World Health Organization

Realizing Equitable Global Access

Interfaces between Public Health, Innovation and Intellectual Property

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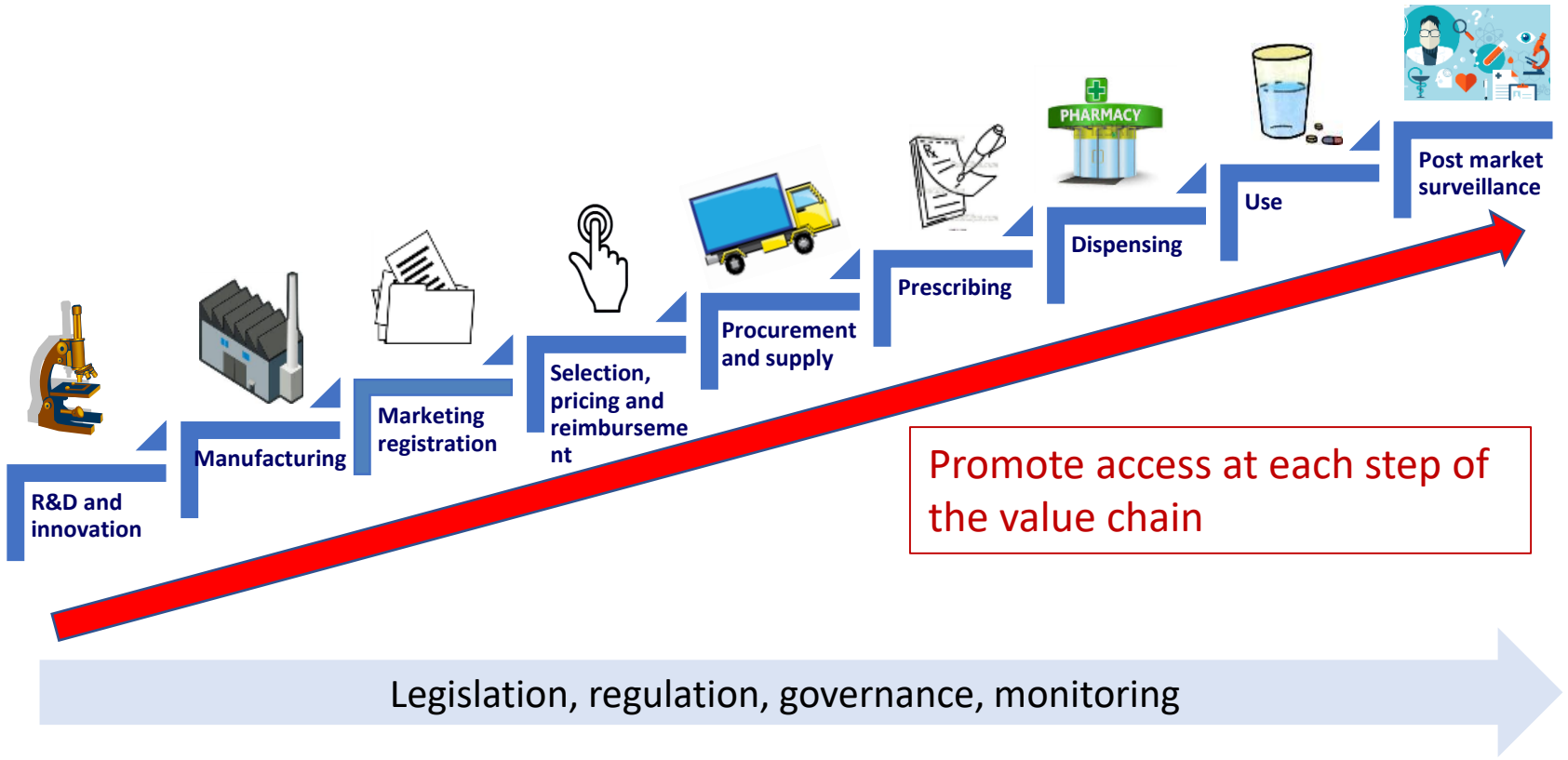
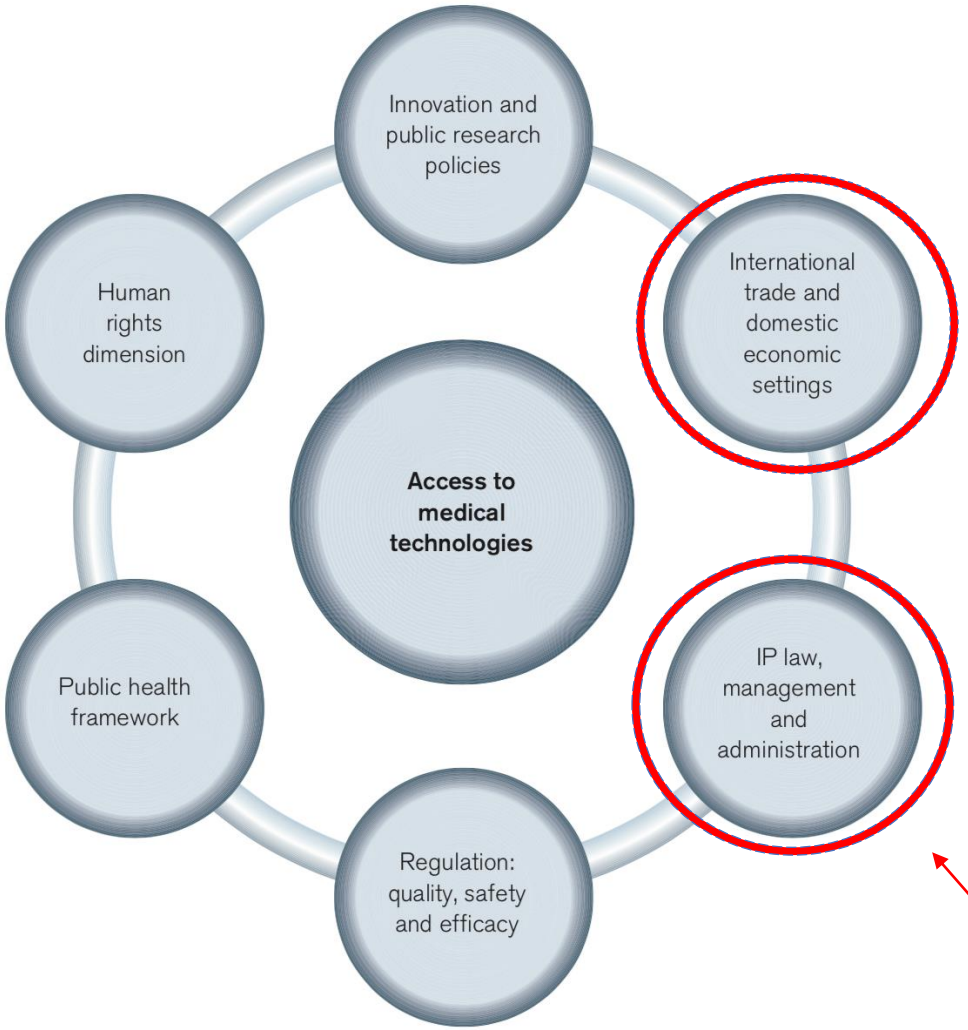
WHO works on the entire value chain of health products

