Intellectual Property Law Related to Pharmaceutical Sector

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Outline

- Inter-linkages between UHC and IP
- Importance of IP to the Pharma Sector
- The International IP Law affecting the Pharma Sector
- Promoting access to medical technologies and innovation as part of UHC in the MENA region
- The way forward for a UHC conducive IP governance in the MENA region.

The Interlinkage between UHC and IP

WHO defines UHC as follows:

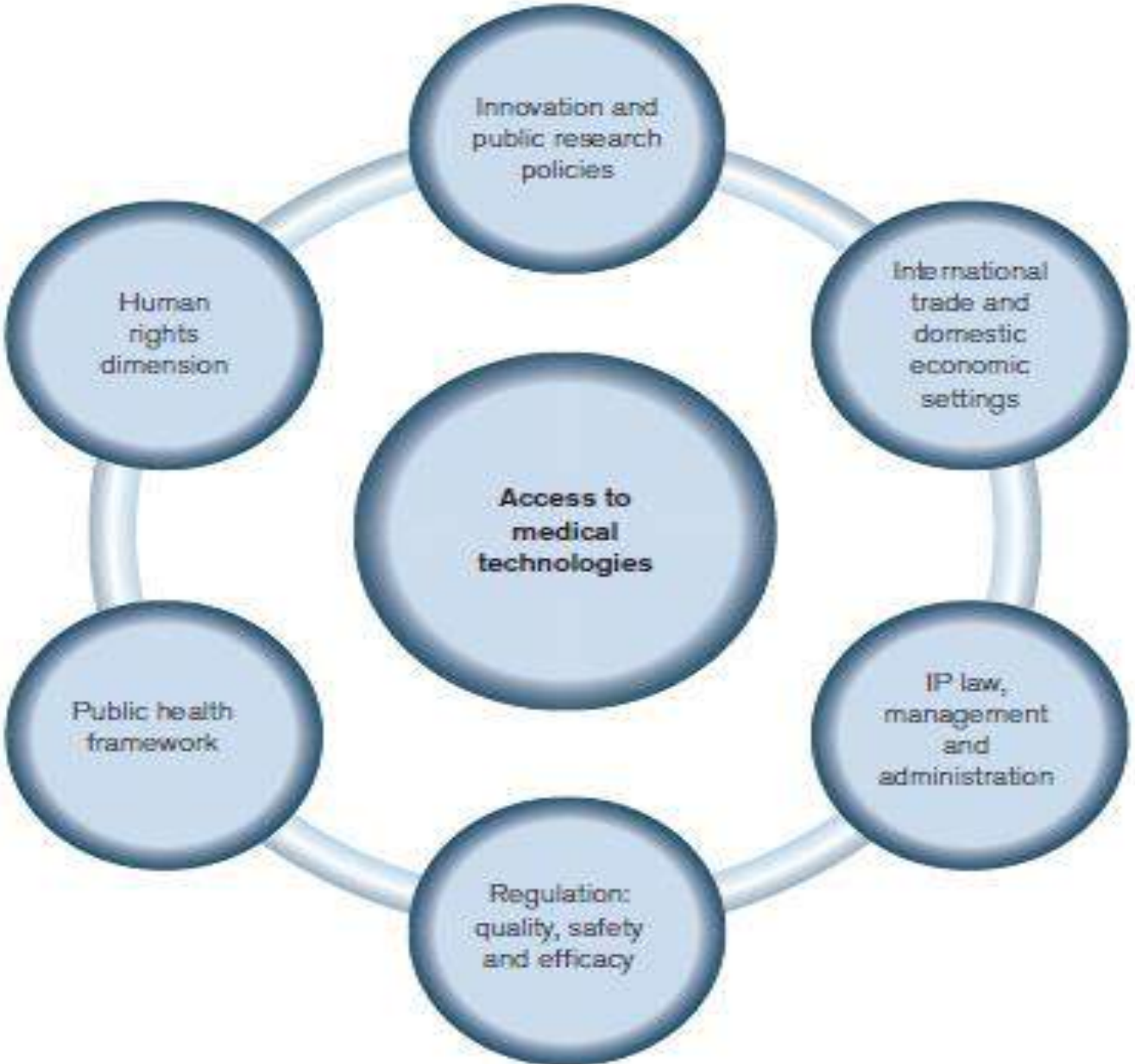
To ensure that *all* people obtain the health services they need without suffering financial hardship when paying for them. This requires:

- a strong, efficient, well-run health system;
- a system for financing health services;
- ***access to essential medicines and technologies;***
- a sufficient capacity of well-trained, motivated health workers.

