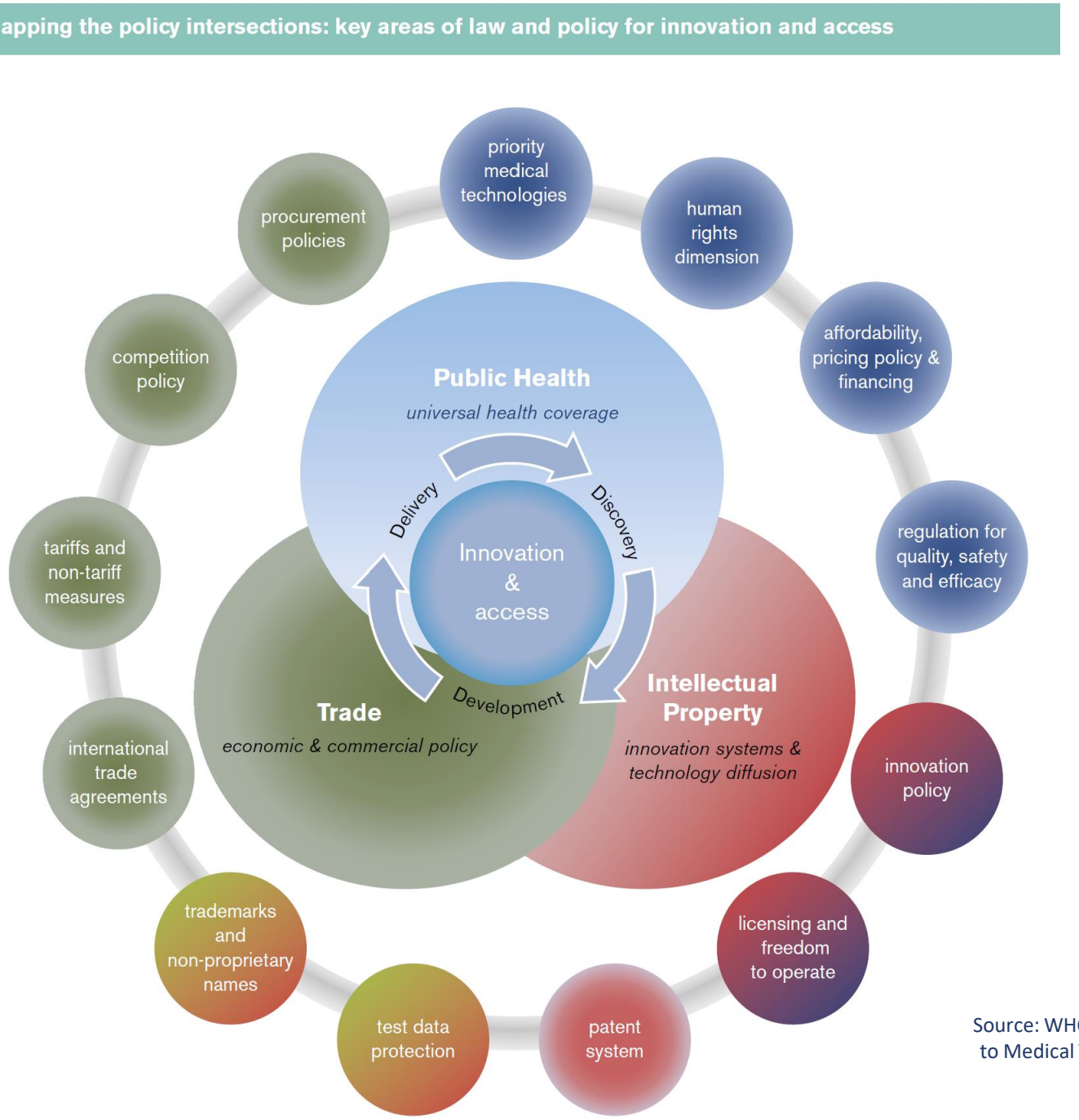
25 Years of the TRIPS Agreement –
Past, Present and Future
24 November 2020