Ensuring access to medicines and health products requires…



Key policies to improve Innovation and access

Figure 1.3. **The distinct policy domains of public health**



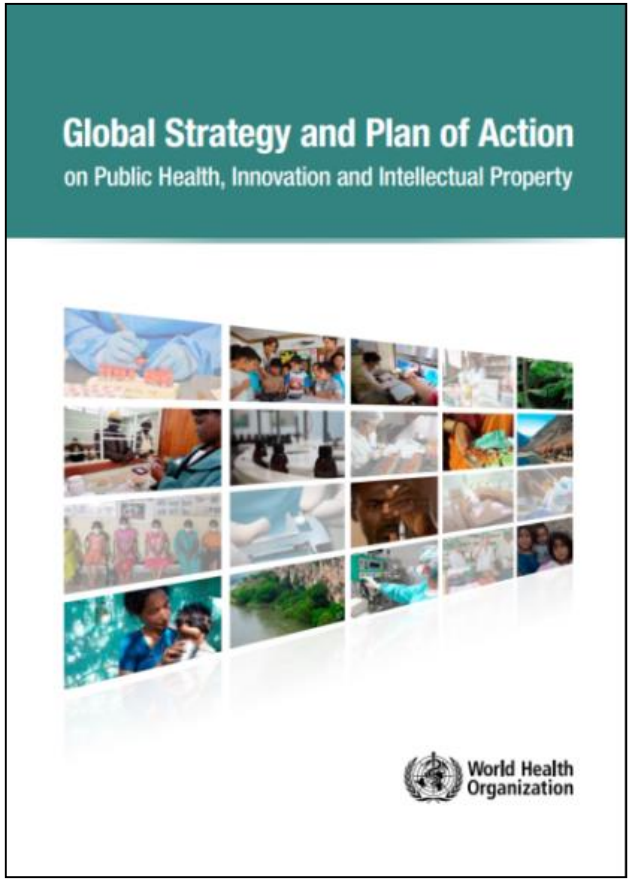
Source: WHO-WIPO-WTO trilateral study http://www.who.int/phi/promoting_access_medical_innovation/en/

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

- **GSPA-PHI document** (GSPA) was agreed by Member States (IGWG 2008) several recommendations and progress indicators to foster innovation and improve access for people in developing countries. (WHA61.21 and WHA62.16)

8 Elements GSPA-PHI:

1. Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology
5. Application and management of intellectual property
6. Improving delivery and access
7. Promoting sustainable financing mechanisms
8. Establishing and monitoring reporting systems



GSPA-PHI
Overall programme review

WHA62.16 requested an overall programme review of the GSPA-PHI in 2014 (achievements, remaining challenges and recommendations)

WHA68.18 decided "**to extend the time frames of the plan of action** on public health, innovation and intellectual property **from 2015 until 2022**." (composition of the Overall review panel)

- Panel report considered that the **8 elements of the GSPA remain broadly valid,** noting that the **main problem is the lack of its implementation**.

- **Prioritized 33 recommendations** and indicators for implementation and monitoring.

GSPA-PHI Report on progress and implementation plan 2020-2022

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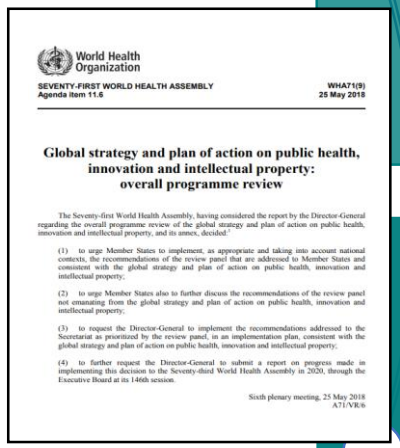
Decision
WHA71(9)



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SEVENTY-FIRST WORLD HEALTH ASSEMBLY
Agenda item 11.6

WHA71(9)
25 May 2018

Global strategy and plan of action on public health, innovation and intellectual property: overall programme review

The Seventy-first World Health Assembly, having considered the report by the Director-General regarding the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property, and its annex, decided:[1]

(1) to urge Member States to implement, as appropriate and taking into account national contexts, the recommendations of the review panel that are addressed to Member States and consistent with the global strategy and plan of action on public health, innovation and intellectual property;

(2) to urge Member States also to further discuss the recommendations of the review panel not emanating from the global strategy and plan of action on public health, innovation and intellectual property;

(3) to request the Director-General to implement the recommendations addressed to the Secretariat as prioritized by the review panel, in an implementation plan, consistent with the global strategy and plan of action on public health, innovation and intellectual property;

(4) to further request the Director-General to submit a report on progress made in implementing this decision to the Seventy-third World Health Assembly in 2020, through the Executive Board at its 146th session.

