Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property: Implications for Regulators

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Overview

- Background:
  - Burden of Disease
  - Gaps

- WHA Response: Various Resolutions and Intergovernmental Working group (IGWG)

- Global Strategy and Plan of Action

- Specific Actions

- Implications for Regulatory Authorities
Burden of Disease

- Communicable diseases account for 50% of the developing countries burden of disease
- HIV/AIDS, Tuberculosis, burden high in Africa
- There is the threat of multidrug resistance
- About 1 billion people affected by one or more Neglected Tropical Diseases (NTDs)
- Currently 14 diseases are listed as NTDs
- Emerging and re-emerging diseases
R&D Gap - expenditures grow, new drugs are launched, but few for tropical diseases

Between 1975 and 1997 -
- 1,223 new compounds launched
- only 11 for tropical diseases

New chemical entities launched (number)

R&D expenditure (US$ billions - top companies)

Affordability of medicines gap - number of working hours to pay full treatment course

The burden falls heaviest on those least able to pay:
- High income countries: 50-90% publicly funded
- Low/middle income countries: 50-90% out-of-pocket
- Medicines often the largest household health cost

Based on average worldwide price and national per capita income. Source: WHO/EDM
Staggering world wide gaps exist in nearly every aspect of health

- Poverty
- Health status and risk factors
- Research capacity
- Poor health systems
- Human resources & appropriate expertise
The World Health Assembly (WHA) has over the years adopted several resolutions with the aim of managing the interface between trade, intellectual property and public health effectively in order to:

- Ensure access to medicines, related technologies (vaccines & diagnostics) particularly in developing countries
- Ensure that there is capacity in member states to implement agreed–to strategies
- Response to challenges of diseases that largely affect developing countries
• In 2004: Resolution 56.27 requested the DG to establish a time-limited body to analyse the relationship between:
  – intellectual property rights
  – innovation
  – public health *(WHO Commission on Intellectual Property Rights, Innovation and Public Health - CIPIH)*

• The Commission's report was published in April 2006, raising global awareness of problems around innovation and access to health products, especially in the developing world.
• The Commission made sixty recommendations
• It also considered the impact of funding and other incentive mechanisms to foster innovation capacity in developing countries.
• 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.
• **Issues raised in CIPIH report:**
  - Speed of regulatory processes
  - Capacity of regulatory assessors
  - Challenges of infrastructure
  - Resource constraints
  - Ensuring proper ethical standards in the conduct of clinical trials

• **Initiatives to support medicine regulation**
  - Harmonisation
  - Information sharing
  - Cooperative actions at regional level
In May 2006, the 59th World Health Assembly adopted resolution WHA 59.24 requesting the DG to convene an Intergovernmental Working Group to draw up a global strategy and plan of action based on the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH).

The Working Group considered eight elements of a draft plan of action:

- prioritizing research and development needs;
- promoting research and development;
- building and improving innovative capacity;
- improving delivery and access;
- ensuring sustainable financing mechanisms;
- and establishing monitoring and reporting systems.
- transfer of technology,
- and management of intellectual property.
WHA Resolutions: 2008

- In May 2008 the 61st World Health Assembly **adopted** the Global Strategy & Plan of Action (GSPOA):
  - Urged Member States to implement specific actions & consider providing adequate resources
  - Relevant stakeholders e.g. Governments (including NRAs, and research institutions), International Intergovernmental Organizations (WIPO, WTO, UNCTAD), NGOs, (including professional associations) to work with WHO in the implementation of GSPOA
  - WHO to prepare a start-up programme and implement elements which fall under its responsibility
  - Examine current, new and innovative financing mechanisms to stimulate relevant R&D
  - Monitor progress of implementation.
Elements of the GSPOA with specific reference to NRAs

- Prioritizing research & development needs
- Promoting research and development
- Building and improving innovative capacity
- Transferring of technology
  - Application and management of intellectual property to contribute to innovation and promote public health
- Improving delivery and access
## Prioritizing research & development needs

### Sub-element
- Mapping global R&D in order to identify gaps in R&D on diseases that disproportionately affect developing countries

### Specific Actions
- Develop methodologies and mechanisms to identify gaps
- Disseminate information
- Assess gaps in order to guide research aimed at developing affordable and therapeutically sound products
## Prioritizing research & development needs

<table>
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<tr>
<th>Sub-element</th>
<th>Specific Actions</th>
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| • Encourage R&D in Traditional Medicines | • Set research priorities  
• Early-stage drug research  
• Facilitation of South-South Cooperation to discover new medicines from traditional medicine |

*China and India are investing in alternative paths to drug discovery (reverse pharmacology)*
Promote research & development

**Sub-element**
- Promoting upstream research and product development in developing countries
- Improving cooperation, participation and coordination of health and biomedical R&D

**Specific Actions**
- Build capacity to conduct clinical trials and promote public & other sources of funding clinical trials, taking into account international ethical standards
- Stimulate & improve global cooperation and coordination in research and development, in order to optimize resources
- Enhance existing mechanisms to improve the coordination and sharing of information on R&D activities
Promote research & development

- Early involvement by NRAs during drug development
- Enabling legal environment (domestic & international) to facilitate information sharing
- Cooperation and collaboration between well-resourced NRAs and resource-constrained NRAs
- Creation of an enabling and conducive institutional environment for drug development

*FDA and EMEA are already collaborating and cooperating in research and development of paediatric medicines*
Build and Improve Innovative Capacity

Sub-elements
• Building capacity of developing countries to meet R&D needs for health products
  • Framing, developing & supporting policies that promote the development of capacities for health innovation

Specific Actions
• Support existing & new R&D groups and institutions, including regional centres of excellence, in developing countries
  • Establish & strengthen regulatory capacity in developing countries
  • Strengthen human resources in R&D through long-term national capacity building plans
  • Encourage international cooperation to develop effective policies for retention of health professionals
## Build and Improve Innovative Capacity

### Sub-element

- Supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account relevant international instruments

- Providing support for improving innovative capacity in accordance with the needs of developing countries

### Specific Actions

- Promote standard setting to ensure quality, safety and efficacy of traditional medicine, including funding research necessary to establish such standards

- Encourage research on their mechanisms of action and pharmacokinetics

- Promote South-South collaboration

- Intensify North-South and South-South partnerships and networks to support capacity building
# Transfer of Technology

## Sub-element
- Promoting transfer of technology and the production of health products in developing countries
- Supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development

## Specific Actions
- Explore possible new mechanisms and improve use of existing ones to facilitate transfer of technology and technical support to build and improve innovative capacity for health related R&D, particularly in developing countries
- Through identification of best practices, and investment & capacity building provided by developed and developing countries where appropriate
- Encourage North-South and South-South cooperation (institutions and the pharmaceutical industry)
- Facilitate local & regional networks for collaboration
Improve delivery & access

Sub-element
• Establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices

Specific Actions
• Develop and / or strengthen the capacity of NRAs
• Initiate, where appropriate programmed actions at regional & sub-regional levels with the ultimate goal of harmonization of processes used by NRAs for marketing approvals
• Promote ethical principles for clinical trials involving human beings & support regional networks in this regard
**Sub-element**

- Establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices….cont

**Specific Actions**

- Promote research to maximise the appropriate use of new and existing products
- Strengthen the WHO pre-qualification program
Improve delivery & access

Sub-element
• Encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system

Specific Actions
• Increase investment in human resource development
• Invest in developing health developing infrastructure and encourage financing of health products
• Develop effective and sustainable mechanisms in LDCs to improve access to existing medicines, acknowledging the transitional period until 2016
Improve delivery & access

**Sub-element**
- Promoting competition to improve availability and affordability of health products consistent with public health policies and needs

**Specific Actions**
- Support production & introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and / or policies that promote generic production & entry including a “regulatory exception” or “Bolar”-type provision
Improve delivery & access

- **Hamonisation initiatives within regional blocs**
  - Guidelines, technical documents, standardised formats

- **Enabling legal environment to facilitate information sharing**
  - Mutual recognition arrangements
  - Shared expertise
  - Strengthening collaboration between Research Ethics Committees and NRAs
  - New thinking on cooperation in strengthening regulatory capacity and to maximise efficiencies
  - Sharing information on evaluations among regulators

- **Cooperation and collaboration between well-resourced NRAs and resource-constrained NRAs**
  - EU Scientific opinion
  - FDA tentative approval
  - Canadian Access Initiative

- **Creation of an enabling and conducive institutional environment for drug development**
  - Approval for retention of fees and increase in the resource base and capacity of regulatory authorities
State of Readiness

• Should NRAs be involved in IP issues?
• Should they be involved in pricing issues?
• How will regulators deal with biotechnology challenges and capacity to regulate genomics, proteomics, pharmacogenetics, within current resource constraints?
• How will regulators deal with Confidentiality Clauses, Access to Information legislation within a sharing environment?
Conclusion

• The strategy emphasises co-operation, confidence, co-ordination, trust and partnerships
• Implies pooled resources, skills, experience and organisational cultures
• Implies agenda setting i.e. identification of:
  – Essentials (must do’s)
  – Expected (ought to do’s)
  – Desirable (can do’s)
• Traditional medicines require different pathways & research of appropriate methodologies
• Is it the right thing to do? If so, it is all in our hands!
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