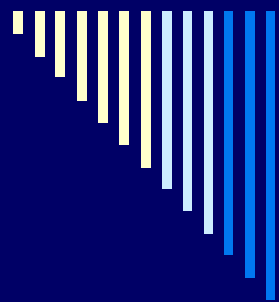


# WHO CIPIH STUDIES WORKSHOP - DAY ONE: THEME B (INTELLECTUAL PROPERTY)

**IP: Implications for access to new  
treatments - legal and economic aspects**

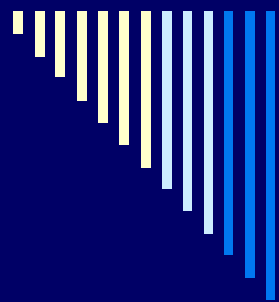
**Sisule F. Musungu, South Centre**

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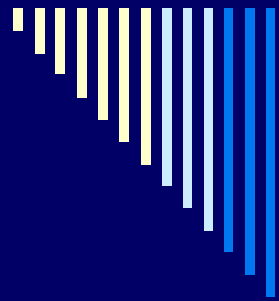
# Public Health Principles for the Implementation of IP Protection in the Pharmaceutical Sector (1)

- The analysis in study 4C on whether the use of TRIPS flexibilities can promote access to medicines, is underpinned by what we consider key principles that should guide the manner in which we address IP protection in the pharmaceutical sector. We recommend that these principles, among others, should also be the basis for the Commission's final analysis. They require implementing and interpreting IP rules in a manner that ensures:
  - ✓ a rapid and effective response to public health needs;
  - ✓ sustainability of supply of quality medicines at affordable prices;



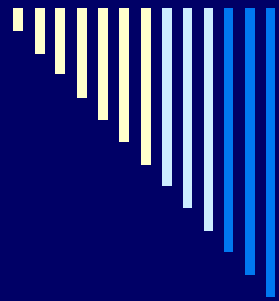
## Public Health Principles for the Implementation of IP Protection in the Pharmaceutical Sector (2)

- ✓ competition, through the facilitation of multiplicity of potential suppliers, both from developed and developing countries; and
- ✓ the provision for a wide range of pharmaceuticals to meet an array of health needs, as well as, the need to ensure equality of opportunities for countries in need irrespective of their level of technological capacity including countries with insufficient or lack of manufacturing capacity, and irrespective of their membership in the WTO.



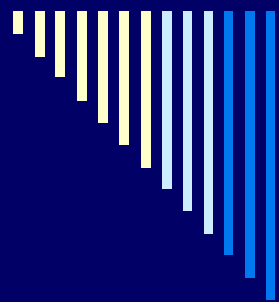
# Implementation of Public Health-Related TRIPS Flexibilities in Developing Countries (1)

- The Basis for Analysis in the study: Review of national legislation and literature on actual use.
- Structure of Analysis on flexibilities: Meaning of Flexibility – Review of Implementation in Developing Countries including case studies on actual use— Key Recommendations on Each Flexibility.
- The Case Studies include: India (transition period); Zimbabwe and Malaysia (CL and govt use); and Kenya (parallel importation).



# Implementation of Public Health-Related TRIPS Flexibilities in Developing Countries (2)

- The flexibilities examined include: transition periods, compulsory licensing and government use including the 30 August 2003 Decision, exhaustion of patent rights, exceptions to patent rights, exemptions from patentability, and test data protection.
  
- Key Findings:
  - ✓ Most developing countries reviewed have incorporated one or more public health-related TRIPS flexibility and there is growing use of these flexibilities in these countries as the case studies demonstrate; and
  
  - ✓ There remain, however, important gaps in the effective use of the flexibilities which need to be addressed as a number of countries have not even introduced the flexibilities in national laws and the actual use of flexibilities in some countries are problematic.

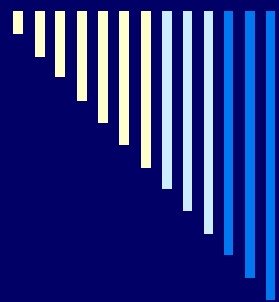


# IP-Related Trade Policies of Key Developed Countries and Public Health in Developing Countries (1)

- The relevance of these policies for public health in developing countries –economic, political and military power of developed countries.

- The United States:

A policy predominantly focused on foreign trade and security goals and aimed at preserving the unparalleled economic, political and military power of the US, underpinned by the concerns of key export industries and reflecting in developing countries laws a standard of IP protection similar to that obtaining in the US.

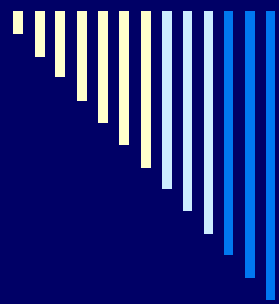


# IP-Related Trade Policies of Key Developed Countries and Public Health in Developing Countries (2)

- The EU:

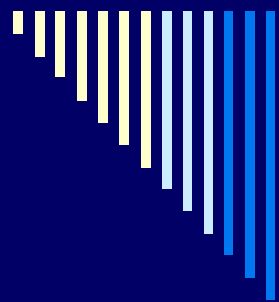
A policy that is more favourable to public health needs in developing countries than the US policy but also with important limitations especially the stated goals of ensuring adequate protection in line with international standards and the predominant (sole) focus in enforcement strategies on the concerns of export industries.