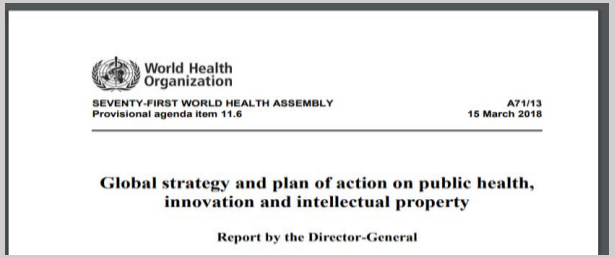
Sixth plenary meeting, 25 May 2018
A71/VR/6

Urged "Member States to implement, as appropriate and taking into account national contexts, the recommendations of the review panel that are addressed to Member States and consistent with the global strategy and plan of action on public health, innovation and intellectual property."

Requested "the Director-General to implement the recommendations addressed to the Secretariat as prioritized by the review panel, in an implementation plan, consistent with the global strategy and plan of action on public health, innovation and intellectual property"

Other WHO related Resolutions

- **Transparency resolution**: Calls on transparency on patent status information and licensing https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf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SEVENTY-FIRST WORLD HEALTH ASSEMBLY
Provisional agenda item 11.6

A71/13
15 March 2018

Global strategy and plan of action on public health, innovation and intellectual property

Report by the Director-General

- **Local production resolution**: Among other aspects make reference to the use of the TRIPS flexibilities to promote equitable access and also make reference to the voluntary mechanisms to promote technology transfer, including WHO C-TAP https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf

Solidarity Call to Action

Making the response to COVID-19 a public common good
Solidarity Call to Action

To realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data.

45 Member States have joined the Solidarity Call to Action so far

Argentina; Bangladesh; Barbados; Belgium; Belize; Bhutan; Bolivia; Brazil; Chile; Costa Rica; Dominican Republic; Ecuador; Egypt; El Salvador; Honduras; Indonesia; Lebanon; Luxembourg; Malaysia; Maldives; Mexico; Mongolia; Mozambique; Norway; Oman; Pakistan; Palau; Panama; Paraguay; Peru; Portugal; Saint Vincent and Grenadines; South Africa; Sri Lanka; Sudan; The Netherlands; Timor-Leste; Turkmenistan; Uruguay; Zimbabwe

