



WHO's current work on IP and access to achieve UHC

Licensing and access provisions for medicines and health technologies

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“Ensure healthy lives and promote well-being for all at all ages”

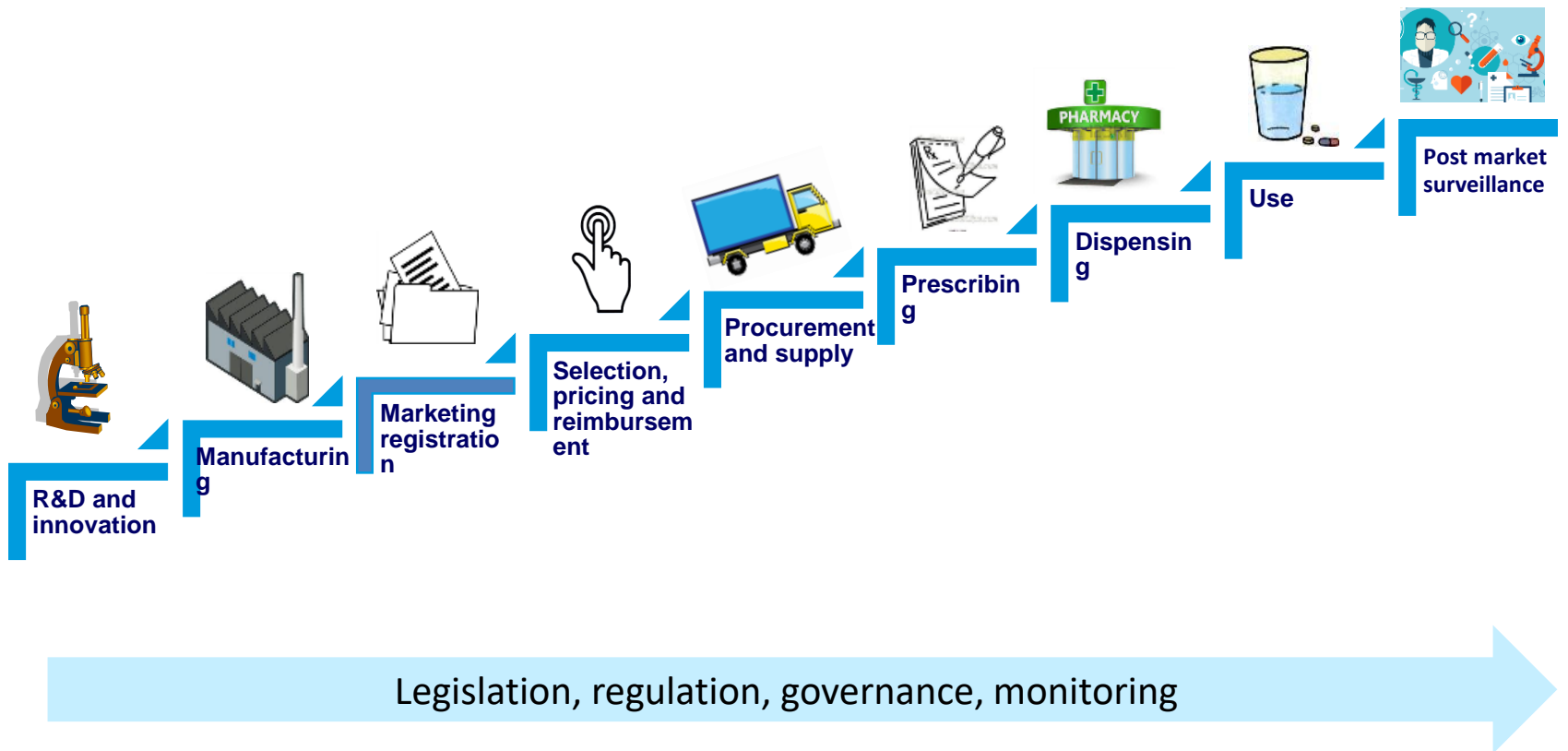


UHC is WHO’s current top priority and **access to essential medicines and health technologies is a key component of UHC**

