Public health, innovation and intellectual property: global strategy and plan of action

Proposed progress indicators

Report by the Secretariat

1. Resolution WHA61.21 requested the Director-General, inter alia, to finalize the outstanding components of the plan of action, including progress indicators, and submit them for consideration to the Sixty-second World Health Assembly. A set of progress indicators was presented to the Executive Board at its 124th session and, based on comments received, a revised set is presented below.

2. The indicators will form the basis for regular reporting to the Health Assembly on performance and overall progress made over a two-year reporting period. Each element has a set of indicators that measures results achieved with respect to key objectives relevant to that particular element. Where linkages exist between action items of more than one element, the indicator measuring this activity has been placed under the element determined to be the most relevant. In addition, two overarching indicators were developed for measurement of overall progress.

3. The indicators being proposed apply to the scope of diseases as defined by the global strategy (i.e. Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases) and, where feasible, are applicable to both research-based pharmaceutical products and traditional medicines.

INDICATORS BY ELEMENT

4. Element 1. Prioritizing research and development needs

Indicators

• analysis of research and development gaps, including the public health consequences of these gaps in developing countries, completed and a report on this analysis produced, published and disseminated

• number of developing countries with national health-related research and development capacity-building plans which prioritize research and development based on identified public health needs and research and development gaps

1 Document EB124/2009/REC/2, summary record of the tenth meeting.
• number of consensus reports published on global research needs and priorities for a disease or type of intervention.

5. **Element 2. Promoting research and development**

*Indicators*

• number of countries whose national strategic plans for the health workforce and related professionals include a research and development component

• number of new or strengthened national, regional and global coordination initiatives on health-related research and development, including between public and private entities

• number of new or strengthened initiatives aimed at providing efficient and affordable access to publications and information such as research knowledge, results and technology

• number of new or strengthened initiatives aimed at enhancing capacities to analyse and manage clinical trial data

• proportion of peer-reviewed publications where the main author’s institution is in a developing country.

6. **Element 3. Building and improving innovative capacity**

*Indicators*

• number of new and existing research centres in developing countries strengthened through comprehensive institutional development and support

• proportion of developing countries in which national health research systems meet international standards

• number of countries whose national regulatory authorities have been assessed, supported and accredited

• number of new or updated global quality and ethical standards, reference preparations, guidelines and tools for promoting the quality and effective regulation of health products\(^1\) and technologies

• number of countries with a national traditional medicines policy that includes research and development.

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\(^1\) The term “health products” hereafter should be understood to include vaccines, diagnostics and medicines in accordance with resolution WHA59.24.
7. **Element 4. Transfer of technology**

*Indicators*

- number of national, regional and global coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities

- number of countries with technology transfer strategies that include health-related technologies and relevant capacity-building components.

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

*Indicators*

- number of countries engaged in initiatives to strengthen capacities to manage and apply intellectual property rights to contribute to innovation and promote public health

- number of countries promoting and supporting efforts to strengthen capacities in the management and application of intellectual property rights in a manner oriented to public health needs and priorities of developing countries

- number of countries integrating flexibilities for protection of public health of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights into national legislation

- number and type of initiatives between secretariats and governing bodies of relevant regional and international organizations aimed at coordinating work relating to intellectual property and public health.

9. **Element 6. Improving delivery and access**

*Indicators*

- number of countries formulating and implementing official national policies on access, quality and use of essential medical products and technologies

- number of countries designing or strengthening comprehensive national procurement and supply systems

- number of priority health products and diagnostic tools that have been assessed and prequalified for procurement by the United Nations

- number of countries possessing and implementing national or regional strategic plans for the health workforce and related professionals, including policies and management practices on incentives, regulation and retention

- number of countries that have an adequate number of qualified or trained health-related regulatory professionals and the specific areas of specialization where gaps exist.
10. Element 7. Promoting sustainable financing mechanisms

*Indicators*

- submission of report of expert working group on research and development and financing
- number of new or strengthened sustainable financing initiatives including public–private initiatives
- increase in sustainable health-related research and development funding relevant to the strategy\(^1\) over the reporting period.

11. Element 8. Establishing monitoring and reporting systems

*Indicators*

- regular reporting on progress towards the implementation of the strategy\(^2\)
- number of new or strengthened sustainable initiatives at national, regional and global levels, including those by nongovernmental stakeholders, to promote the implementation of the strategy
- submission of reports on the respective issues addressed in Element 8 of the strategy.

12. Additional overarching strategic indicators

- number of new and improved health products receiving internationally recognized approval for use, including information on the nature and novelty of these products
- number of new and improved interventions and implementation strategies whose effectiveness has been determined and the evidence made available to appropriate institutions for policy decisions.

**ACTION BY THE HEALTH ASSEMBLY**

13. The Health Assembly is invited to consider the proposed progress indicators.

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\(^1\) Baselines/guidance to be provided by the expert working group on research and development and financing, established in accordance with resolution WHA61.21.

\(^2\) A qualitative assessment measuring progress on the objectives of the strategy to be included as a key component in the comprehensive four-year evaluation required by paragraph 41 of the Global strategy.