Evolution of the TRIPS Agreement: Doha, the Public Health Dimension & Subsequent Cooperation

Roger Kampf, WTO Secretariat

I.
Setting the Scene:
TRIPS & Health –
Working in a Complex Environment

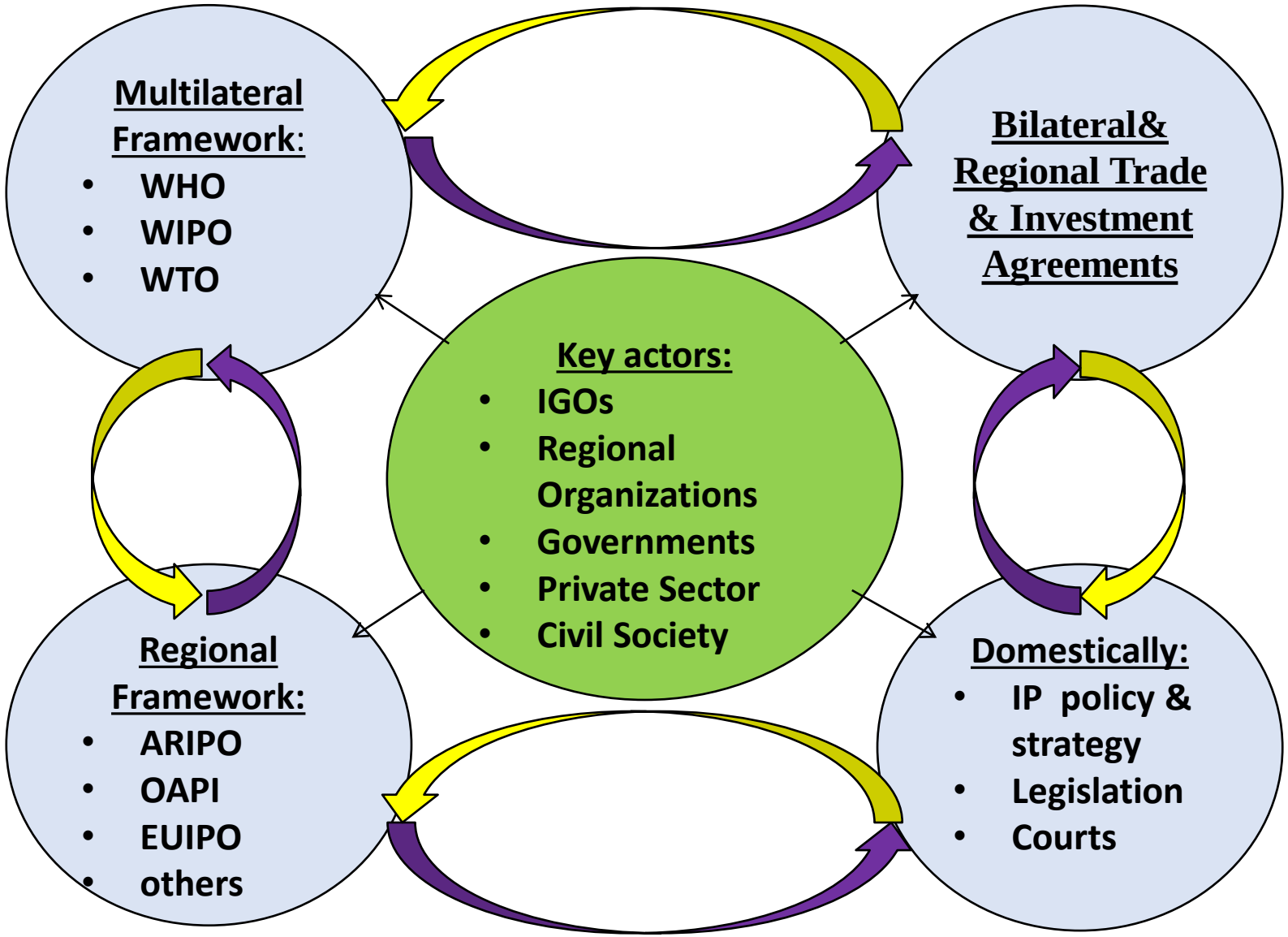
Pulling the relevant policy dimensions together: Intersections between health, IP and trade



