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WIPO WORLD INTELLECTUAL PROPERTY ORGANIZATION

INTERNATIONAL CONFERENCE

Intellectual Property and Health Innovation – Challenges for the Future

Topic 2: Promoting access to medical technologies and innovation

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WORLD TRADE ORGANIZATION

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World Health Organization

Promoting Access to Medical Technologies and Innovation

Intersections between public health, intellectual property and trade

"*intersections* between health, trade & intellectual property"

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.

access to medical technologies

innovation of medical technologies

access to medical technologies

$$\sum_{\forall i} x_i = 0$$

innovation of medical technologies

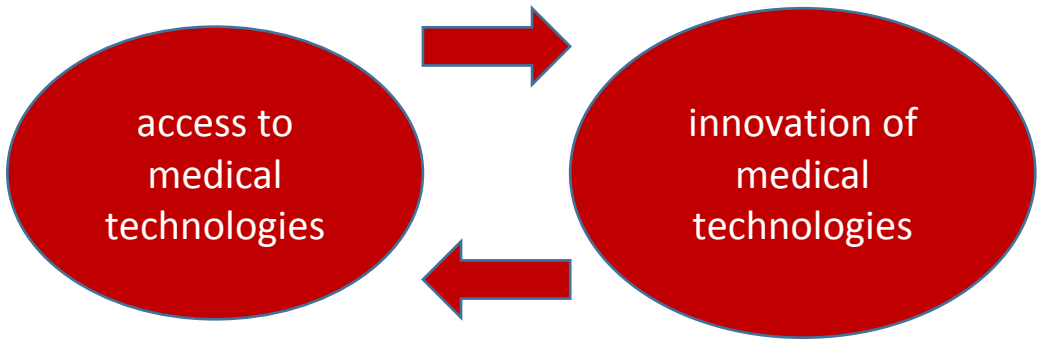
- WHO WIPO WTO report emphasises that innovation and access must be seen holistically
  - innovation without effective access offers scant public health benefit;
  - yet simply to leverage access to an existing pharmacopeia without encouraging the development of new medicines and new medical technologies would diminish health outcomes.
- The study points out the importance of the patent system for the pharmaceutical sector,
  - while also identifying alternative incentive mechanisms that seek to enable much needed new products in neglected diseases.

the policy context:
TRIPS articulates the "should" of IP

protection of intellectual property rights should:

- contribute to the promotion of technological innovation and
- to the transfer and dissemination of technology,
- to the mutual advantage of producers and users of technological knowledge and
- in a manner conducive to social and economic welfare, and
- to a balance of rights and obligations."

WTO TRIPS Agreement, art. 7


access to medical technologies
innovation of medical technologies

- TRIPS and the Doha Declaration helped frame the debate over the role of intellectual property in the context of public health, development, and human rights
  - these remain central concerns in continuing policy debate
- ...but policymakers dealing with the "intersections" of public health, IP, and trade, now work within a broader perspective
- What factors determine access to needed medical technologies? How do they interact? How should they?
- How to promote innovation of new medical technologies, especially when conventional incentives fail?
  - How are these two questions linked?
  - For medical technologies, what does it mean to take an holistic approach to access and innovation?


human rights dimension
procurement strategies and pricing policies
tailored R&D policies and incentives for health
projected disease burden
research and technology transfer policy
trade and competition settings
intellectual policy settings for ‘mutual advantage’
access to medical technologies
innovation of medical technologies