WHO works on the entire value chain of health products

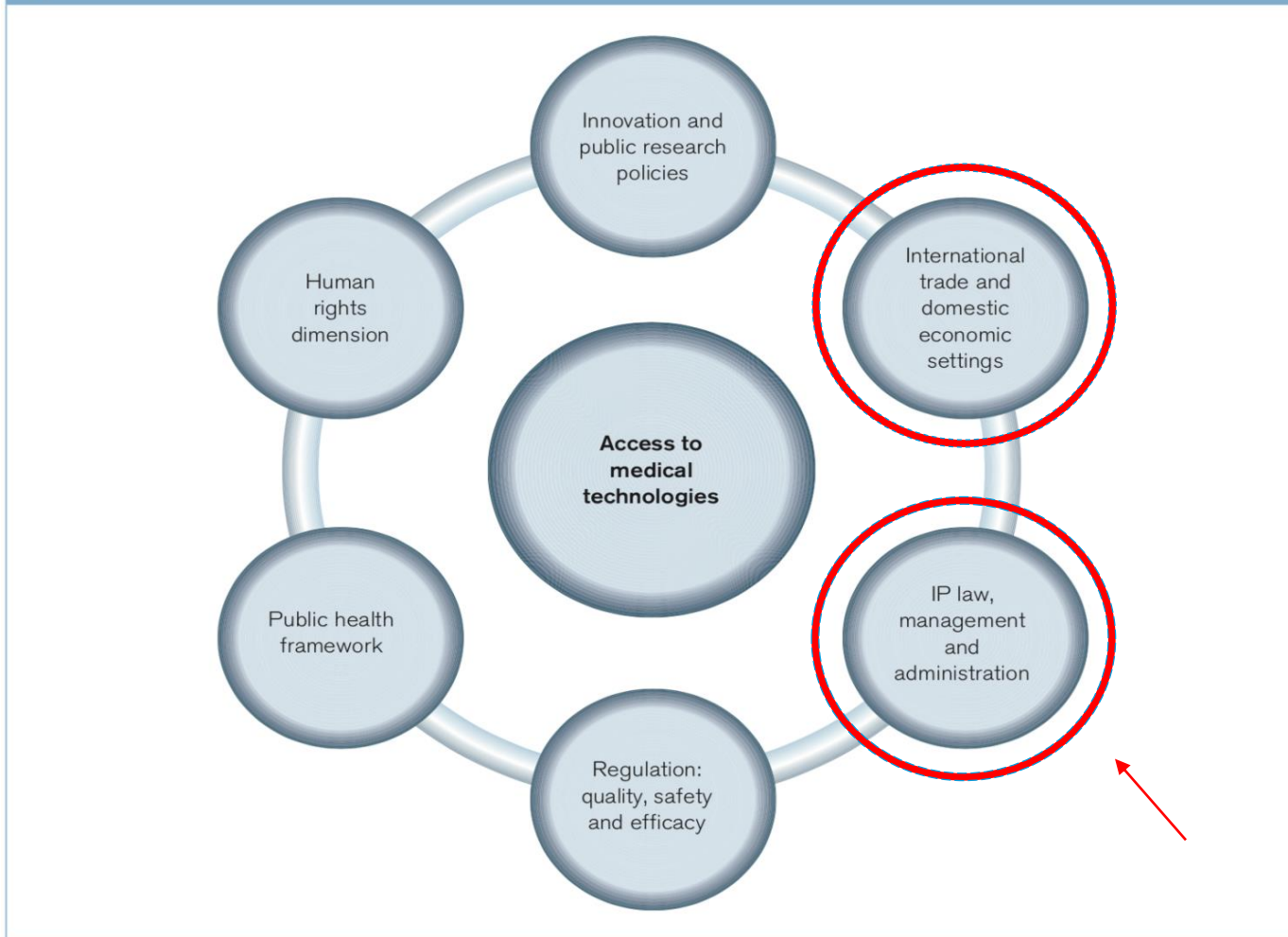


Ensuring access to medicines and health products requires...



Key areas to improve innovation and access to medical technologies

Figure 1.3. The distinct policy domains of public health



World Health Assembly (WHA)



- Addressing the **global shortages of, and access to, medicines and vaccines**(e.g. R&D; Pricing policies; Application and management of IP)
- Implementation plan and progress report of the **Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPA-PHI)**
- 72 WHA last month approved **“Transparency Resolution”**: Pricing, clinical data and patent information

“Seriously concerned about the high prices for some health products, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which impede progress towards achieving Universal Health Coverage”



Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPA-PHI)

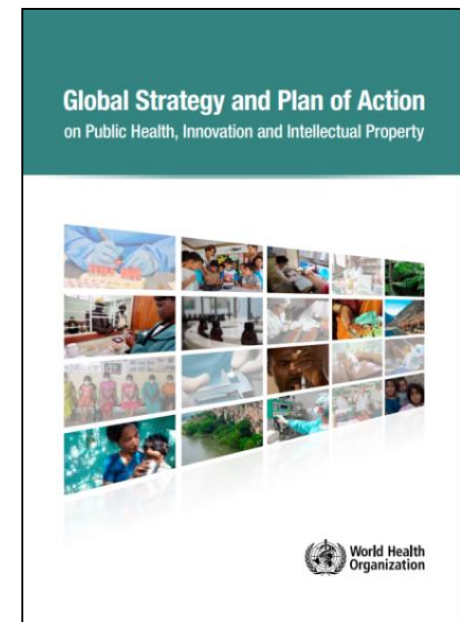


➤ Promoting research and development

2.4. 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 nondiscriminatory terms;***

➤ Transfer of technology

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;***

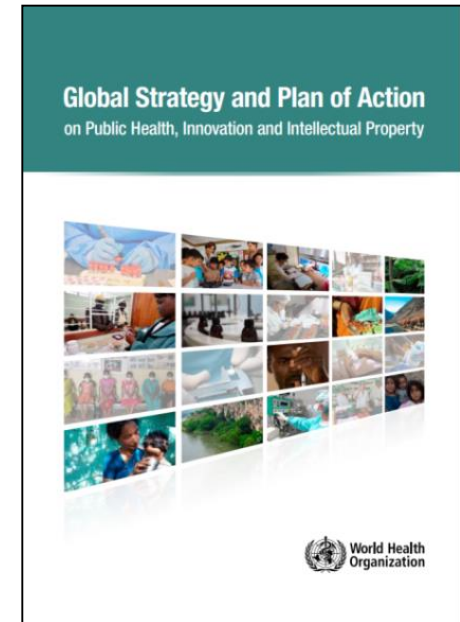


Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPA-PHI)



- **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: (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***



<http://www.who.int/phi/publications/gspa-phi/en/>

Public health-oriented terms and conditions in voluntary licenses (VLs)



- Purely commercial licenses **vs. public health licenses** (private contracts; contractual restrictions; lack of transparency; etc)
- Evolution of pro-access VLs and their key terms and conditions to promote access to **medicines in territories included in and excluded from the licenses**
- **VLs complementary to other access strategies**
- **Best-practices in licensing terms** for delivering meaningful access to health products:
 - **Expand geographic scope**
 - **Increase competition** - number/selection of licensees, freedom to make APIs
 - **Do not harm competition** – do not prevent access where there is no patent in force; “no challenge provisions”
 - **Open to all qualified producers**, without territorial restrictions on the place of production, and should seek to assure affordable access.

Public health-oriented terms and conditions in VLs



Best practices (cont.)