Factors Pertaining to the Access Debate

- The most important factors pertaining to the Access debate include, but not limited to:
- Rational selection and use of medicines.
- Affordable prices.
- Sustainable financing.
- Reliable health and supply systems.
- *Intellectual Property Rights.*

The Access Diagram



Access is a dynamic not static concept

- The Changing Disease Burden in the MENA Region from Communicable to Non-Communicable Diseases.

- The innovation/access system has to adjust to this changing disease pattern.

- Access debate in the MENA region should be broadened with an increasing focus on access to treatment for Non-Communicable Diseases.

Why IP is important for the Pharma Sector?

- Innovation is key to drug development.
- IP provides market based incentives for stakeholders to invest resources in product development and marketing of new technologies.
- While estimates vary of the actual cost of medical research and product development, innovation is undoubtedly costly and time consuming.
- Three types of costs: R&D, risk of product failure and regulatory approval.
- Facilitating licensing and Technology Transfer.

The Evolving Innovation Landscape

- Market-based incentives may suffer limitations.
- Due to market failure, new models of innovation and for financing R&D are emerging.
- Examples of market failure in health innovation?
- Initiatives are exploring new strategies for product development, such as open innovation structures, a range of push and pull incentives, including schemes such as prize funds that would de-link the price of products from the cost of R&D.

IP and Pharma: Key considerations

- Risks associated with IP protection systems (excluding others, inhibiting forms of competition, and hindering further innovation).
- IP law and policy at the center of access and innovation debate.
- ***Therefore, ensuring balance is a key imperative in all forms and components of any IP regime: policy, law, administration and enforcement.***

IP law affecting Pharma sector

- Patent system
- Test data protection
- Trademark
- Copyright

- ***IP flexibilities as a cross-cutting and an integral element of IP law to ensure balance between innovation and access.***

IP law relating to Pharma Sector: The Legal Instruments

- Paris Convention 1967
- Berne Convention 1971
- TRIPS 1994
- TRIPS Doha Declaration 2001
- TRIPS amendment Protocol 2003
- *In addition to,*

  Bilateral and regional agreements containing TRIPS-Plus standards, such as patent term extension, data exclusivity and patent linkage.

The Patent System

- Patents, in principle, promote innovation by providing incentive to invest in R&D, a particular consideration for the private sector.

- Patent protection must be granted for innovations in all fields of technology, provided they are new, involve an inventive step (or are non-obvious) and are capable of industrial application, i.e. the three patentability criteria.

Protection of Test Data

- Protecting clinical trials test data against unauthorized disclosure and unfair commercial use is mandated by TRIPS Agreement.

- Certain forms of test data protection potentially delay the entry of generic medicines.

- TRIPS does not specify the exact form of protection, henceforth national authorities have taken diverse approaches (part of IP flexibilities)

Promoting access to medical technologies and innovation as part of UHC in the MENA region - I

- Transitional period for Least-developed countries.
- Differing IP exhaustion regimes (parallel imports).
- Policy space for implementing the three criteria of patent grant.

Promoting access to medical technologies and innovation as part of UHC in the MENA region - II

- Pre-grant and post-grant opposition procedures.
- Exceptions and limitations to patent rights once granted, such as: regulatory review exception (“Bolar” exception) to facilitate market entry of generics; experimental use and/or scientific research; preparation of medicines.
- Compulsory Licenses and government use.

Promoting access to medical technologies and innovation as part of UHC in the MENA region - III

- In addition, the creation of *sound competitive market structures* through competition law and enforcement has an important role to play in enhancing both access to medical technology and fostering innovation in the pharmaceutical sector.

- It can serve as a corrective tool if IP rights hinder competition and thus constitute a potential barrier to innovation and access

Towards a conducive UHC IP governance in MENA region - I

- Previous policy options can be used by MENA countries to improve access to medicines for communicable and non-communicable diseases.
- The policy objective is to facilitate timely availability of quality generic medicines at more affordable prices through competition, which contributes to fulfillment of UHC in the region.

Towards a conducive UHC IP governance in MENA region - II

- IP policy and governance should be country tailored while adhering to internationally agreed standards of protection.
- Ensuring access to patented products through effective use of IP flexibilities.
- Enhancing and strengthening local production capacities and facilitating technology transfer.
- Encouraging various models and approaches to innovation.
- Most importantly, sustaining robust and effective inter-agency coordination and collaboration.

In conclusion,

Universal health coverage is not possible without innovation and sustainable supply of affordable medicines and health technologies … If there are new effective essential health products, we also have to ensure that they are affordable and accessible to those who need them, otherwise innovation remains an empty promise

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Thank you

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