World Trade Organization

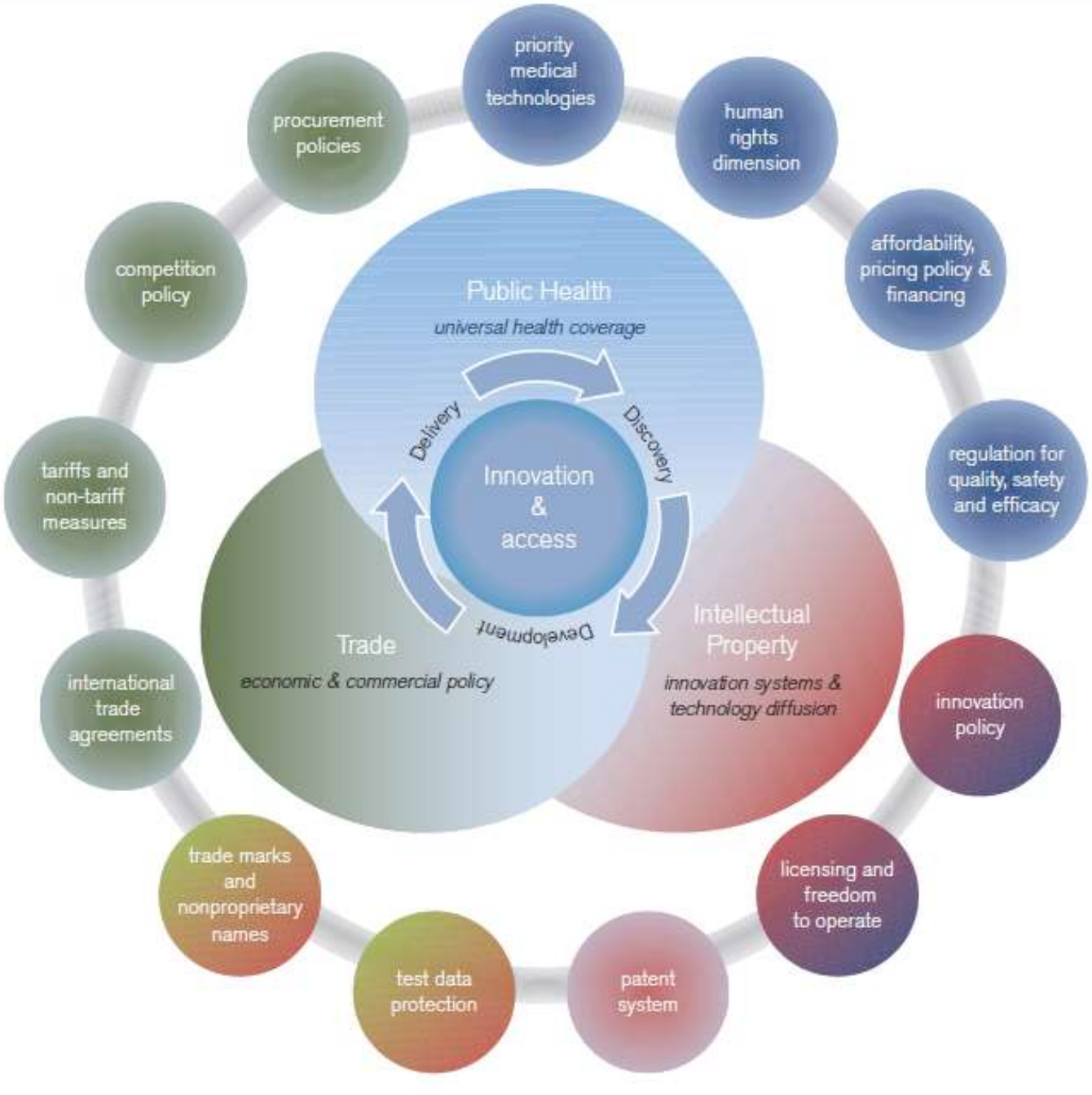
WIPO World Intellectual Property Organization

World Health Organization

Promoting Access to Medical Technologies and Innovation

Intersections between public health, intellectual property and trade

Mapping the policy intersections: key areas of law and policy for innovation and access



- Doha: recognized that the IP system is not an isolated specialist domain, nor yet a monolithic barrier to public health.
  - an element of the complex set of policy tools required to solve global problems.
- emphasis on how different policy measures work together coherently and to mutual benefit — the policy 'intersections'.
- a blueprint for the coherence agenda that the trilateral study elaborates.
- catalyses understanding that access to medicines requires the right mix of health policies, IP rules and trade policy settings
  - entails judicious and informed use of a range of measures including competition policy, procurement strategies, tariffs and other trade related drivers of cost, and choices within the IP system.
- coherence between these is key to finding sustainable solutions.