Source: WHO-WIPO-WTO Study on Access to Medical Technologies and Innovation, 2nd edition, 2020

Different Levels & Actors

Ensuring policy coherence



Link Between Public Health, IPRs and Trade: Key Questions Framing the Debate

- IPR as an important factor for development of new medicines, but: concerns expressed about effect on prices

How best to reconcile the need for incentives to invest in R&D and access to medicines?

- Importance of flexibilities recognized, but: need to preserve balance of rights and obligations

How best to achieve an optimal balance between IPRs and public health?

- TRIPS as *part* of wider national and international action to address health problems, but: cannot solve issues on its own

How best to ensure capacity to deal with innovation-access cycle in a holistic manner?

II.

Doha Declaration & Subsequent Instruments: Affirming Capacity to Respond to Pressing Needs & Making TRIPS Part of the Broader Picture

Why to Adopt the Doha Declaration?

- Context:
  - HIV/AIDS crisis in Africa in late 1990s
  - Coincides with TRIPS implementation by developing countries in 2000
- Purpose:
  - Respond to concerns about impact of strengthened IPR protection on access to medicines
- Significance:
  - Different views about the nature and scope of TRIPS flexibilities
  - Interpretation of TRIPS flexibilities in a broad pro-public health manner
  - Concerns about pressure from trading partners not to use existing flexibilities

Doha Declaration: A Blueprint for Policy Coherence

WORLD TRADE ORGANIZATION	WT/MIN(01)/DEC/2 20 November 2001 (01-5860)
MINISTERIAL CONFERENCE **Fourth Session** **Doha, 9 - 14 November 2001**	

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

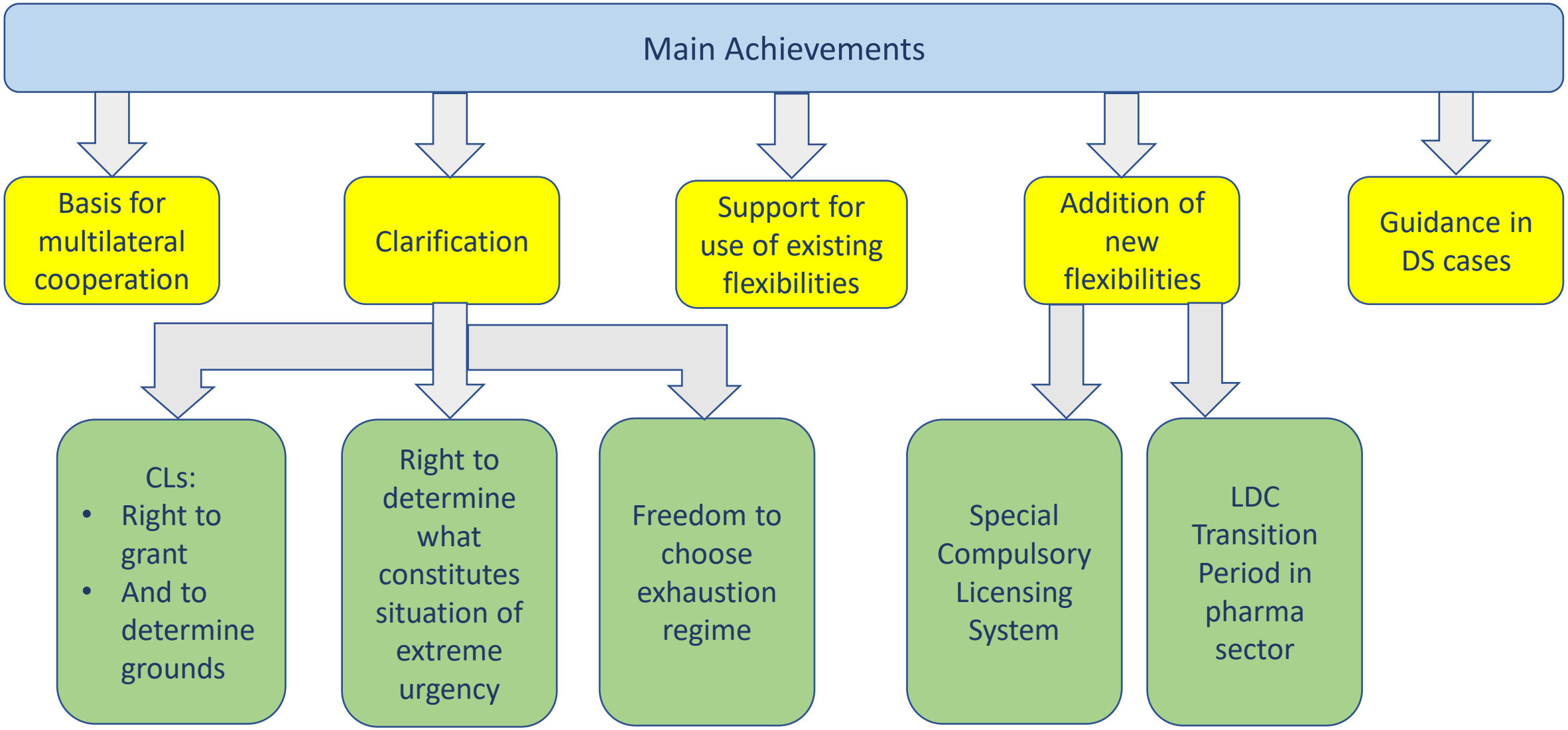
1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking

Doha Declaration: A Milestone for the WTO



Clarifying Policy Options: The Example of Standard Compulsory Licences

- Implementation (WIPO document SCP/30/3, 2019):
  - 156 jurisdictions provide for CL/government use licences
  - Plus several regional instruments
- Use:
  - Initially limited in most jurisdictions
  - But: increased use in relation to pharmaceutical patents since 2010
  - Trilateral Study analyzes 34 selected cases in which CL/government use licences have been considered or granted
  - Other sources report 108 cases since 2001 with CL granted in 74 cases

Table 4.1: Selected country experiences with compulsory licences and government-use licences

Disclaimer: *This table is not exhaustive. While every effort has been made to verify this information against primary sources such as judicial decisions, Presidential Decrees or official WTO documents, this has not always been possible as not all information is in the public domain and no official comprehensive registry or database exists.*

Country	Year	Medicine	Type of licence	Outcome	Indication (non-exhaustive)	Further information
Brazil (see section C.3(a)(ii), "Country experiences")	2001	NFV	CL	Not issued	HIV/AIDS	Licence considered – price discounts secured.
	2005	LPV/r	CL	Not issued	HIV/AIDS	
	2007	Efavirenz (EFV)	CL	Issued	HIV/AIDS	By 2012, the estimated savings for the Brazilian Government reached US$ 236.8 million.[239] Local production impossible for two years after grant of CL, during which time generic imported from India.[240]
Colombia (see Box 4.2)	2014	Imatinib mesylate	CL	Not issued	Leukaemia	Price control applied.
Ecuador	2010	Ritonavir (RTV)	CL	Issued	HIV/AIDS	Maximum price for 30 x 100 mg RTV tablets set at US$ 29.40 from US$ 289.99, 4 per cent royalty rate based on tiered royalty method (TRM)[241] or 0.42 per cent of the US price.[242]
	2013	Abacavir/lamivudine (ABC/3TC)	CL[243]	Issued	HIV/AIDS	Maximum price for ABC set at US$ 6.11 from US$ 24.83. 5 per cent royalty rate based on TRM.[244] A 30–70 per cent saving on the cost of purchase has been reported by the Ecuadorian Ministry of Public Health.[245]