- Switzerland, Japan and Canada – review to be include in final version of the study.



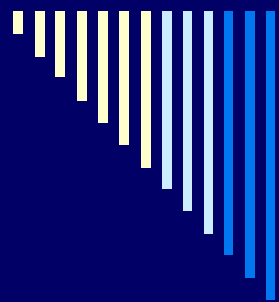
# FTAs: Practical Implications for Access to Medicines in Developing Countries (1)

- Developing Countries and FTAs: The trade-based net benefits analysis.
- Recent FTAs between developed and developing countries, particularly FTAs involving the US, pose a serious risk for the effective use of TRIPS flexibilities in developing countries.
- The FTAs have implications for:



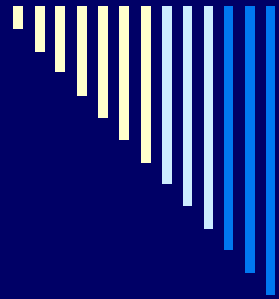
## FTAs: Practical Implications for Access to Medicines in Developing Countries (2)

- ✓ **The object and purpose of IP protection and general exceptions;** There is no clear object and purpose for the protection of IP in the FTA context which would be important in preserving TRIPS flexibility and for the public health-sensitive interpretation of the FTA provisions, particularly due to the application of non-violation complaints. The approach to general exceptions follows the TRIPS agreement except the restriction on exports with respect to the early working exception.
- ✓ **Test data protection and patent term;** the FTAs require a mandatory exclusivity model, establish a prohibition on registration of generics based on evidence of marketing approval in third countries even where data is not required by regulatory agencies, eliminate the requirements for new chemical entity and introduces the principle of patent term extension notwithstanding the holding in the Canada Generics case and links test data protection to the patent.



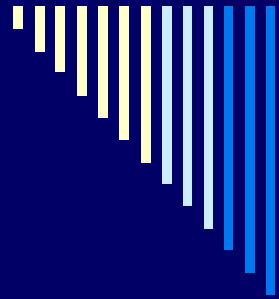
# FTAs: Practical Implications for Access to Medicines in Developing Countries (3)

- ✓ **Compulsory Licensing including export licences under the 30 August 2003 Decision and govt use;** the effect of FTAs on compulsory licensing and government use powers of developing countries is limited, but limits of the ground for issue in some FTAs may create important barriers.
- ✓ **Exemptions from patentability;** FTAs are imposing the US definition of key patentability criteria with no account taken of the problems and downsides of applying the standard in the US, EU etc. (e.g. in the area of biotechnology) and, they are requiring patenting for plants and animals which may have important implications including in the area of genomics.
- ✓ **Parallel importation;** the restrictions of the application of an international exhaustion regime in FTAs is so far not widespread but there are some cases such as in the US-Morocco FTA which prohibit parallel imports.



# Key Recommendations to the CIPIH (1)

- **Important Qualification:** Though the use of TRIPS flexibilities can improve access to essential medicines, the flexibilities as such, can not address the central question that the CIPIH has been tasked to address; **the lack of innovation and investments in R & D for diseases that disproportionately affect developing country populations.**
  
- Recommendations:
  - ✓ The achievement of public health objectives must be the guiding principle for the adoption, implementation and interpretation of IP rules and policies in all countries, particularly developing countries;



# Key Recommendations to the CIPIH (2)

- ✓ The review of developing countries national laws and actual practice demonstrate that **the use of flexibilities is growing as the TRIPS Agreement get implemented and awareness in developing countries grow**. Based on the specific recommendation on the use of each flexibility in the study and other evidence, **the CIPIH can provide important guidance on the effective use of flexibilities for public health**.
- ✓ Developed countries, particularly the US and the EU, have significant influence on how developing countries implement their IP policies generally and with respect to patent protection in the pharmaceutical sector, in particular, due to their economic, political and military power. **Because of this power developed countries have a key role to play in ensuring that developing countries can effectively use TRIPS flexibilities. This can only be done, however, if the US and the EU appropriately revise their IP-related trade policies to better take developing countries public health interests into account.** Their policies should not be solely driven by foreign trade and security interests and be informed by export industries' views only.



# Key Recommendations to the CIPIH (3)

- ✓ A review of the public health related provisions of the FTAs show that the flexibility available to developing countries under TRIPS are being eroded significantly especially under US FTAs. Consequently, the US and other developed countries should take measures to clarify, and where necessary, amend FTA provisions that unduly limit the use of TRIPS flexibilities by developing countries trading partners. Developing countries currently negotiating FTAs should ensure that they preserve their TRIPS flexibilities. **Based on the analysis in this study and other existing literature and evidence the CIPIH can provide important guidance on what developing countries should avoid in FTAs including a more nuanced approach to the net gains analysis that appears to be driving developing countries in FTAs at the moment.**