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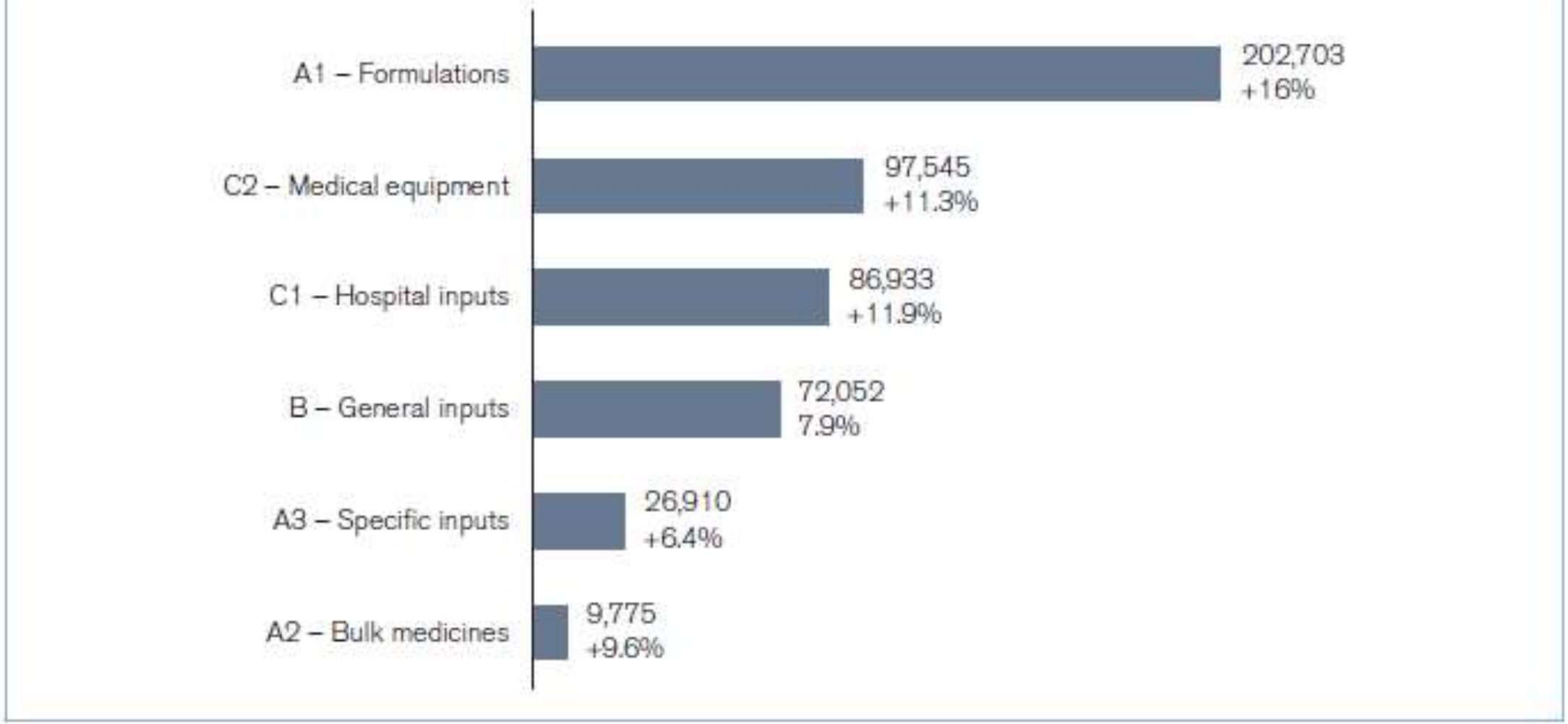
- International trade is crucial to ensuring access to medicines and other medical products.
- No country is entirely self-reliant for the products and equipment it needs for its public health systems – most rely heavily on imports. Trade increasingly important for ensuring supplies of goods required for public health, such as medicines, medical devices and other technologies. Of the 139 countries surveyed, only 24 were net exporters of health-related products in 2010.
- Trade in health-related products has been dominated by a few developed countries but the study highlights the growing presence of emerging economies.
  - India: fourth largest exporter of bulk medicines, fifth largest of finished formulations
- Developing countries, least-developed countries (LDCs) and transition economies comprise 85 per cent of the world's population but account only for 30 per cent of imports and 20 per cent of exports of internationally traded health-related products.
- Imports of health-related products represent 5 per cent or more of all imports for 40 countries – 17pc in Panama, 14pc in Venezuela and 12pc in Burundi