Source: WHO-WIPO-WTO Study on Access to Medical Technologies and Innovation, 2nd edition, 2020

Creating Additional Flexibilities (1): Trade-Related Compulsory Licences for Export

- Para.6 Doha Declaration
  - Identified difficulties for Members with insufficient/no manufacturing capacities in the pharmaceutical sector to make effective use of CL
- Concern: availability of supply from generic producers in third countries
  - Art. 31(f): production under CL "predominantly for the supply of the domestic market“
  - Countries with important generic industry obliged to provide full patent protection for pharma products since 2005
- The solution: derogations from restrictive conditions in Art. 31(f) and (h) TRIPS
- A System that addresses…

…a health problem
In the importing Member

…a legal problem
In the exporting Member

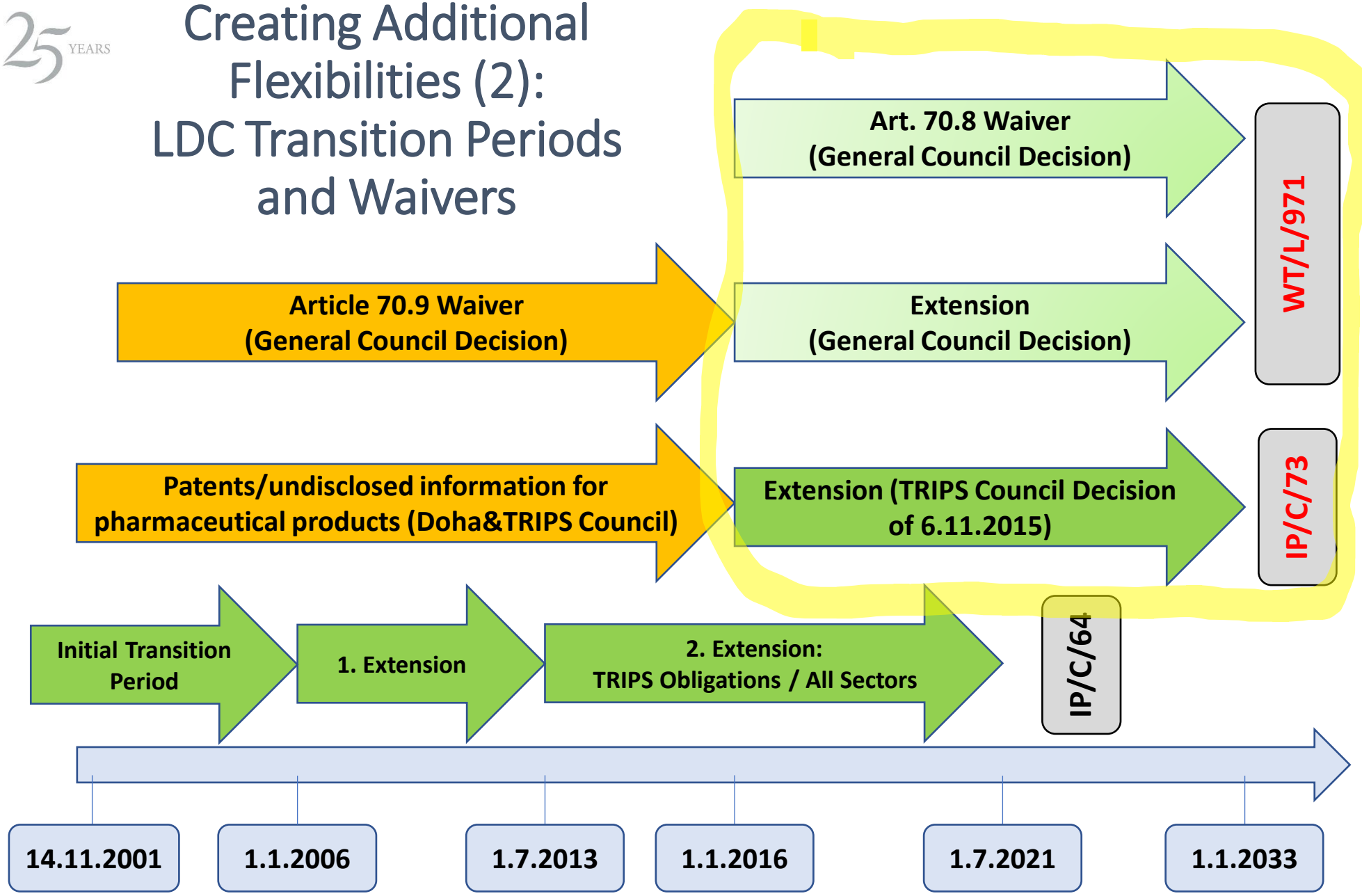
Steps Towards Putting the System in Place

Members' Voices (30 Jan. 2017):

- "Marks a significant step forward for the Members of the WTO" (LDC Group)
- "Truly a historic measure that has been taken, the first ever amendment to the WTO Agreements" (Bangladesh)
- "Important because it demonstrates that the WTO is capable of responding in an adequate way to essential needs beyond trade policy" (EU)
- "Provides legal certainty to our quest for affordable medicines" (African Group)
- "An important signal to everyone that this Organization is not only about trade liberalization" and "the System is part of a broader picture which includes other important aspects" (South Africa)

- 30 August 2003
  - Adoption of waiver decision
- 6 December 2005
  - Adoption of Protocol Amending TRIPS
- 23 January 2017
  - Entry into force of permanent TRIPS Amendment

Creating Additional Flexibilities (2): LDC Transition Periods and Waivers



III.
Cooperation:
Evolving from Silos to Inclusiveness

Intensifying Cooperation with External Partners

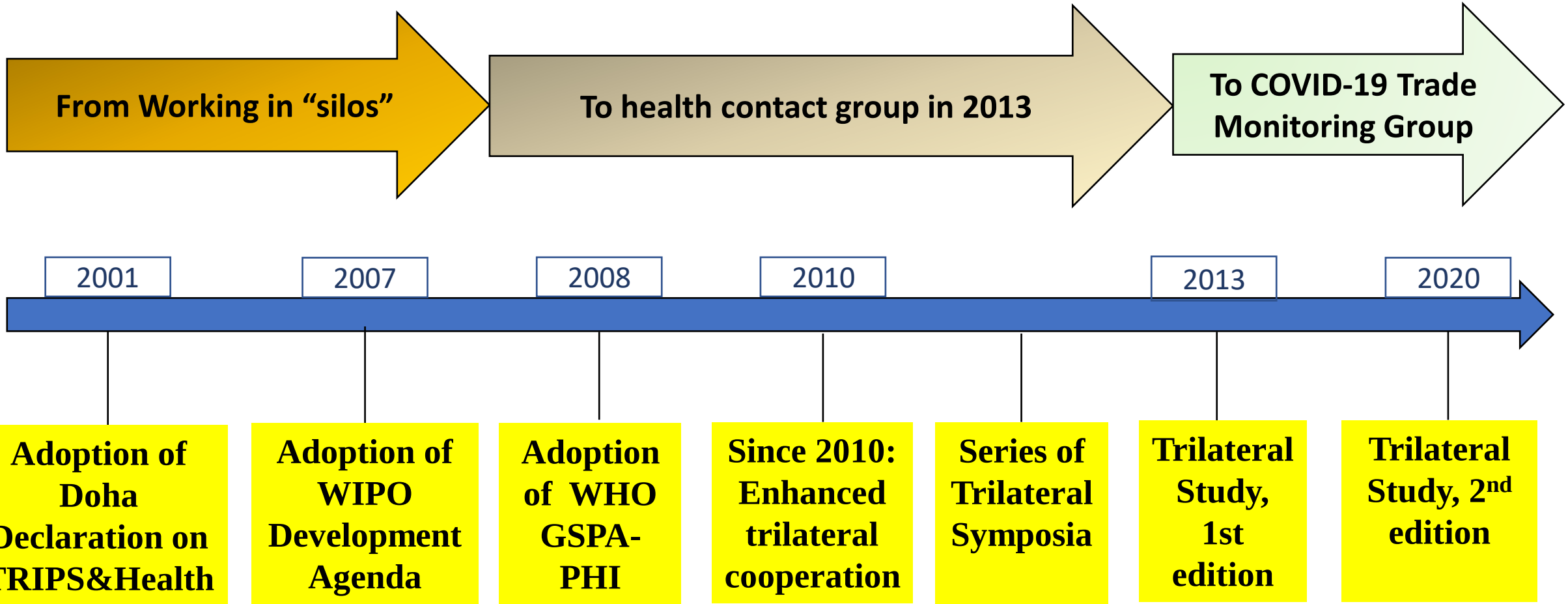
Promoting Medical Innovation and Access, Together

stakeholders from all sectors: private, public, intergovernmental organizations (IGOs) and nongovernmental organizations (NGOs).

This paper addresses the trilateral partnership be-

- More than 10 years of trilateral cooperation: WHO, WIPO, WTO
  - ➢ Pulls expertise in different areas together
- Reach-out to other IGOs and key stakeholders
- For this to be effective: need to mirror close cooperation at domestic level

WTO Secretariat: Not Working in Silos Anymore!



Exemplifying Joint Secretariat Efforts to Ensure Transparency and to Build Capacity

COVID-19 Related Work:

- Regularly updated list of measures regarding trade-related aspects of IPRs, goods and services
- Information notes, e.g.:
  - The TRIPS Agreement and COVID-19 (Oct. 2020)
  - How WTO Members have used trade measures to expedite access to COVID-19 critical medical goods and services (July 2020)
- Vaccines Checklist of Issues with Trade Impact and Infographic (November 2020)
- Other resources:
  - List of Members' proposals
  - List of Members' notifications
  - Enquiry points

https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm

IV. Capacity Building: Evolving Towards an Integrated and More Tailored Approach

Annual Trade and Public Health Workshop

WORLD TRADE ORGANIZATION

TRADE AND PUBLIC HEALTH WORKSHOP

Organized by the WTO Secretariat

in collaboration with the Secretariats of WHO and WIPO

WORLD TRADE ORGANIZATION
ORGANISATION MONDIALE DU COMMERCE
ORGANIZACIÓN MUNDIAL DEL COMERCIO

WORKSHOP ON INTELLECTUAL PROPERTY AND PUBLIC HEALTH

Organized by the WTO Secretariat
in collaboration with the Secretariats of WHO and WIPO

Geneva, 10 to 13 October 2011 - Centre William Rappard, Room C

Programme
(each session to include appropriate time for discussion)

- Organized by WTO Secretariat since 2005
- Initial focus on IP
- Integrated approach since 2014
- Based on close collaboration with WHO and WIPO Secretariats
- Organisation of similar activities at regional and national level

News item and presentations available at:

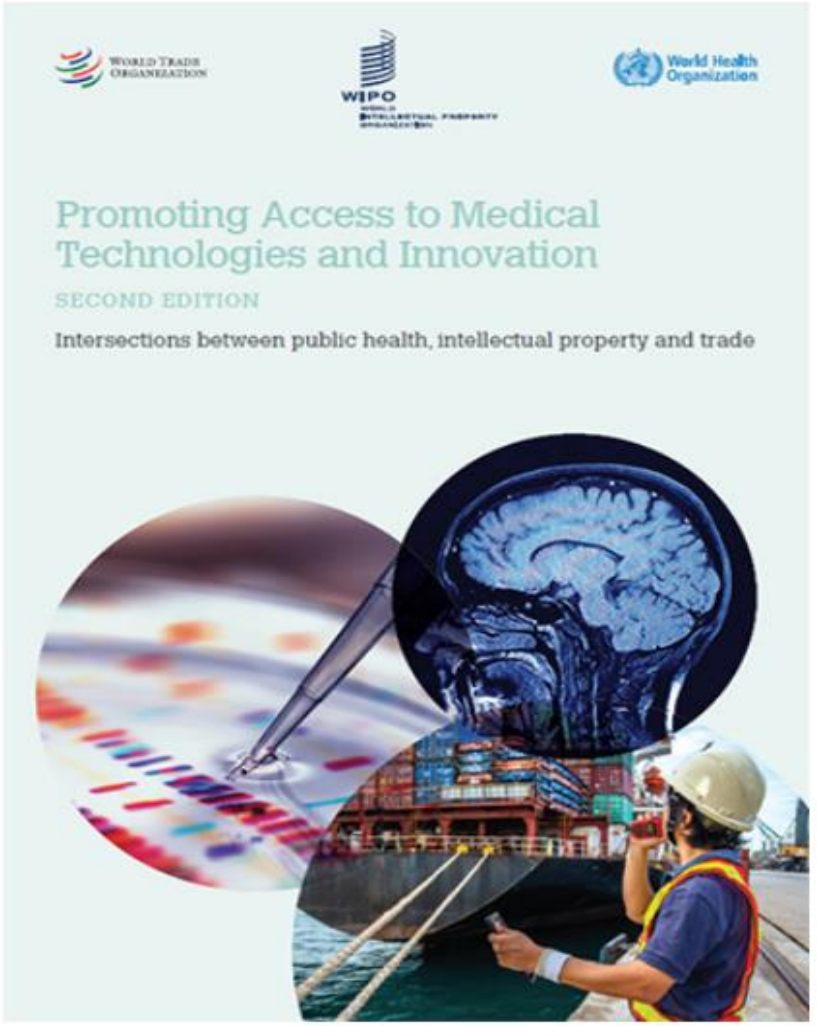
https://www.wto.org/english/news_e/news20_e/heal_21oct20_e.htm

WHO-WIPO-WTO Study (2nd edition, 2020)

Full publication:
https://www.wto.org/trilateralstudy2020

COVID-19 Extract:

https://www.wto.org/english/res_e/booksp_e/extract_who-wipo-wto_2020_e.pdf



Trilateral Symposia: Gathering Empirical Data

2019	Technical Symposium to address opportunities and challenges of cutting-edge health technologies
2018	Trilateral Symposium to examine how innovative technologies can promote health-related SDGs
2016	WHO, WIPO, WTO Symposium to examine how to foster appropriate use of antibiotics, access and innovation
2015	Symposium on Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future
2014	Symposium on Innovation and Access to Medical Technologies: Challenges for Middle-Income Countries
2013	Technical Symposium on Medical Innovation — Changing Business Models
2011	Symposium on Access to Medicines: Patent Information and Freedom to Operate
2010	Symposium on Access to Medicines: Pricing and Procurement Policies

V.
Personal Thoughts:
Looking at the Way Forward

Taking Stock

- Experience from TRIPS implementation shows positive developments:
  - Responding to pressing public health needs
  - Placing TRIPS into broader context, developing from an IP-focused to an integrated approach
  - Enhancing and exemplifying cooperation both in house and key stakeholders
  - Demonstrating
    - Possible positive sum impact of working within the existing framework
      - Example: COVID-19 vaccines development within record time
    - Need for non-static legislation, subject to constant review to adapt to specific circumstances
      - Example: streamlining and facilitating domestic compulsory licensing provisions in the context of COVID-19 pandemic
- How to build on this experience?

Future Developments: What Is Needed?

- Empirical data and evidence to support informed decision-making
- More tailored capacity building responding to specific needs of Members
- Transparency, including easy access to patent information and patent landscape reports
- Further development of integrated approach:
  - Government strategy for R&D and access, including financing and IP management
  - Efficient and expeditious marketing approval mechanisms
  - Transparent and efficient rules governing public procurement
  - Legal and institutional framework for the effective application of competition law
  - Alignment of industrial policy objectives with public health goals
  - Consideration of broader trade issues, in particular as regards export/import opportunities
- Doha Declaration 2.0?