Anti-Counterfeit Initiatives and Implications for A2M

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TWN

Anti-counterfeit Initiatives to Eliminate the Flexibilities in IP Enforcement

- Public Private Partnerships on to check counterfeit
- Legal instruments
  - FTA
  - Anti-Counterfeits Trade Agreements (ACTA)
  - Medi-crime Conventions
  - National or Regional Anticounterfeit Legislations

What is a Counterfeit products?

TRIPS Definition

- "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation”

ACTA Definition

- “Counterfeit trademark goods means any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country in which the procedures set forth in Chapter II (Legal Framework for Enforcement of Intellectual Property Rights) are invoked”.

What is a counterfeit Medicine?

Quality Compromised Medicine ????

Medi Crime Convention

- the term “counterfeit” shall mean a false representation as regards identity and/or source

- Preamble : Considering that this Convention does not seek to address issues concerning intellectual property rights;

WHO –IMPACT Definition of Counterfeit Medicines

- *The term counterfeit medical product describes a product with a false representation (a) of its identity (b) and/or source(c). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components(d), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.*

Do you agree with the statement?

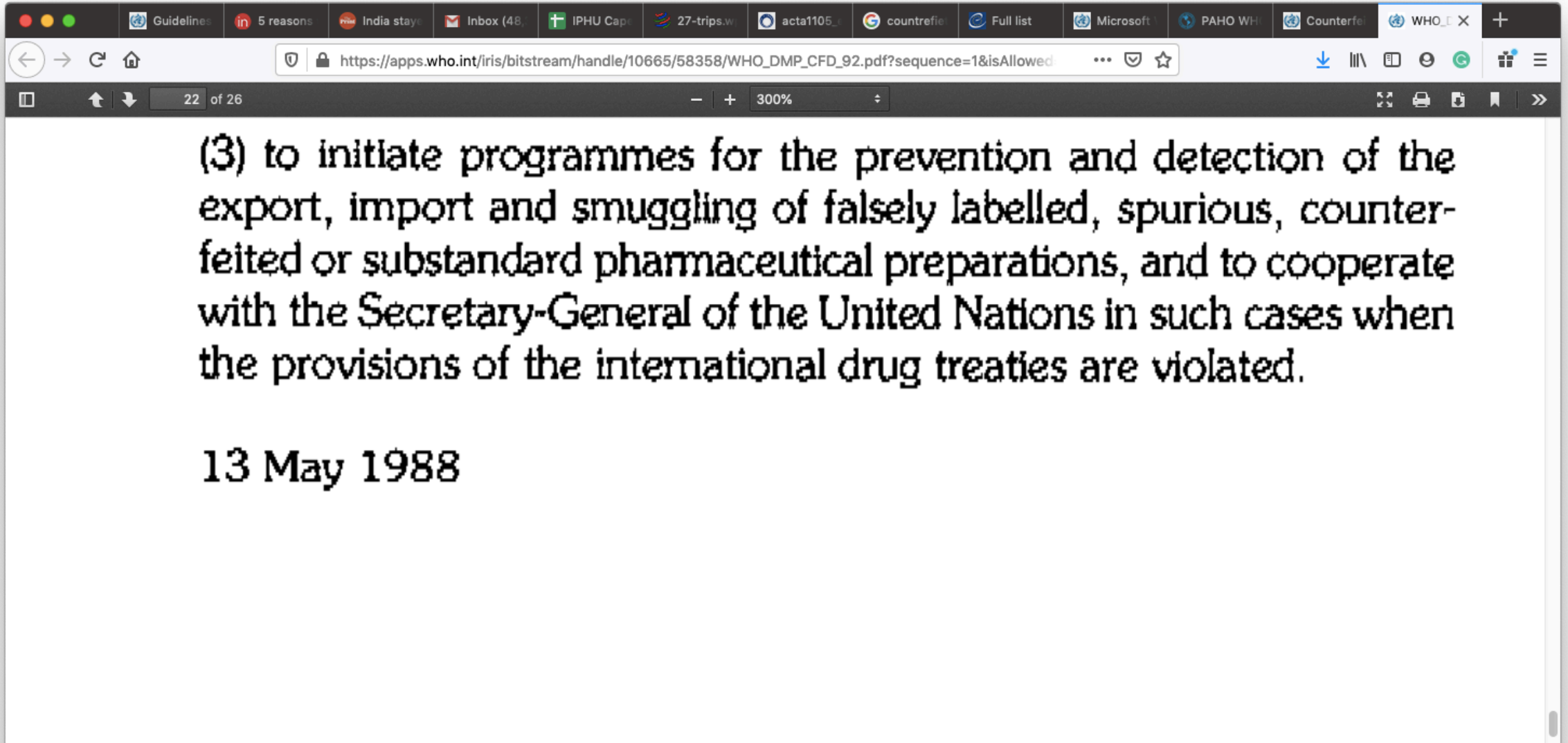
What are these

- Fake
- Falsified medicine
- Fraudulent medicines
- Spurious
- Adulterated
- Substandard

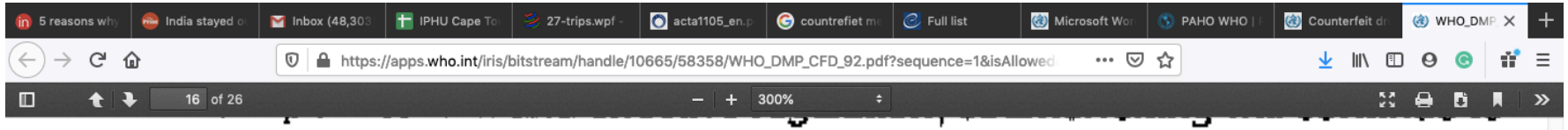
Forum Capturing on Counterfeit Medicines

- WHO : IMPACT
- WIPO : Respecting IP
- INTREPOL : Pharma Crime Unit
- IPU : Resolution
- WCO : SECURE
- UNODC : Model Law on Fraudulent Medicines
- Council of Europe Medicrime Convention

WHO and Counterfeit Medicines



1992 IFPMA –WHO Workshop



thrive.