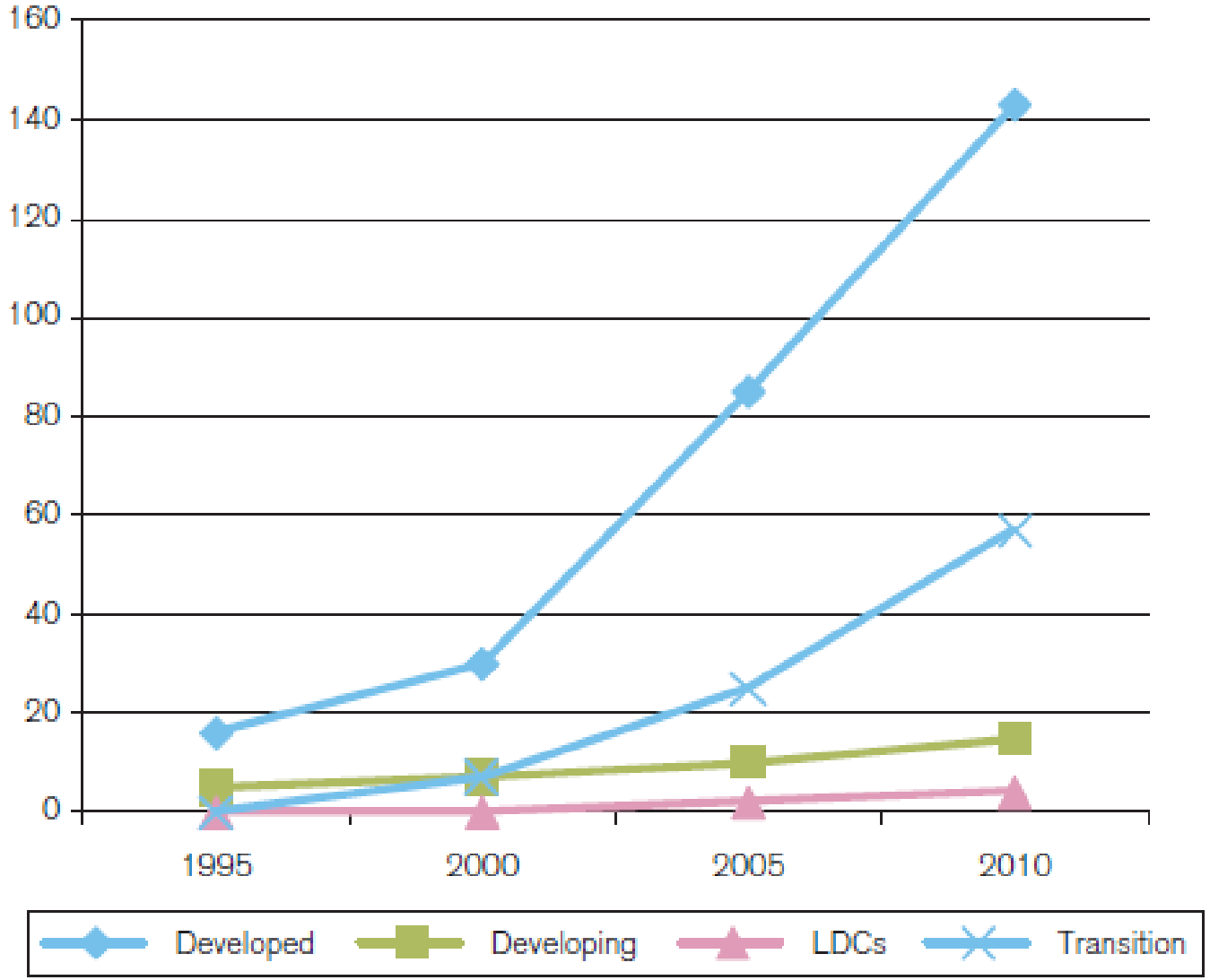
- Over fifteen years from 1995
  - China became a major exporter, exporting US$ 27.8 billion of health-related products in 2010, ten times its 1995 exports.
  - From being a net exporter of health products, the United States became a very large net importer (only the Russian Federation and Japan import more).
  - The 27 EU member states, net importers in 1995, exported more than they imported in 2010.
  - Developed countries' per capita imports grew eightfold, from US$ 16.02 to US$ 127.42.
  - Transition economies showed the strongest relative growth, rising from the lowest level of US$ 0.20 to US$ 48.21 in 2009.
  - Developing countries imports grew sixfold from US$ 1.63 to US$ 9.64.
  - The per capita increase for LDCs was lowest and grew least, from US$ 0.65 to US$ 1.97.