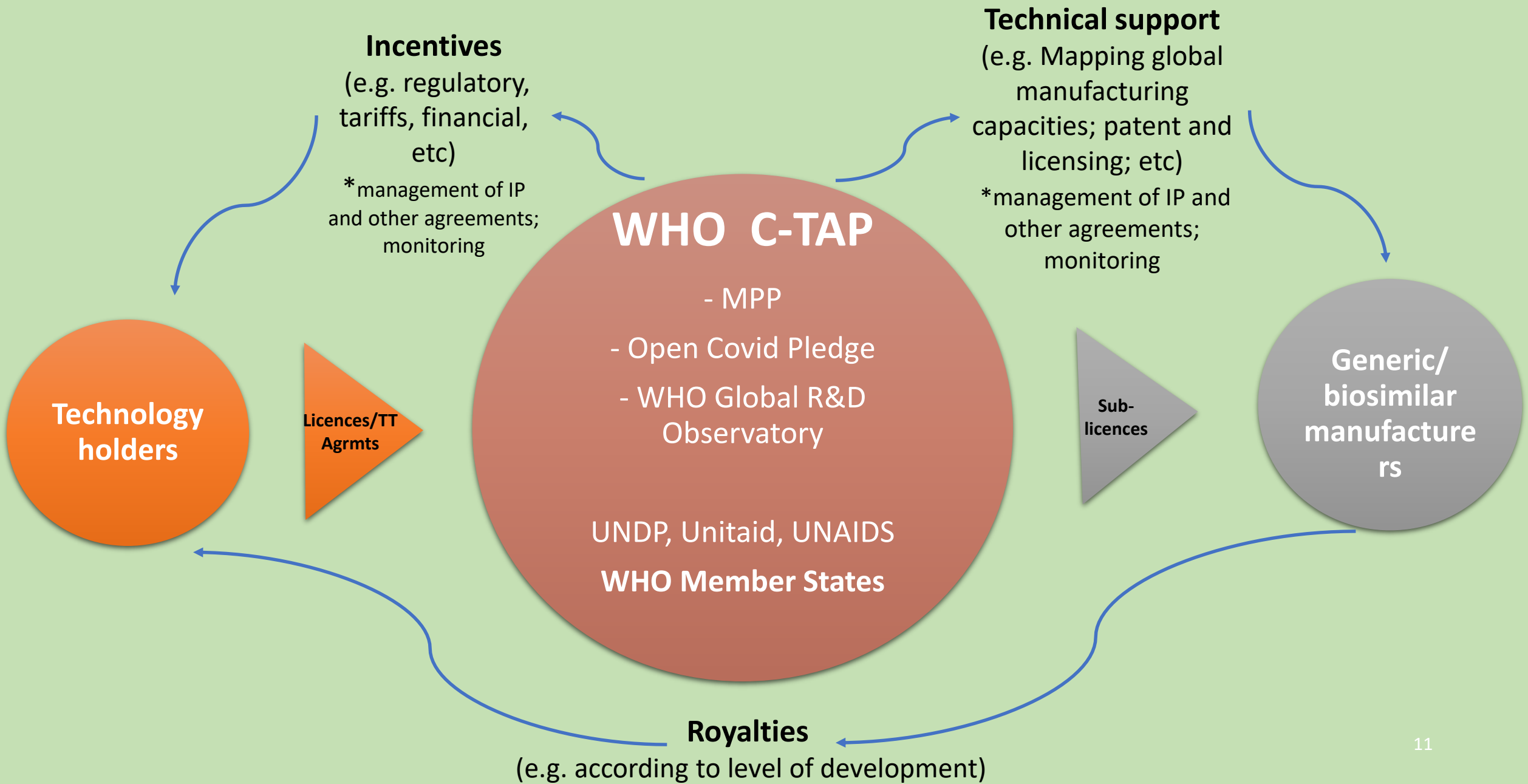
C-TAP – Objectives

- To **promote open science** in order to accelerate product development by pooling intellectual property, data and know-how.
- To accelerate the **scale-up of manufacturing** and facilitate speedy and equitable access to new technologies, through transparent, non-exclusive, and public health-driven licensing and enhanced technology transfer.
- To foster active engagement of key partners including **funders, research institutions and governments** to facilitate sharing of knowledge, data and the licensing of products, in order to maximize global access.

C-TAP Operating Model

- **C-TAP Secretariat and WHO technical staff from different departments (Tx, Dx, Vx)**
- **Technical Advisory Group (TAG)**
- **Steering Committee:** UNDP, Unitaid, UNAIDS, MPP, UN Tech Bank,
- **Implementing partners:**
  - The Medicines Patent Pool (MPP)
  - The Open COVID Pledge (OCP)
  - Global Initiative on Sharing All Influenza Data (GISAID)
  - The WHO Global Observatory on Health R&D

How C-TAP works to facilitate technolgy sharing and increase scale up?



WHO C-TAP Prioritized activities 2021-2022

The goals and objectives are defined according to the principles included in the Solidary Call to Action, some of the deliverables include:

- **Engagement with holders of IP and know-how** to promote sharing through C-TAP and its partners (vaccines, therapeutics and diagnostics)
- **Policy recommendations for funders** to promote equitable access principles through best terms and conditions in publicly funded R&D agreements
- **C-TAP website and database**, established and maintained to promote transparency in relation to key relevant information about prioritized COVID-19 products to facilitate use in research, development and scale-up
- **Communications strategy** to increase support for different stakeholders' engagement and contribution to C-TAP initiative to scale-up at global level
- **Further engagement with Member States, civil society organizations**, other COVID-19 initiatives and other stakeholders to promote C-TAP objectives.

WHO C-TAP Engagement with technology holders

- Bilateral discussions with manufacturers:

  - **Diagnostics**: Offer from Spanish Research Institute (CSIC) license agreement being discussed with the MPP; Indian Institute CRISPR Diagnostic; discussions with the IP owners of CRISPR technology willing to support transfer of technology for COVID-19; few more offers in pre-assessment by WHO Dx team.

  - Vaccines: 2 EUL approved manufacturers; 1 offer of a vaccine in assessment for EUL; 2 vaccines approved at the national level; other discussions with manufacturers exploring the possibility to share vaccines in development.

  - **Therapeutics:** recently included in WHO EUL - mAbs (widely patented and/or technology transfer needed)

  - MPP in bilateral discussions for other **therapeutics**

***IFPMA:** Providing further clarifications at the technical level on C-TAP objectives and operating model

IP related access initiatives for COVID-19 response

	TRIPS Waiver proposal	TRIPS flexibilities/ Compulsory licenses	Access oriented voluntary licenses/ WHO C-TAP	Traditional bilateral voluntary licenses
IP coverage	-Covers not only all patents related to a product but other IP rights like trade secrets, copyrights, industrial designs, undisclosed information. -Neither grant nor enforce existing patents	Patents: Product by product and country by country	Patents: - Public-health driven, non-exclusive and transparent licenses - Product by product for several countries through patent pooling mechanisms (e.g. MPP) - Multiple manufacturers	Patents: - Bilaterals (lack of transparency – deals among companies) - Exclusive-licenses or limited to few manufacturers - Other potential contractual restrictions
Other market exclusivities	Depends on the implementation at the national level (Waivers could be included)	Depends on the implementation at the national level (waivers could be included in the text of the CL)	Waivers to data exclusivity protection generally included in the licenses	Unknown (Should be included by the company)
Duration	Pandemic	Duration of the patent (Can be less according to the legislation)	Pandemic or pandemic +	Pandemic or pandemic +
Scope	All WTO Members (Implemented at the National level)	Each country should grant it	Broad coverage, usually including most LICs and lower-MICs (difficult to include certain Upper MICs with manufacturing capacity)	Country by country (or small number of countries in some cases)
Legal certainty to operate for manufacturers	Fast and high during the pandemic. Unknown after the pandemic.	-Fast and high during and after the pandemic -Needs political willingness to do it	Negotiations may take time (However it can be done to multiple manufacturers with WHO's technical support LP, tech transfer hubs, etc)	Negotiations may take time
Technology transfer	-Not included. -Reverse engineering possible. - Tech transfer collaboration could take place among manufacturers	- Not included -Reverse engineering possible. - Tech transfer collaboration could take place among manufacturers	Included and supported by WHO C-TAP initiative and implementing partners	Included
Transparency	Yes	Yes	Yes	No
Freedom to operate need?	No (All the patents even the unknown patents are included, no need of deep analysis)	No (If all related patents to a specific product are covered by the CL)	Yes (According to the geographical scope of the license)	Yes
Compatibility with TRIPS flexibilities	With Marrakesh Agreement (WTO)	Yes	Yes	Unknown/unlikely (restrictions where found in the past)

WHO: Alternatives for a pandemic situation response

WHO DG:

*"But boosting manufacturing won't happen by itself. We are living through an exceptional moment in history, and must rise to the challenge. Whether it's dose sharing, tech transfer or voluntary licensing, as the WHO's own Covid-19 Technology Access Pool initiative encourages, or waiving intellectual property rights, as South Africa and India have suggested, we need to pull out all the stops." (*The Guardian)

Source MPP website