2. Counterfeiting is an international problem which needs to be addressed by the implementation of international laws. A sound legal framework is provided by the proposed anti-counterfeiting provisions in the draft GATT–TRIPS Agreement (General Agreement on Tariffs and Trade-Aspects of Intellectual Property Rights including Trade in Counterfeit Goods), which is based on effective international trademark protection and supported by enforceable sanctions and penalties (including imprisonment). The workshop looks forward to a speedy conclusion of the current negotiations on this matter.

3. Governments should implement appropriate legislation that identifies the import, national transit and export of counterfeit goods into, across and out of their customs territories as a customs offence and should confer upon their customs services the necessary legal powers to seize the goods with a view

2006 : Establishment of IMPACT

- International Medical Product Anticounterfeiting Taskforce (IMPACT)
- A PPP consisting of WHO, Member States, Regulatory Agencies and IFPMA
- Hosted by WHO
- Created 5 Taskforces

WHO

- 2008 : WHA draft resolution to endorse IMPACT
- 2010 : WHA Resolution to set up a Intergovernmental Woking Group SSFFC
- 2012: MSM Mechanism on SSFFC
- 2016 : Removal of the term counterfeit

Definition of falsified medicine

- Medical products that deliberately/fraudulently misrepresent their identity, composition or source.
- Any consideration related to intellectual property rights does not fall within this definition.
- Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.“
- Identity” shall refer to Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product. "Composition” shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.
- “Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.
- Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country

Seizure of Medicines in Transit

- June 2009
- Freedom of Information Act request filed by Health Action International that the Dutch authorities in 2008 conducted 17 seizures of medicines bound for Brazil, Peru, Colombia, Ecuador, Mexico, Portugal, Spain and Nigeria.

One Example

- Amoxicillin is an essential medicine used to treat a wide range of bacterial infections. The shipment that was seized comprised 3,047,000 tablets of Amoxicillin (250 mg), worth approximately 28,000 Euros. This is equivalent to 76,000 courses of treatment. The batch was detained on grounds of alleged trademark violation, but was released after four weeks. The customs authorities had informed GlaxoSmithKline (GSK), the former patent holder for Amoxil, a brand name for amoxicillin, but subsequently GSK informed the German customs authorities that there was no trademark infringement.

GATT Article V

- Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment,

WHO Proposal on Medicine in Transit

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THE TIMES OF INDIA

Will Indian drug exports to other countries get stuck in EU ports?

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Indian drug exporters fear that their exports to the world could be held up in transit in Europe. While this happened repeatedly in 2008, it stopped after India took the EU to World Trade Organisation's dispute settlement body. But a recent WHO discussion document on medicines in transit has triggered fears that it could become a problem again.

The issue of medicines in transit will be taken up at a WHO meeting from November 28 to December 1 in Geneva. A discussion document prepared by the WHO secretariat outlines criteria that could justify a country's customs authorities intervening to check medicines passing through their ports on grounds of public health concerns. With the past experience of European countries seizing Indian drugs to Latin America transiting through Europe, it is feared that these new criteria are an attempt to legitimise such practices.

In 2008, 17 shipments (16 from India and one from China) were detained in Europe on grounds of infringement of intellectual property. India had taken the issue to WTO's disputes settlement body in May 2010 against the EU and Netherlands, where the shipments were detained. Brazil, Canada, Ecuador, China, Japan and Turkey had joined the dispute. A settlement was reached in 2011 and the EU agreed not to seize generic drugs transiting through its territory. However, the case remains pending and if there is any breach, India has the option of reagitating the case, Rajiv Kher, former commerce secretary said.

The WHO discussion document details circumstances in which customs officials would be justified in "intervening" in medical products in transit on grounds that they are substandard, falsified and unregistered/unlicensed or a genuine threat to public health or environment. Saying such products have the potential to endanger the health of patients, it argues that "part of the function of national customs authorities is to protect the health and safety of their populations".

Kenya High Court on Judgement

NEWSROOM | PRESS RELEASE

Kenya's High Court Strikes Down Anti-Counterfeit Act

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unconstitutional.

On April 20, 2012, Kenya's High Court ruled that the act violates the right to life, human dignity, and health, as outlined in the Constitution of Kenya, and that intellectual property rights should not override these fundamental rights. The court further ordered Kenya's Parliament to review the act and to remove ambiguities that could result in arbitrary seizures of generic medicines under the pretext of counterfeits. The case, which was filed by three people living with HIV, argued that the act could destabilize a legitimate supply of low-cost generic medicines, including antiretroviral treatments.

In her ruling, Judge Mumbi Ngugi said that "the Act is vague and could undermine access to affordable generic medicines since [it] failed to clearly distinguish between counterfeit and generic medicines."

Kenya was not exception

- Uganda
- East African Community Model Law

State of play on Other Initiative

- Still on
  - INTERPOL
  - WCO
  - Medicine convention
- Discontinued
  - WHO IMPACT
- In Making
  - UNODC Model law

Move forward

- Addresses cause not the symptoms ..HOWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWWW