/8.

² Document A53/14.

³ See Annex 3.

(4) to increase provision of support to the work of the Secretariat to prevent and control noncommunicable diseases, including the implementation of the action plan;

(5) to give high priority to the implementation of the elements of the WHO Framework Convention on Tobacco Control;

3. REQUESTS the Director-General:

(1) to continue to give suitably high priority to the prevention and control of noncommunicable diseases and to consider allocating, within the framework of the Medium-term strategic plan 2008–2013 a higher proportion of budget to their prevention and control, with a focus on the development of core capacity of the Member States and increased technical capacity of the WHO Secretariat;

(2) to report to the Sixty-third World Health Assembly, and subsequently every two years to the Health Assembly, through the Executive Board, on progress in implementing the global strategy on prevention and control of noncommunicable diseases and the action plan.

(Eighth plenary meeting, 24 May 2008 –
Committee A, third report)

WHA61.15 Global immunization strategy

The Sixty-first World Health Assembly,

Having considered the report on the global immunization strategy;¹

Applauding the remarkable investments in human and financial resources made by Member States and partner agencies in support of vaccines and immunization as well as the launch of innovative financing mechanisms, such as the International Finance Facility for Immunization, and the advance market commitment for a pneumococcal conjugate vaccine through the GAVI Alliance;

Recognizing the immense contribution that immunization has made to the control of the common communicable diseases in the countries where it has been effectively applied;

Recognizing that continued efforts are also required to strengthen surveillance of communicable diseases and ensure the quality of the production, management and administration of vaccines;

Recalling resolution WHA56.20 on reducing global measles mortality, and commending Member States' and their partners' success in exceeding the goal of reducing deaths worldwide due to measles by 50% by the end of 2005 compared with the 1999 level;

Commending also Member States' and their partners' progress in increasing the availability, affordability and uptake of hepatitis B vaccine worldwide;

¹ Document A61/10.

Recognizing the availability of new and underutilized vaccines that could have significant impact on the health of the peoples of the world, including the achievement of the health-related Millennium Development Goals;

Encouraged by the progress in molecular biology and genetics that is accelerating the discovery and development of new vaccines and by the increasing number of developing-country manufacturers producing vaccines that meet WHO requirements for vaccines of assured quality;

Concerned that many developing countries are not on track to meet the internationally agreed targets in the health-related Millennium Development Goals, particularly the target of reducing the under-five mortality rate;

Concerned that there are insufficient resources available for introduction of new and underutilized vaccines, especially in low- and middle-income countries, and given the costs related to procurement and introduction of these vaccines, and taking into account the need to expand the number of manufacturers, particularly in developing countries, that can produce to the standards required for attaining, and maintaining, WHO-prequalification and create a competitive market place for these vaccines;

Stressing the vital role that vaccine and immunization programmes can play in reducing under-five mortality and in facilitating the delivery of a package of life-saving interventions,

1. URGES Member States:

- (1) to review national strategy and programme performance, to identify areas for improvement and to implement fully the strategy for reducing measles mortality in order to achieve the goal set in the Global Immunization Vision and Strategy 2006–2015 of a 90% reduction in the global measles mortality rate between 2000 and 2010;
- (2) to enhance efforts to improve delivery of high-quality immunization services in order to achieve the target of equitable coverage of at least 80% in all districts by 2010 set in the Global Immunization Vision and Strategy 2006–2015;
- (3) to stimulate rapid introduction and uptake of life-saving vaccines into national immunization schedules in accordance with national priorities and to expand coverage of these vaccines in order to accelerate the achievement of the health-related Millennium Development Goals;
- (4) to expand further access to, and coverage of, available, affordable and cost-effective new life-saving vaccines of assured quality and desired efficacy, while maintaining efforts to strengthen regular vaccination programmes in accordance with the burden of disease and national priorities, for all target populations in order to accelerate the achievement of the health-related Millennium Development Goals, and to promote and strengthen long-term financial and programmatic sustainability;
- (5) to develop, strengthen and/or maintain surveillance systems for vaccine-related adverse events, linked with systems for monitoring compliance with safe injection practices;
- (6) to strengthen efforts to protect, promote and support early and effective breastfeeding, in order to boost the development of infants' overall immune systems;
- (7) to strengthen surveillance systems for vaccine-preventable diseases and monitoring of vaccination programmes;

2. REQUESTS the Director-General:

- (1) to work and increase collaboration with Member States in order to sustain political commitment at all levels for achieving high immunization coverage rates with all available cost-effective vaccines;
- (2) to collaborate with international partners and intergovernmental partners in order to provide technical support to expand the number of manufacturers, particularly in developing countries, that can meet the standards required to attain and maintain WHO-prequalification standards;
- (3) to collaborate with international partners, intergovernmental partners and donors as well as vaccine producers in mobilizing necessary resources to support low- and middle-income countries with the aim of increasing the supply of affordable vaccines of assured quality;
- (4) to work with UNICEF and the GAVI Alliance on building existing international efforts and partnerships and facilitating the development of a consensus among developing and developed countries for meeting the financial gaps and other requirements for the attainment of the health-related Millennium Development Goals through immunization;
- (5) to take measures, as appropriate, to assist developing countries to establish and strengthen their capacity for vaccine research, development and regulation, for the purpose of improving the output of vaccine production with the aim of increasing the supply of affordable vaccines of assured quality;
- (6) to provide guidelines and technical support to Member States in order to establish integrated surveillance of adverse events following immunization and to minimize unnecessary vaccine-related adverse events;
- (7) to facilitate scientific, technical and financial investments in the research and development of safe and effective vaccines against poverty-related and neglected diseases;
- (8) to monitor progress towards achievement of global immunization goals and report on such progress to the Sixty-fourth World Health Assembly;
- (9) to accelerate the implementation of the global framework for vaccine-preventable disease surveillance and immunization programme monitoring, through the gathering of the comprehensive epidemiological data required to guide immunization programmes, and to strengthen national capacity for making evidence-based policy decisions to adopt new vaccines.

(Eighth plenary meeting, 24 May 2008 –
Committee A, third report)

WHA61.16 Female genital mutilation

The Sixty-first World Health Assembly,

Having considered the report on female genital mutilation;¹

Recalling resolution WHA47.10 on maternal and child health and family planning: traditional practices harmful to the health of women and children;

Recalling the Beijing Declaration and Platform for Action of the Fourth World Conference on Women (Beijing, 1995), the Programme of Action of the International Conference on Population and Development (Cairo, 1994) and their five- and ten-year reviews as well as the United Nations Millennium Declaration 2000 and the commitments relevant to the girl child made at the United Nations General Assembly special session on children (2002), and in United Nations General Assembly resolution 60/1 on the 2005 World Summit Outcome, and affirming that all these outcomes constitute an essential framework for advancing the rights of women and girls and eliminating female genital mutilation;

Affirming that the International Covenant on Civil and Political Rights (1976), the Convention on the Elimination of All Forms of Discrimination against Women (1979) and the Convention on the Rights of the Child (1989) constitute an important contribution to the legal framework for the protection and promotion of the human rights of girls and women, and recognizing the importance African States attach to the African Charter on the Rights and Welfare of the Child (1990) and the Solemn Declaration on Gender Equality in Africa (2004) in this regard;

Recognizing the entry into force of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, adopted in Maputo on 11 July 2003, whose provisions on female genital mutilation mark a significant milestone towards the abandonment of this practice;

Recalling also the resolution of the United Nations Commission on the Status of Women² on ending female genital mutilation (March 2008);

Recognizing that female genital mutilation violates the human rights of girls and women including their right to the enjoyment of the highest attainable standard of physical and mental health;

Noting that, whereas there is evidence that the practice is in decline, it is still widespread in some parts of the world, with an estimated 100 million to 140 million girls and women having undergone the practice and at least another three million being at risk of undergoing the practice every year;

Deeply concerned about the serious health consequences of female genital mutilation; the risk of immediate complications, which include severe pain, shock, haemorrhage, tetanus, sepsis, urine retention, ulceration of the genital region and injury to adjacent genital tissue; the long-term consequences, which include increased risk of maternal morbidity, recurrent bladder and urinary tract infection, cysts, infertility and adverse psychological and sexual consequences; and increased risk of neonatal death for babies born to mothers having undergone female genital mutilation;

¹ Document A61/11.

² Document E/CN.6/2008/L.2/Rev.1.

Also concerned about emerging evidence of an increase in carrying out female genital mutilation by medical personnel in all regions where it is practised;

Emphasizing that concerted action is needed in sectors such as education, finance, justice and women's affairs as well as in the health sector, and that many different kinds of actor must be engaged, from governments and international agencies to nongovernmental organizations,

1. URGES all Member States:

- (1) to accelerate actions towards the elimination of female genital mutilation, including education and information necessary for full understanding of the gender, health and human rights dimensions of female genital mutilation;
- (2) to enact and enforce legislation to protect girls and women from all forms of violence, particularly female genital mutilation, and ensure implementation of laws prohibiting female genital mutilation by any person, including medical professionals;
- (3) to support and enhance community-based efforts to eliminate the practice of female genital mutilation, particularly ensuring men's and local leaders' participation in the process to eliminate the practice;
- (4) to work with all sectors of government, international agencies and nongovernmental organizations in support of the abandonment of the practice as a major contribution to attainment of the Millennium Development Goals on promoting gender equality and empowerment of women, reducing child mortality, and improving maternal health;
- (5) to formulate and promote guidelines for the care, particularly during childbirth, of girls and women who have undergone female genital mutilation;
- (6) to develop or reinforce social and psychological support services and care and to take measures to improve health, including sexual and reproductive health, in order to assist women and girls who are subjected to this violence;

2. REQUESTS the Director-General:

- (1) to provide increased support to Member States for implementing actions to advocate the elimination of female genital mutilation and other forms of violence against girls and women;
- (2) to work with partners both within and outside the United Nations system on promoting actions to protect the human rights of girls and women;
- (3) to increase support for research on different aspects of female genital mutilation in order, inter alia, to achieve its elimination;
- (4) to provide support to Member States in strengthening their health information systems for monitoring progress made towards elimination of female genital mutilation;
- (5) to report every three years to the Health Assembly, through the Executive Board, on actions taken by the WHO Secretariat, Member States and other partners.

WHA61.17 Health of migrants

The Sixty-first World Health Assembly,

Having considered the report on health of migrants;¹

Recalling the United Nations General Assembly resolution 58/208 underlining the need for a high-level dialogue on the multidimensional aspects of international migration and development (New York, 23 December 2003);

Recalling the first plenary session of the United Nations General Assembly on migration issues and the conclusions of the High-level Dialogue on Migration and Development (New York, 14–15 September 2006) with their focus on ways to maximize the development benefits of migration and to minimize its negative impacts;

Recognizing that the International Health Regulations (2005) include provisions relating to international passenger transport;

Recalling resolutions WHA57.19 and WHA58.17 on international migration of health personnel: a challenge for health systems in developing countries, calling for support to the strengthening of health systems, in particular human resources for health;

Recognizing the need for WHO to consider the health needs of migrants in the framework of the broader agenda on migration and development;

Recognizing that health outcomes can be influenced by the multiple dimensions of migration;

Noting that some groups of migrants experience increased health risks;

Recognizing the need for additional data on migrants' health and their access to health care in order to substantiate evidence-based policies;

Taking into account the determinants of migrants' health in developing intersectoral policies to protect their health;

Mindful of the role of health in promoting social inclusion;

Acknowledging that the health of migrants is an important public health matter for both Member States and the work of the Secretariat;

Noting that Member States have a need to formulate and implement strategies for improving the health of migrants;

Noting that policies on migrants' health should be sensitive to the specific health needs of women, men and children;

Recognizing that health policies can contribute to development and to achievement of the Millennium Development Goals,

¹ Document A61/12.

1. CALLS UPON Member States:

- (1) to promote migrant-sensitive health policies;
- (2) to promote equitable access to health promotion, disease prevention and care for migrants, subject to national laws and practice, without discrimination on the basis of gender, age, religion, nationality or race;
- (3) to establish health information systems in order to assess and analyse trends in migrants' health, disaggregating health information by relevant categories;
- (4) to devise mechanisms for improving the health of all populations, including migrants, in particular through identifying and filling gaps in health service delivery;
- (5) to gather, document and share information and best practices for meeting migrants' health needs in countries of origin or return, transit and destination;
- (6) to raise health service providers' and professionals' cultural and gender sensitivity to migrants' health issues;
- (7) to train health professionals to deal with the health issues associated with population movements;
- (8) to promote bilateral and multilateral cooperation on migrants' health among countries involved in the whole migratory process;
- (9) to contribute to the reduction of the global deficit of health professionals and its consequences on the sustainability of health systems and the attainment of the Millennium Development Goals;

2. REQUESTS the Director-General:

- (1) to promote migrants' health on the international health agenda in collaboration with other relevant international organizations;
- (2) to explore policy options and approaches for improving the health of migrants;
- (3) to analyse the major challenges to health associated with migration;
- (4) to support the development of regional and national assessments of migrants' health status and access to health care;
- (5) to promote the inclusion of migrants' health in the development of regional and national health strategies where appropriate;
- (6) to help to collect and disseminate data and information on migrants' health;
- (7) to promote dialogue and cooperation on migrants' health among all Member States involved in the migratory process, within the framework of the implementation of their health strategies, with particular attention to strengthening of health systems in developing countries;

- (8) to promote interagency, interregional and international cooperation on migrants' health with an emphasis on developing partnerships with other organizations and considering the impact of other policies;
- (9) to encourage the exchange of information through a technical network of collaborating centres, academic institutions, civil society and other key partners in order to further research into migrants' health and to enhance capacity for technical cooperation;
- (10) to promote exchange of information on migrants' health, nationally, regionally and internationally, making use of modern information technology;
- (11) to submit to the Sixty-third World Health Assembly, through the Executive Board, a report on the implementation of this resolution.

(Eighth plenary meeting, 24 May 2008 –
Committee A, third report)

WHA61.18 Monitoring of the achievement of the health-related Millennium Development Goals

The Sixty-first World Health Assembly,

Recalling the 2005 World Summit Outcome and the commitments taken by the international community to implement fully the Millennium Development Goals;

Concerned by the relatively slow progress made, especially in the sub-Saharan African countries, in achieving the Millennium Development Goals, and in particular the health-related Goals;

Concerned by the fact that achievement of Millennium Development Goals varies from country to country and from Goal to Goal;

Concerned that high rates of morbidity and mortality are underpinned by social determinants of health and high levels of malnutrition and noting that these social determinants of health may further undermine achievement of the health-related Millennium Development Goals;

Recalling the General Assembly resolution 60/265 dated 12 July 2006 on follow-up to the development outcome of the 2005 World Summit, including the Millennium Development Goals and the other internationally agreed development goals, and the WHO Medium-term strategic plan 2008–2013;

Welcoming the report on monitoring achievement of the health-related Millennium Development Goals;¹

Underlining in particular the need to build sustainable national health systems; strengthen national capacities; fully honour financing commitments made by national governments and their development partners in order to better fill many of the resource gaps in the health sector; to take

¹ Document A61/15.

concrete, effective and timely action in implementing all agreed commitments on aid effectiveness and to increase predictability of aid;

Reaffirming the commitments by many developed countries to achieve the target of 0.7% of gross national income for official development assistance by 2015 and to reach at least 0.5% of gross national income for official development assistance by 2010, as well as the target of 0.15% to 0.20% for least developed countries, and urging those developed countries that have not yet done so to make concrete efforts in this regard in accordance with their commitments,

1. DECIDES:

(1) to include the monitoring of the achievement of the health-related Millennium Development Goals as a regular item on the agenda of the Health Assembly;

(2) to support the United Nations Secretary-General's call to action, including the United Nations High-Level Event on the Millennium Development Goals (New York, 25 September 2008);

2. URGES Member States to continue sustaining high-level political commitments and work with development partners towards strengthening national health systems, including health information systems for monitoring progress towards achievement of the Millennium Development Goals;

3. REQUESTS the Director-General:

(1) to submit annually a report on the status of progress made, including on main obstacles and ways to overcome them, according to the new monitoring framework, in achievement of the health-related Millennium Development Goals, through the Executive Board to the Health Assembly;

(2) to that effect, to continue to cooperate closely with all other United Nations and international organizations involved in the process of achieving the health-related Millennium Development Goals in the framework of WHO's Medium-term strategic plan 2008–2013;

(3) to work with all relevant partners to help to ensure that action on the health-related Millennium Development Goals is one of the main themes of the United Nations High-Level Event on the Millennium Development Goals (New York, 25 September 2008).

(Eighth plenary meeting, 24 May 2008 –
Committee B, third report)

WHA61.19 Climate change and health

The Sixty-first World Health Assembly,

Having considered the report on climate change and health;¹

Recalling resolution WHA51.29 on the protection of human health from risks related to climate change and stratospheric ozone depletion and acknowledging and welcoming the work carried out so far by WHO in pursuit of it;

¹ Document A61/14.

Recognizing that, in the interim, the scientific evidence of the effect of the increase in atmospheric greenhouse gases, and of the potential consequences for human health, has considerably improved;

Noting with concern the recent findings of the Intergovernmental Panel on Climate Change that the effects of temperature increases on some aspects of human health are already being observed; that the net global effect of projected climate change on human health is expected to be negative, especially in developing countries, small island developing States and vulnerable local communities which have the least capacity to prepare for and adapt to such change, and that exposure to projected climate change could affect the health status of millions of people, through increases in malnutrition, in death, disease and injury due to extreme weather events, in the burden of diarrhoeal disease, in the frequency of cardiorespiratory diseases, and through altered distribution of some infectious disease vectors;

Noting further that climate change could jeopardize achievement of the Millennium Development Goals, including the health-related Goals, and undermine the efforts of the Secretariat and Member States to improve public health and reduce health inequalities globally;

Recognizing the importance of addressing in a timely fashion the health impacts resulting from climate change due to the cumulative effects of emissions of greenhouse gases, and further recognizing that solutions to the health impacts of climate change should be seen as a joint responsibility of all States and that developed countries should assist developing countries in this regard;

Recognizing the need to assist Member States in assessing the implications of climate change for health and health systems in their country, in identifying appropriate and comprehensive strategies and measures for addressing these implications, in building capacity in the health sector to do so and in working with government and nongovernmental partners to raise awareness of the health impacts of climate change in their country and take action to address them;

Further recognizing that strengthening health systems to enable them to deal with both gradual changes and sudden shocks is a fundamental priority in terms of addressing the direct and indirect effects of climate change for health,

1. URGES Member States:

- (1) to develop health measures and integrate them into plans for adaptation to climate change as appropriate;
- (2) to enhance the capability of public health leaders to be proactive in providing technical guidance on health issues, be competent in developing and implementing strategies for addressing the effects of, and adapting to, climate change, and show leadership in supporting the necessary rapid and comprehensive action;
- (3) to strengthen the capacity of health systems for monitoring and minimizing the public health impacts of climate change through adequate preventive measures, preparedness, timely response and effective management of natural disasters;
- (4) to promote effective engagement of the health sector and its collaboration with all related sectors, agencies and key partners at national and global levels in order to reduce the current and projected health risks from climate change;

(5) to express commitment to meeting the challenges posed to human health by climate change, and to provide clear directions for planning actions and investments at the national level in order to address the health effects of climate change;

2. REQUESTS the Director-General:

(1) to continue to draw to the attention of the public and policy-makers the serious risk of climate change to global health and to the achievement of the health-related Millennium Development Goals, and to work with FAO, WMO, UNDP, UNEP, the United Nations Framework Convention on Climate Change secretariat, and other appropriate organizations of the United Nations, in the context of United Nations reform initiatives, and with national and international agencies, to ensure that these health impacts and their resource implications are understood and can be taken into account in further developing national and international responses to climate change;

(2) to engage actively in the UNFCCC Nairobi Work Programme on Impacts, Vulnerability and Adaptation to Climate Change, in order to ensure its relevance to the health sector, and to keep Member States informed about the work programme in order to facilitate their participation in it as appropriate and access to the benefits of its outputs;

(3) to work on promoting consideration of the health impacts of climate change by the relevant United Nations bodies in order to help developing countries to address the health impacts of climate change;

(4) to continue close cooperation with Member States and appropriate United Nations organizations, other agencies and funding bodies in order to develop capacity to assess the risks from climate change for human health and to implement effective response measures, by promoting further research and pilot projects in this area, including work on:

- (a) health vulnerability to climate change and the scale and nature thereof;
- (b) health protection strategies and measures relating to climate change and their effectiveness, including cost-effectiveness;
- (c) the health impacts of potential adaptation and mitigation measures in other sectors such as marine life, water resources, land use, and transport, in particular where these could have positive benefits for health protection;
- (d) decision-support and other tools, such as surveillance and monitoring, for assessing vulnerability and health impacts and targeting measures appropriately;
- (e) assessment of the likely financial costs and other resources necessary for health protection from climate change;

(5) to consult Member States on the preparation of a workplan for scaling up WHO's technical support to Member States for assessing and addressing the implications of climate change for health and health systems, including practical tools and methodologies and mechanisms for facilitating exchange of information and best practice and coordination between Member States, and to present a draft workplan to the Executive Board at its 124th session.

WHA61.20 Infant and young child nutrition: biennial progress report

The Sixty-first World Health Assembly,

Having considered the report on infant and young child nutrition: biennial progress report;¹

Reaffirming the significance of the adoption by the Health Assembly of the International Code of Marketing of Breast-milk Substitutes (resolution WHA34.22), and resolutions WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA45.34, WHA47.5, WHA49.15, WHA54.2, WHA55.25, WHA58.32 and WHA59.21 on infant and young child nutrition;

Reaffirming, in particular, resolutions WHA54.2, WHA55.25 and WHA58.32, which recognize the importance of exclusive breastfeeding for the first six months of life, the Global Strategy for Infant and Young Child Feeding, and the evidence-based public health risks of intrinsic contamination of powdered infant formula, the potential for introduced contamination and the need for safe preparation, handling and storage of prepared infant formula;

Recalling resolution WHA49.15 on infant and young child nutrition, which recognizes the need to ensure that the commitment and support for breastfeeding and optimal infant and young child nutrition are not undermined by conflicts of interest;

Affirming that early initiation and exclusive breastfeeding is the natural and optimal means to achieve food security and optimal health for infants and young children, and concerned that the rates have remained low;

Welcoming the biennial progress report and noting the salient points that need further consideration, specifically persistent malnutrition – one of the most severe public health problems, as indicated by the alarmingly high rates of under-five mortality;

Noting further the need to improve implementation and monitoring of the International Code of Marketing of Breast-milk Substitutes;

Aware that powdered infant formula is not a sterile product and that it can contain pathogenic bacteria, and welcoming the WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula;²

Encouraged by the work of FAO and WHO through the Codex Alimentarius Commission on the revised proposed draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children,

1. URGES Member States:

(1) to strengthen implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions by scaling up efforts to monitor and enforce national measures in order to protect breastfeeding while keeping in mind the Health Assembly resolutions to avoid conflicts of interest;

¹ Document A61/17 Add.1.

² World Health Organization in collaboration with the Food and Agriculture Organization of the United Nations. *Safe preparation, storage and handling of powdered infant formula*. Geneva, World Health Organization, 2007.

(2) to continue action on the Global Strategy for Infant and Young Child Feeding and the Innocenti Declaration of 2005 on infant and young child feeding and to increase support for early initiation and exclusive breastfeeding for the first six months of life, in order to reduce the scourge of malnutrition and its associated high rates of under-five morbidity and mortality;

(3) to implement, through application and wide dissemination, the WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula in order to minimize the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission and taking into account resolution WHA58.32;

(4) to investigate, as a risk-reduction strategy, the possible use and, in accordance with national regulations, the safe use of donor milk through human milk banks for vulnerable infants, in particular premature, low-birth-weight and immunocompromised infants, and to promote appropriate hygienic measures for storage, conservation, and use of human milk;

(5) to take action through food-safety measures, including appropriate regulatory measures, to reduce the risk of intrinsic contamination of powdered infant formula by *Enterobacter sakazakii* and other pathogenic microorganisms during the manufacturing process as well as the risk of contamination during storage, preparation and handling, and to monitor the effectiveness of these measures;

2. REQUESTS the Director-General:

(1) to continue monitoring progress through reports to the Health Assembly each even year, along with the report on the status of implementation of the International Code of Marketing of Breast-milk Substitutes and the relevant resolutions of the Health Assembly, on progress in the consideration of matters referred to the Codex Alimentarius for its action;

(2) to continue to promote breastfeeding and infant and young child nutrition as essential for achieving the Millennium Development Goals, in particular those relating to the eradication of extreme poverty and hunger and to the reduction of child mortality;

(3) to intensify support for the implementation of the International Code of Marketing of Breast-milk Substitutes;

(4) to provide support urgently for research on the safe use of expressed and donated breast milk, owing to the current challenges facing countries in the implementation of safe infant feeding practices, mindful of the national rules and regulations and cultural and religious beliefs;

(5) to provide support for strengthening of national information systems in order to improve the evidence base for policies in this area;

(6) to review the global current situation of infant and child nutrition including nutrition and HIV, and submit a report to the Sixty-third World Health Assembly.

WHA61.21 Global strategy and plan of action on public health, innovation and intellectual property

The Sixty-first World Health Assembly,

Having considered the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property;¹

Recalling the establishment pursuant to resolution WHA59.24 of an intergovernmental working group to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

Recalling resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14, WHA54.10 and WHA57.14 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA58.34 on the Ministerial Summit on Health Research, WHA59.26 on international trade and health; and WHA60.30 on public health, innovation and intellectual property;

Welcoming the progress made by the Intergovernmental Working Group in elaborating the global strategy and the identification of the stakeholders in the plan of action,

1. ADOPTS the global strategy and the agreed parts of the plan of action² on public health, innovation and intellectual property, attached to this resolution;
2. URGES Member States:³
 - (1) to implement the specific actions recommended in the global strategy and plan of action on public health, innovation and intellectual property;
 - (2) to support actively the wide implementation of the global strategy and plan of action on public health, innovation and intellectual property, and to consider providing adequate resources for its implementation;
3. CALLS UPON relevant international organizations and other relevant stakeholders to give priority within their respective mandates and programmes to implementing the global strategy and plan of action on public health, innovation and intellectual property;
4. REQUESTS the Director-General in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates:

¹ Document A61/9.

² On the specific actions and stakeholder components.

³ Where applicable, also regional economic integration organizations.

- (1) to provide support for Member States, upon request, in implementing the global strategy and plan of action on public health, innovation and intellectual property and in monitoring and evaluating its implementation;
- (2) to support effective promotion and implementation of the global strategy and plan of action on public health, innovation and intellectual property;
- (3) to continue to implement the mandates contained in resolutions WHA49.14 and WHA52.19 on revised drug strategy, WHA53.14, WHA54.10, WHA56.30 and WHA57.14 on HIV/AIDS, WHA56.27 on intellectual property rights, innovation and public health, WHA59.26 on international trade and health, and WHA60.30 on public health, innovation and intellectual property, as well as WHA55.11 on health and sustainable development, WHA55.14 on ensuring accessibility of essential medicines, and WHA60.18 on malaria, including proposal for establishment of World Malaria Day;
- (4) to finalize urgently the outstanding components of the plan of action concerning timeframes, progress indicators and estimated funding needs, and to submit the final plan of action including the open paragraphs on stakeholders for consideration by the Sixty-second World Health Assembly through the Executive Board;
- (5) to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action;
- (6) notwithstanding the request in subparagraph (4) above, to prepare a quick start programme with adequate budget provision and begin immediately to implement the elements of the global strategy and plan of action on public health, innovation and intellectual property that fall under the responsibility of WHO;
- (7) to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the Sixty-second World Health Assembly and the final report to the Sixty-third World Health Assembly through the Executive Board;
- (8) to reflect, as appropriate, the global strategy and plan of action on public health, innovation and intellectual property in the further development of WHO's research strategy;
- (9) to include adequate resources in the forthcoming proposed programme budgets for effective implementation of the global strategy and plan of action on public health, innovation and intellectual property;
- (10) to monitor performance and progress in implementing the global strategy and plan of action on public health, innovation and intellectual property, and to report progress to the Sixty-third World Health Assembly through the Executive Board, and subsequently every two years, until the fulfilment of the time frame, to the Health Assembly, through the Executive Board.

ANNEX

**GLOBAL STRATEGY ON PUBLIC HEALTH, INNOVATION
AND INTELLECTUAL PROPERTY***The context*

1. In resolution WHA59.24 the 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 for WHO Member States and the WHO Secretariat to recognize and better address the increasing prevalence of noncommunicable diseases in those countries.
2. Currently, 4800 million people live in developing countries, representing 80% of the world population. Of this number, 2700 million, representing 43% of the world population, live on less than US\$ 2 a day. Communicable diseases account for 50% of the developing countries' burden of disease. Furthermore, poverty, among other factors, directly affects the acquisition of health products¹ and medical devices, especially in developing countries.
3. Member States,² the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices. More efforts should be made to avoid suffering and reduce preventable mortality and to meet the health-related Millennium Development Goals and to implement States' obligations and commitments arising under applicable international human rights instruments with provisions relevant to health.
4. Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.
5. Advances in biomedical science have provided opportunities to develop new, affordable, safe and effective health products and medical devices, particularly those that meet public health needs. Urgent efforts should be made to make these advances more affordable, accessible and widely available in developing countries.
6. The Report of the Commission on Intellectual Property Rights, Innovation and Public Health provides an analysis of the problems and makes recommendations that form a basis of future actions.

¹ The term "health products" hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.

² Where applicable, also regional economic integration organizations.

7. Intellectual property rights are an important incentive for the development of new health-care products. This incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.

8. The Doha Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent Members from taking measures to protect public health. The Declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights, affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all.

9. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation into 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”.

10. 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”.

11. The price of medicines is one of the factors that can impede access to treatment.

12. International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance.

The aim

13. The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the Report of the Commission on Intellectual Property Rights, Innovation and Public Health, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area.

14. The elements of the global strategy, which are designed to promote innovation, build capacity, improve access and mobilize resources, will:

- (a) provide an assessment of the public health needs of developing countries with respect to diseases that disproportionately affect developing countries and identify their research and development priorities at the national, regional and international levels

- (b) promote research and development focusing on Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases¹
- (c) build and improve innovative capacity for research and development, particularly in developing countries
- (d) improve, promote and accelerate transfer of technology between developed and developing countries as well as among developing countries
- (e) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the research and development needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for research and development
- (f) improve delivery of and access to all health products and medical devices by effectively overcoming barriers to access
- (g) secure and enhance sustainable financing mechanisms for research and development and to develop and deliver health products and medical devices to address the health needs of developing countries
- (h) develop mechanisms to monitor and evaluate the implementation of the strategy and plan of action, including reporting systems.

The principles

15. WHO's Constitution states that "the objective of WHO shall be the attainment by all peoples of the highest possible level of health". Accordingly, WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant Health Assembly resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, WHO, including its regional and, when appropriate, country offices, needs to strengthen its institutional competencies and relevant programmes in order to play its role in implementing this global strategy with its plan of action.
16. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.
17. The promotion of technological innovation and the transfer of technology should be pursued by all States and supported by intellectual property rights.
18. Intellectual property rights do not and should not prevent Member States from taking measures to protect public health.

¹ For the purposes of this strategy, the definitions of Type I, II and III diseases are as referred to by the Commission on Macroeconomics and Health and as further elaborated in the Report of the Commission on Intellectual Property Rights, Innovation and Public Health: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. The prevalence of diseases and thereby their categorization in the typology can evolve over time.

19. International negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.
20. The strengthening of the innovative capacity of developing countries is essential to respond to the needs of public health.
21. Research and development of developed countries should better reflect the health needs of developing countries.
22. The global strategy and the plan of action should promote the development of health products and medical devices needed by Member States, especially developing countries, that are:
- (i) developed in an ethical manner
 - (ii) available in sufficient quantities
 - (iii) effective, safe and of good quality
 - (iv) affordable and accessible
 - (v) used in a rational way.
23. Intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain.
24. Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices.

The elements

Element 1. Prioritizing research and development needs

25. Health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases 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.
26. The actions to be taken to prioritize research and development needs are as follows:
- (1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries
 - (a) *develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases*

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

(c) *provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs.*

(1.2) formulating explicit prioritized strategies for research and development at country and regional and interregional 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 to combat diseases in developing countries*

(c) *include research and development needs on health systems in a prioritized strategy*

(d) *urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for research and development to address public health needs*

(e) *increase overall research and development efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, and that are user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).*

(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples

(a) *set research priorities in traditional medicine*

(b) *support developing countries to build their capacity in research and development in traditional medicine*

(c) *promote international cooperation and the ethical conduct of research*

(d) *support South–South cooperation in information exchange and research activities*

(e) *support early-stage drug research and development in traditional medicine systems in developing countries.*

Element 2. Promoting research and development

27. There are many determinants of innovation capacity. 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 both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is essential.

28. The actions to be taken to promote research and development are as follows:

(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, 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, where feasible and appropriate, long-term funding

(c) support governments in establishing health-related innovation in developing countries.

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

(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products

(b) promote and improve access to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries

(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools

(d) support basic and applied scientific research on Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases

(e) support early-stage drug research and development in developing countries

(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries

(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries.

(2.3) improving cooperation, participation and coordination of health and biomedical research and development

(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources

(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities

(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including inter alia, an essential health and biomedical research and development treaty

(d) support active participation of developing countries in building technological capacity

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

(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries

(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centres, especially in developing countries

(b) promote public access to the results of government-funded research, by strongly encouraging all investigators funded by governments to submit to an open access database an electronic version of their final, peer-reviewed manuscripts

(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries

(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms

(e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(2.5) establishing and strengthening national and regional coordinating bodies on research and development

(a) develop and coordinate a research and development agenda

(b) facilitate the dissemination and use of research and development outcomes.

Element 3. Building and improving innovative capacity

29. There is a need to frame, develop and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.

30. The actions to be taken to build and improve innovative capacity are as follows:

(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 education and training including in public health

(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries

(c) strengthen health surveillance and information systems.

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

(a) establish and strengthen regulatory capacity in developing countries

(b) strengthen human resources in research and development in developing countries through long-term national capacity-building plans

(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries

(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations.

(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries

(a) develop successful health innovation models in developing innovative capacity

(b) intensify North–South and South–South partnerships and networks to support capacity building

(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries.

(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments

(a) establish and strengthen national and regional policies to develop, support and, promote traditional medicine

(b) encourage and promote policies on innovation in the field of traditional medicine

(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards

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

(e) promote South–South collaboration in traditional medicine

(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation.

(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation

(a) encourage the establishment of award schemes for health-related innovation

(b) encourage recognition of innovation for purposes of career advancement for health researchers.

Element 4. Transfer of technology

31. 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. Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights states that the protection and the enforcement of intellectual property rights should contribute to the promotion of technological innovation and 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 the balance of rights and obligations.

32. 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) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries

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

(c) *promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate.*

(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development

(a) *encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry*

(b) *facilitate local and regional networks for collaboration on research and development and transfer of technology*

(c) *continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights*

(d) *promote the necessary training to increase absorptive capacity for technology transfer.*

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies

(a) *examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices*

(b) *explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific research and development needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health.*

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

33. The international regimes on intellectual property aim, inter alia, to provide incentives for the development of new health products. However, incentive schemes for research and development, especially on Type II and Type III diseases and the specific research and development needs of developing countries in respect of Type I diseases, need to be explored and implemented, where appropriate. There is a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

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

(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health-related innovation and the promotion of public health in developing countries

(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that agreement and meets the specific research and development needs of developing countries

(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries

(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents

(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs

(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement

(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries

(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs

(h) strengthen efforts to coordinate effectively work relating to intellectual property and public health among the secretariats and governing bodies of relevant regional and international organizations in order to facilitate dialogue and dissemination of information to countries.

(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects

of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products

(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, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States

(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help to prevent misappropriation of such traditional knowledge.

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases

(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries.

Element 6. Improving delivery and access

35. Support for and strengthening of 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.

36. International 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, including those contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Declaration on the TRIPS Agreement and Public Health 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.

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

(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system

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

(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016¹

(c) prioritize health care in national agendas

(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines

(e) increase investment in human resource development in the health sector

(f) develop effective country poverty-reduction strategies that contain clear health objectives

(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate.

(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices

(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards

(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings

(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products

¹ In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

(d) *strengthen the WHO pre-qualification programme*

(e) *where appropriate, initiate programmed actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals*

(f) *promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines*

(g) *support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval.*

(6.3) *promoting competition to improve availability and affordability of health products consistent with public health policies and needs*

(a) *support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a “regulatory exception” or “Bolar”-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement*

(b) *frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements*

(c) *consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access*

(d) *encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law*

(e) *consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO’s ongoing work on pharmaceutical pricing*

(f) *consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products*

(g) *increase information among policy makers, users, doctors and pharmacists regarding generic products.*

Element 7. Promoting sustainable financing mechanisms

38. In recent years donors have provided substantial additional financing to make health products available in developing countries through new mechanisms. Additional 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 financing for health products and research and development covered by this strategy need to be identified and analysed.

39. It is important to make maximum use of, and complement as appropriate, feasible current initiatives, thereby contributing to a flow of resources into innovation and implementation.

40. The actions to be taken to promote sustainable financing mechanisms are as follows:

(7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries

(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases

(b) consider 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 as recommended by resolution WHA58.34

(c) create a database of possible sources of financing for research and development.

(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices

(a) document and disseminate best practices in public-private and product development partnerships

(b) develop tools for periodic assessment of performance of public-private and product development partnerships

(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries.

