Global Strategy and Plan of Action: Innovation, Access, Capacity and Financing

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During the past decade, international debate concerning the relationship between intellectual property rights, innovation and public health, has been taking place against a backdrop of discussions on poverty reduction and improving access to health care.
In 2004, WHO tasked an independent commission with analysing the relationship between intellectual property rights, innovation and public health.

The report was published in April 2006 and contained around 60 recommendations aimed at fostering innovation and improving access.
It also considered the impact of other funding and incentive mechanisms,

It concluded that intellectual property rights provide important incentives for the development of new medicines and medical technologies.

However, intellectual property rights do not provide an effective incentive when patient populations are small or poor.
The World Health Assembly in May 2006 adopted resolution WHA59.24 requesting the DG to establish an Intergovernmental Working Group (IGWG).

IGWG was tasked with developing a global strategy and plan of action that aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.
IGWG PROCESS

- IGWG held 3 sessions, in December 2006, November 2007 and resumed session in April 2008.

- The drafting of the strategy was finalised at WHA 61 in May 2008.

- Global Strategy and Plan of Action adopted & Resolution WHA61.21 passed
Fostering Innovation and Facilitating access

1. Fostering Innovation
2. Building Capacity
2. Facilitating Access
4. Mobilising Resources

GSPOA
The Global Strategy on Public Health, Innovation and Intellectual Property

The global strategy is designed to **promote innovation, build capacity, improve access and mobilize resources.**

Eight elements of the plan of action:

- prioritizing research and development needs;
- promoting research and development;
- building and improving innovative capacity;
- transfer of technology;
- application and management of intellectual property;
- improving delivery and access;
- ensuring sustainable financing mechanisms;
- establishing monitoring and reporting systems.
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

(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels

(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
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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

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

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

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

(2.5) Establishing and strengthening national and regional coordinating bodies on research and development
Element 3. Building and improving innovative capacity

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

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

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

(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation
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Element 4. Transfer of technology

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

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

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies
Project on improving access to medicines in developing countries through local production and related technology transfer

EC supported initiative

Initial focus on pharmaceuticals is now being expanded to include vaccines and diagnostics

4 Parallel Research Activities

- Stakeholder survey
- Trends analysis
- Case studies
- Stakeholder workshops
Project on improving access to medicines in developing countries through pharmaceutical-related technology transfer and local production

Stakeholder survey:

Involves a broad interview process covering relevant stakeholders involved in transfer of technology for local production, such as medical professionals, public and private research institutions, international and regional organizations, government and non-government providers of health services, producers (originator and generic, foreign and domestic), government ministries, regulators, enterprises involved in finance of production and procurement (public and private), non-governmental interest groups and others.
Project on improving access to medicines in developing countries through local production and pharmaceutical-related technology transfer

Trends analysis

Determining the current state of activities intended to transfer technology for local production. This analysis is to be accomplished through a combination of desk research and interviews with suppliers and recipients of relevant technologies, as well as others with interests in the process.
Project on improving access to medicines in developing countries through local production and related technology transfer

Case studies

Taking place in different regions and covering projects with different characteristics:

- the geographic location of the production facility
- the public or private character of the investment and the corporate form of the arrangement
- the type of product involved
- and the source of technologies
Project on improving access to medicines in developing countries through local production and related technology transfer

Stakeholder dialogues and Workshops

stakeholders identified with respect to local production and related technology transfer will be brought together in a series of workshops intended to clarify the key prerequisites for these activities.
Element 5. Application and management of intellectual property to contribute to innovation and promote public health

(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

(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 Ministerial 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

(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
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

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

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

(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

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

(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action
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At the 61st World Health Assembly:

Member States adopted the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property (Resolution WHA 61.21)

The strategy proposes that WHO play a strategic and central role in the relationship between public health and innovation and IP within its mandates, capacities and constitutional mandate.

Member States are urged to adopt and support actively the wider implementation of the global strategy in particular through providing adequate resources.

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;

Coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action.
The Global strategy on Public Health, Innovation and Intellectual Property

- Landmark resolution

- Involves many stakeholders: Member States, WHO, other international intergovernmental organizations, other relevant stakeholders

- Taking this strategy forward requires a collective effort and new ways of working

- The prize for success is immense: it is to ensure that people have access to the right health products, both new and old. The commitment and engagement of Governments and other stakeholders is essential.
Project on improving access to medicines in developing countries through local production and related technology transfer

This meeting

- A consultation to collect information
- To focus and dig deep into the issues
- Contribute to development of recommendations and a methodology to guide future work
- This will contribute to the implementation of GSPOA
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Thank You

Documents available on http://www.who.int/gb or http://www.who.int/phi