- **Include all related patents** (pending, granted, appealed, and future, that might adversely impact freedom to operate) and **know-how**
- **Facilitate innovation** - freedom to make FDCs, paediatric formulations
- **Speed access** - prompt development and registration through license management
- **Transparency** – Content of the license and Improve transparency of patent data with patent exhibits
- **Unbundling**/unilateral termination provisions allow for licensee to get rid of unnecessary licence (e.g., Gilead MPP)
- **Data exclusivity waivers**, where necessary
- Include needed licensors **registration-related data**
- *Allow **early working*** for purpose of registration
- Grantback provisions

Public health-oriented terms and conditions in the Medicines Patent Pool VLs



Wide geographical scope



Flexibility to combine different medicines & develop fixed-dose combinations



Strict quality assurance policies



Non-exclusive to encourage competition



Compatibility with other access policies and strategies



Public disclosure of company patent information



Transparent: terms of licences published



Licence management to monitor compliance and prevent market leakage

Socially Responsible Licensing (SRL)

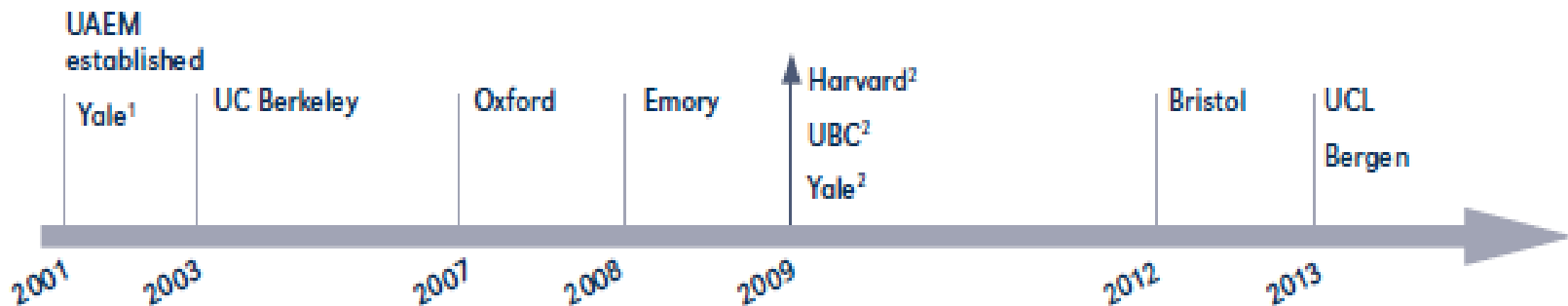


- Public health oriented IP management at Universities or public research institutions may enable access to university-derived health products
- Over the past 2 decades some Universities in different countries have started introducing SRL in order to promote innovation, technology transfer and access
- e.g. differentiated terms and conditions according to level of development, region, manufacturing and distribution costs, etc.
- e.g. Publicly funded research made available freely and widely
- Other practices: transparent licensing, non-exclusive, donations of IP, non-enforcement commitments, public patent pools, humanitarian purposes, flexible models of collaboration to advance health-related innovation while promoting benefit for patients.

Socially Responsible Licensing (SRL)



- Universities developed **different strategies** to implement SRL policies
- The objective was to include **SRL provisions in contracts in order to better monitor their licenses and to benefit public health**
- Below the **timeline of SRL Policy Introduction in some Universities:**



¹ Yale uses SRL provision to allow generic production of stavudine in South Africa

² Universities that adopted the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (AUTM, 2009)

Resources/Publications



WHO Global Strategy and Plan of Action on Public Health, Innovation and IP:
<http://www.who.int/phi/publications/gspa-phi/en/>

WHO-WIPO-WTO study:

https://www.wto.org/english/ress/e/booksp_e/pantiwhowipowtoweb13_e.pdf

WHO Publications related to Public Health, Innovation and IP:

<http://www.who.int/phi/publications/en/>

Access to Hep C Report:

<http://apps.who.int/iris/bitstream/handle/10665/260445/WHO-CDS-HIV-18.4-eng.pdf?sequence=1>

Transparency Resolution:

http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf

WHO Global Price Reporting Mechanism:

<http://www.who.int/hiv/amds/gprm/en/>

Patents and Licensing data base MedsPaL: <http://www.medspal.org>



World Health
Organization



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Thank you!

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