Figure 4.6. **Imports of health-related products 2010 (value, US$ mio), average annual growth 1995–2010, in %**



Source: COMTRADE, WTO Secretariat.

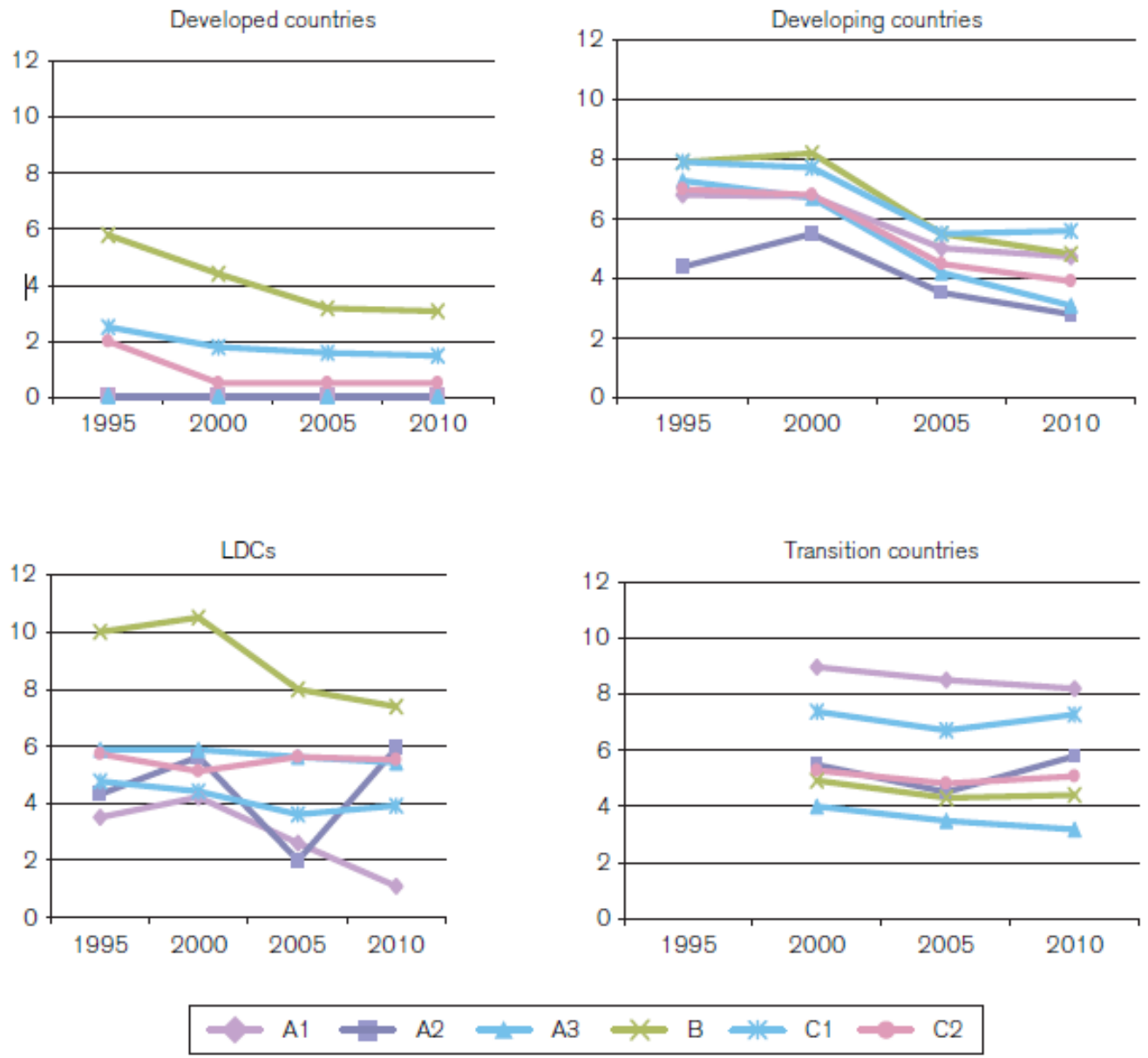
Figure 4.7. **Per capita imports of formulations 1995-2010, in current US$**



Source: Helble (2012).

- Factors affecting imports influence availability as well as prices of health-related products and technologies, and thus have immediate consequences for access.
- Tariffs are one of the key factors influencing imports, but price and availability are also determined by non-tariff measures (e.g. licences, regulations and import formalities) and import-related costs, such as transportation.
  - tariffs remain high in some countries, with direct implications for access - a “tax on health”
  - developed countries have largely eliminated tariffs on health-related products, in line with a WTO agreement on pharmaceutical trade. Tariffs applied by other countries have also fallen significantly, but the picture is still mixed.

Figure 4.8. **Trade-weighted average rates applied to health-related products**



Source: COMTRADE, WTO Secretariat.

MINISTERIAL CONFERENCE: NINTH SESSION, BALI, 3-6 DECEMBER 2013
WT/MIN(13)/36, WT/L/911
11 December 2013

Agreement on Trade Facilitation

Ministerial Decision of 7 December 2013

GENERAL COUNCIL

WT/L/641

8 December 2005

Amendment of the TRIPS Agreement

Decision of 6 December 2005

The pro-health amendment to TRIPS: 'TRIPS flexibility', trade promotion measure, or procurement policy tool?

- 2005 – agreement to amend TRIPS to enable compulsory license for export
  - A new legal 'flexibility' for those countries with limited capacity that rely especially on international trade for access to medicines
  - A compulsory license to enable production especially for export
- It clears a legal hurdle that arises in specific procurement scenario:
  - Lack of capacity means the required product cannot be produced domestically at all, or not in sufficient quantities
  - The preferred producer of the required product (normally, the cheapest supply that best meets regulatory and quality requirements) is located in a country where a patent is in force on that product and that producer needs a distinct compulsory licence in that country to produce for export.
- As a legal pathway for access, it is not self-actuating
  - one component of the procurement toolkit
  - facilitating international trade in medicines specially produced under compulsory licence when this is the most effective and viable avenue for access

Illustrative models for notifying under the Paragraph 6 system

Model 1:
notifying general intent to use

MODEL 1: IMPORTING MEMBER'S GENERAL NOTIFICATION OF INTENT TO USE

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND

Email: crn@wto.org; ipd@wto.org

[Date]

General notification of intention to use the Paragraph 6 System as an importing Member

[Name of WTO Member] intends to use the system set out in the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 as an importing Member.

OPTIONAL: [This notification only applies to use of the system in the case of a national emergency or other circumstances of extreme urgency.] OR [This notification only applies to use of the system in the following limited way: …]

[Name, position and signature
of authorized government official]

Model 2:
notifying need for imports

MODEL 2: IMPORTING MEMBER'S SPECIFIC NOTIFICATION

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND
Email: crn@wto.org; ipd@wto.org

[Date]

Notification of need to import pharmaceutical products under the Paragraph 6 System

1. [Name of Member] needs [names and exported quantities of pharmaceutical product(s)].

2. *EITHER:* [Name of Member] has no manufacturing capacities in the pharmaceutical sector. *[Information on how this was established.]*

   OR: [Name of Member] has found that its manufacturing capacity in the pharmaceutical sector is insufficient to meet its needs for this (or these) pharmaceutical product(s). *[Information on how this was established.]*

3. *OPTIONAL, IF NO PATENTS IN FORCE: [The pharmaceutical product(s) is (are) not protected by patent in the territory of [name of Member].]*

   IF PATENT(S) IN FORCE:

   EITHER: [Name of Member] has authorized (or intends to authorize) use of the subject matter of the patent or patents in force for the pharmaceutical product(s) without the consent of the patent owner in accordance with the provisions of Article 31 of the TRIPS Agreement and the provisions of the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003.

   OR (for LDC Members): Having regard to the transitional period for LDC Members in Article 66.1 of the TRIPS Agreement, as extended for pharmaceutical products in line with Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, [name of LDC Member] will not enforce any patents in force for this (or these) pharmaceutical product(s).

[Name, position and signature
of authorized government official]

Model 3:
notifying export license

MODEL 3: EXPORTING MEMBER'S NOTIFICATION

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND

Email: crn@wto.org; ipd@wto.org

[Date]

Notification of compulsory license to export under the Paragraph 6 System

[Name of exporting Member] has granted [a license] [licenses] to use the subject matter of a patent or patents solely for the purposes of production of [a pharmaceutical product] [pharmaceutical products] and [its][their] export under the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003. The details of the [license] [licenses] granted are as follows:

- Name and address of the licensee(s): [ ]
- Product(s) for which the license(s) has/have been granted: [ ]
- Quantity(ies) for which the license(s) has/have been granted: [ ]
- Country(ies) to which the product(s) is/are to be supplied: [ ]
- Duration of the license(s): [ ]
- *OPTIONAL: [Any other license conditions not set out above] [Other information, such as the patent number(s)]*

The licensee will post information before shipment on the quantities being supplied to each destination and the distinguishing features of the product(s) on the following website: [ ]

[Name, position and signature
of authorized government official]

a ‘big data’ challenge

- Where much of our access to medical technologies is inevitably a function of trade…
- …making use of such policy tools as ‘paragraph 6’ requires *coherence* between IP settings, procurement programs, and commercial and industrial capacity…
- …but also a surer information platform*:*
  - awareness among potential users – the procurement community above all
  - integrated information combining data on
    - Patent coverage
    - Disease burden, current access and projected needs of medicines
    - Price and quality/sustainability factors
    - Regulatory and trade settings

- Assessment and effective communication of current demand and projected needs
  - To design, create and make use of the necessary procurement measures