Element 8. Establishing monitoring and reporting systems

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

42. Steps to be taken will include:

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

(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action

(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries

(c) continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly

(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices

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

PLAN OF ACTION

Explanatory Notes

* **Stakeholder(s)**

Lead stakeholders are indicated by bold typeface. Bracketed text indicates that consensus has not been reached.

Reference to **Governments** means that WHO Member States¹ are urged to take action.

WHO means that the Director-General is requested to take action.

Other international intergovernmental organizations, both global and regional, means that WHO Member States, or WHO Secretariat as mandated by Member States through this plan of action, invite these organizations to take action. Member States are urged to raise appropriate issues in the governing bodies of the organizations. The Director-General is requested to bring this global strategy and plan of action to the attention of all relevant international organizations and invite them to consider the relevant provisions of this global strategy and plan of action.

Other relevant stakeholders means that WHO Member States, or WHO Secretariat as mandated by its Member States through this plan of action, invite these relevant actors to take action. These include, inter alia, as appropriate, international and national research institutions; academia; national and regional regulatory agencies; relevant health-related industries, including both public and private; public-private partnerships; public-private and product development partnerships; nongovernmental organizations; concerned communities; development partners; charitable foundations; publishers; research and development groups; and regional bodies; and regional organizations.

¹ Where applicable, also regional economic integration organizations.

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 1. Prioritizing research and development needs			
(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases	WHO; Governments; other relevant stakeholders	2008–2015
	(b) disseminate information on identified gaps, and evaluate their consequences on public health	WHO; Governments; other relevant stakeholders	2008–2015
	(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs	WHO; Governments; other relevant stakeholders	2008–2015
(1.2) formulating explicit prioritized strategies for research and development at country and regional and interregional levels	(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments	Governments; regional organizations	2008–2015
	(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries	Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions and public–private partnerships)	2008–2015
	(c) include research and development needs on health systems in a prioritized strategy	Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public–private partnerships)	2008–2015

	(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for research and development to address public health needs	WHO ; Governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)	2008–2015
	(e) increase overall research and development efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, that are user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability)	Governments ; WHO ; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, and public–private partnerships)	2008–2015
(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples	(a) set research priorities in traditional medicine	Governments ; WHO ; other international intergovernmental organizations; other relevant stakeholders (including academia; national research institutions; public–private partnerships; and concerned communities)	2008–2015
	(b) support developing countries to build their capacity in research and development in traditional medicine	Governments ; WHO ; other international intergovernmental organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public–private partnerships)	2008–2015
	(c) promote international cooperation and the ethical conduct of research	Governments ; WHO ; other international intergovernmental organizations; other relevant stakeholders	2008–2015

	(d) support South–South cooperation in information exchange and research activities	Governments; WHO; other international intergovernmental organizations; regional organizations; other relevant stakeholders	2008–2015
	(e) support early-stage drug research and development in traditional medicine systems in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015
Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 2. Promoting research and development			
(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area	(a) promote cooperation between private and public sectors on research and development	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding	Governments; regional organizations; WHO (technical assistance); other relevant stakeholders	2008–2015
	(c) support governments in establishing health-related innovation in developing countries	Governments; regional organizations; WHO (technical assistance); other relevant stakeholders	2008–2015
(2.2) promoting upstream research and product development in developing countries	(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015

	(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international – that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools	Governments; WHO; other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	2008–2015
	(d) support basic and applied scientific research on Type II and Type III diseases and on the specific research and development needs of developing countries in relation to Type I diseases	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(e) support early-stage drug research and development in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, academia, international and national research institutions; donor agencies; development partners; nongovernmental organizations)	2008–2015
	(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries; academia; development partners; charitable foundations; public–private partnerships; nongovernmental organizations)	2008–2015

	(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries	Governments; WHO; other international intergovernmental organizations, other relevant stakeholders (including academia, international and national research institution; relevant health-related industries and development partners)	
(2.3) improving cooperation, participation and coordination of health and biomedical research and development	(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	2008–2015
	(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities	Governments; WHO; other relevant stakeholders	2008–2015
	(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including, inter alia, an essential health and biomedical research and development treaty	Interested Governments; [WHO]; other relevant stakeholders (including nongovernmental organizations)	[2008–2010]
	(d) support active participation of developing countries in building technological capacity	Governments; WHO; other relevant stakeholders	2008–2015
	(e) promote the active participation of developing countries in the innovation process	Governments; WHO; other relevant stakeholders	2008–2015
(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries	(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centres, especially in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)	2008–2015

	(b) promote public access to the results of government-funded research, by strongly encouraging all investigators funded by governments to submit to an open access database an electronic version of their final, peer-reviewed manuscripts	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and research institutions)	2008–2015
	(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries)	2008–2015
	(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to, open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and national research institutions)	2008–2015
	(e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights	Governments	
(2.5) establishing and strengthening national and regional coordinating bodies on research and development	(a) develop and coordinate a research and development agenda	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015
	(b) facilitate the dissemination and use of research and development outcomes	Governments; regional organizations; WHO; other relevant stakeholders	2008–2015

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 3. Building and improving innovative capacity			
(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 education and training including in public health	Governments; other international intergovernmental organizations; other relevant stakeholders (including development partners)	2008–2015
	(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries	Governments; other international intergovernmental organizations; other relevant stakeholders (including research and development groups, relevant health-related industries and development partners)	2008–2015
	(c) strengthen health surveillance and information systems	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	2008–2015
(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	(a) establish and strengthen regulatory capacity in developing countries	Governments; WHO; other relevant stakeholders (including national and regional regulatory agencies)	2008–2015
	(b) strengthen human resources in research and development in developing countries through long-term national capacity-building plans	Governments; other international intergovernmental organizations; other relevant stakeholders (including development partners; international and national research institutions)	2008–2015

	(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries	Governments; WHO; other international intergovernmental organizations (including IOM and ILO); other relevant stakeholders	2008–2015
	(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations	Governments	2008–2015
(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	(a) develop successful health innovation models in developing innovative capacity	Governments; WHO; other international intergovernmental organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health-related industries and developmental partners)	2008–2015
	(b) intensify North–South and South–South partnerships and networks to support capacity building	Governments; WHO; other International intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries)	2008–2015
	(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries	Governments; WHO; other relevant stakeholders (including academia and research institutions)	2008–2015

(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments	(a) establish and strengthen national and regional policies to develop, support and promote traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)	2008–2015
	(b) encourage and promote policies on innovation in the field of traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, concerned communities)	
	(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies; international and national research institutions; development partners; concerned communities)	
	(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; relevant health-related industries; concerned communities)	
	(e) promote South–South collaboration in traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions, regional bodies, academia)	2008–2015

	(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies, relevant health-related industries)	2008–2015
(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation	(a) encourage the establishment of award schemes for health-related innovation	Governments; WHO; other international intergovernmental organizations [(including WIPO)]; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	
	(b) encourage recognition of innovation for purposes of career advancement for health researchers	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; development partners; charitable foundations)	
Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 4. Transfer of technology			
(4.1) promoting transfer of technology and the production of health products in developing countries	(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries	Governments; WHO; other international intergovernmental organizations (including WTO, UNCTAD, UNIDO, WIPO); other relevant stakeholders (including international and national research institutions; relevant health-related industries)	

	(b) promote transfer of technology and production of health products in developing countries through investment and capacity building	Governments; WHO; other intergovernmental organizations; other relevant stakeholders (including health-related industries)	
	(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries; academia; nongovernmental organizations; development partners; charitable foundations)	2008–2015
(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development	(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries; international and national research institutions; academia; nongovernmental organizations; development partners)	2008–2015
	(b) facilitate local and regional networks for collaboration on research and development and transfer of technology	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, national research institutions, academia; nongovernmental organizations)	2008–2015

	(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	Governments	2008–2015
	(d) promote the necessary training to increase absorptive capacity for technology transfer	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions)	2008–2015
(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institutions; relevant health-related industries, nongovernmental organizations; academia)	
	(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific research and development needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that Agreement, which provide flexibilities to take measures to protect public health	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)	

Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 5. Application and Management of intellectual property to contribute to innovation and promote public health			
(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries	(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that Agreement and meets the specific research and development needs of developing countries	<p>[Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]</p> <p>[Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)]</p>	
	(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries	Governments; WHO/[WHO] ; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], UNCTAD ; other relevant stakeholders (including international and national research institutions and development partners)	

	<p>(c) Facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents</p>	<p>[Governments]/[Governments]; [WHO]/[WHO]; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], [UNCTAD]); other relevant stakeholders (including international and national research institutions and development partners)]</p>	
	<p>(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs</p>	<p>Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant health-related industries)</p>	
	<p>(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement</p>	<p>Governments; [WHO]/[WHO]; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], [UNCTAD]/[UNCTAD]); other relevant stakeholders (including international and national research institutions and development partners)</p>	

	(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries	Governments; [WHO; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)]	
	(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs	Governments	
	(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the secretariats and governing bodies of relevant regional and international organizations in order to facilitate dialogue and dissemination of information to countries	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, and UNCTAD)	
(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products	(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, including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO and UNCTAD)	

	(b) Take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States	Governments; [WHO; other international intergovernmental organizations (including WIPO, WTO and UNCTAD)]	
	(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	Governments	
	(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	Governments	
	(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider, where appropriate, legislative and other measures to help to prevent misappropriation of such traditional knowledge	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including concerned communities)	

(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases	(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries	[Governments; [WHO]/[WHO]; other international inter-governmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries; nongovernmental organizations)]	
Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 6. Improving delivery and access			
(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system	(a) invest in developing health-delivery infrastructure and encourage financing of health products	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)	
	(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016 ¹	Governments; WHO; other international intergovernmental organizations (including WTO); other relevant stakeholders	
	(c) prioritize health care in national agendas	Governments	2008–2015
	(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines	Governments; WHO	

¹ In line with the extension, provided to least-developed countries, by Article 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

	(e) increase investment in human resource development in the health sector	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners; nongovernmental organizations; charitable foundations)	2008–2015
	(f) develop effective country poverty-reduction strategies that contain clear health objectives	Governments; other relevant stakeholders (including development partners)	2008–2015
	(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	
(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards	Governments; WHO; other relevant stakeholders (including national and regional regulatory agencies and development partners)	
	(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	
	(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products	Governments; WHO; other relevant stakeholders (including national regulatory bodies; relevant health-related industries; development partners)	2008–2015

	(d) strengthen the WHO pre-qualification programme	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders (including development partners)	
	(e) where appropriate, initiate programmed actions on regional and subregional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	Governments ; [WHO]/[WHO]; other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	
	(f) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines	Governments ; WHO ; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies)	
	(g) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval	Governments ; WHO ; other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	
(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs	(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a “regulatory exception” or “Bolar”-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement	Governments	

	(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements.	Governments; WHO; other international intergovernmental organizations (including WTO and WIPO); other relevant stakeholders	
	(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access	Governments	
	(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries)	
	(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing	Governments	
	(f) consider, where necessary, and provided that they are consistent with the provisions of the Agreement on TRIPS, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products	Governments	

	(g) increase information among policy makers, users, doctors and pharmacists regarding generic products	Governments; WHO other relevant stakeholders (including nongovernmental organizations and relevant health related industry)	
Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 7. Promoting sustainable financing mechanisms			
(7.1) endeavouring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders	
	(b) consider 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 as recommended by the resolution WHA58.34	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, international and national research institutions, academia, private sector and relevant health-related industries)	
	(c) create a database of possible sources of financing for research and development	Governments; WHO ; other relevant stakeholders	
(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical devices	(a) document and disseminate best practices in public-private and product development partnerships	Governments; WHO ; other relevant stakeholders (including research institutions, public-private and product development partnerships)	2008–2015

	(b) develop tools for periodic assessment of performance of public–private and product development partnerships	Governments; WHO ; other relevant stakeholders (including research institutions; public–private and product development partnerships; charitable foundations)	2008–2009
	(c) support public–private and product development partnerships and other appropriate research and development initiatives in developing countries	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, charitable foundations, development partners, nongovernmental organizations; academia; research institutions)	2008–2015
Elements and sub-elements	Specific actions	Stakeholder(s)*	Time frame
Element 8. Establishing monitoring and reporting systems			
(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action	Governments; WHO	From 2009
	(b) monitor and report periodically to WHO’s governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries	Governments; WHO	[From 2009]
	c) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly	Governments; WHO ; other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	

	(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	
	(e) monitor and report on investment in research and development to address the health needs of developing countries	Governments; WHO; other relevant stakeholders	

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Committee A, fifth report)