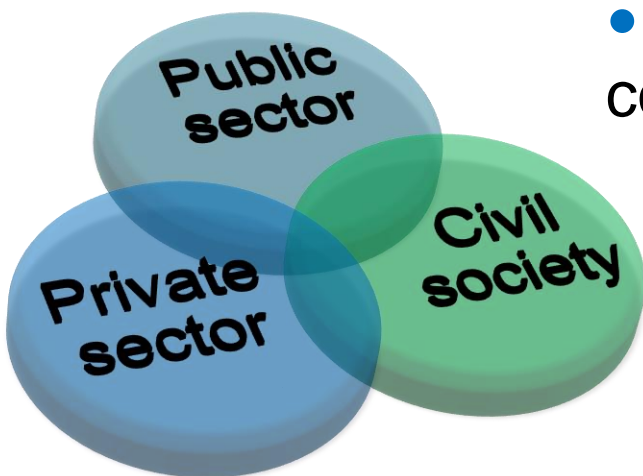
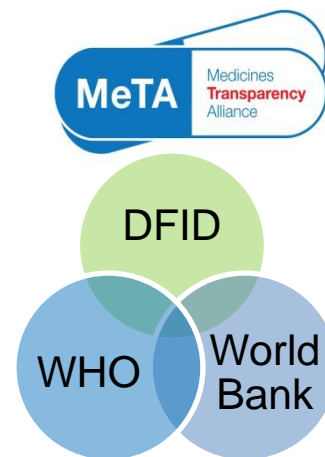


COUNTERFEITS,- A view from the Medicines Transparency Alliance (MeTA) countries

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What is MeTA?

- International multi-stakeholder alliance to **promote dialogue** and **encourage and support change**.

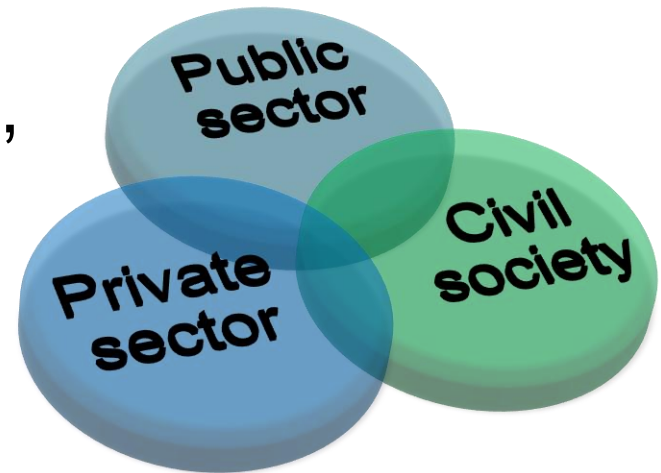


- Multi-stakeholder alliances in seven pilot countries to focus on what can be done to:
 - increase **access to quality medicines**
 - improve information and increase transparency: on **price, quality, availability and promotion**
 - support **stronger governance and more accountability**

- **Country support** through the MeTA International Secretariat, **funds** from DFID, and **technical assistance** from partners.

Mutual accountability through mutli-stakeholder action

- A **multi-stakeholder approach** that involves all sectors – private, public and civil society - will lead to **greater accountability**



The scope of MeTA



- Currently 7 pilot countries
- Possibility of expansion to others after evaluation of pilot

Counterfeits in MeTA countries



- Observations about the extent of the problem and different styles of response in different countries
- A view from the field and information on MeTA's experience and initiatives in the area
- The need or otherwise for national governments, pharma and international bodies, including civil society, to work together to address the problems

Positive environment



Environment exists in which the production and distribution of the fake medicines can prosper,

- ❖ The lack of social conscience
- ❖ The lack of penal sanctions.
- ❖ Ease of entry – porous borders
- ❖ Lack of strong Drug Regulatory Authorities
- ❖ Need for affordable medicines.
- ❖ Multiple distribution points multiply opportunities

Counterfeits in MeTA countries



- Little or no data on the actual extent of the problem.
- Confusion on definition of cfs, minilabs find poor quality drugs but not specifically counterfeits
- cfs are illegal, and drug regulatory authorities in each country need to deal with this.
- DRAs are weak (limited resources - e.g. Zambia), have inadequate legislation (e.g. Peru, KG) and need more support and training (especially of their inspectorates)

Overview



Lack of Data

	Peru	Jordan	Kyrg	Ghana	Uganda	Zambia	Phil
Problem	Serious	Small	Big	Big	Big	Big	?
Incidence	10%?	2%	?	30%	?	?	?
Impact	Serious	Low	Serious	High	Serious	Serious	Serious
Distribution	Black market	Regular channels	Black market	All channels	All channels	Black market	?
Response	Strong	Strong	Weak	Strong	Weak	Weak	Medium

Uganda



- Counterfeits a major concern to health and in Uganda, 30% of antimalarial medicines (Newvision 2008)
- Uganda's porous borders, NDA has no capacity to monitor .
- The NDA /Interpol seizing counterfeit cosmetics and medicines.
- Ministry of Trade, Tourism, Industry Counterfeit Goods Bill, big debate with CSOs, NDA confusion on definitions and NDA role

Philippines

(Counterfeit Drugs, Pharmacovigilance Seminar, FDA Philippines, Oct 6, 2009, Cebu City)



- Cf exists. usually top market brands
- FDA has apprehended clinics that sell unregistered drug products
- Steps to eliminate problem
 - Consumer Reports.
 - Food and Drug Administration, is at the forefront of the campaign
 - FDA advisories, product recalls – needs support
 - Police action

Jordan



- 2007, -JD 10 million; - 2% of total imports – FDA
- 2007 -FDA closed down 56 pharmacies for periods not exceeding one month , - 10 in 2006
- 2007, -Jordanian courts - 51 cases lodged by drugstores, agents of pharmaceutical companies, and the FDA,

Zambia



- A Task Force,- Pharmaceutical Regulatory Authority (PRA), Drug Enforcement Commission (DEC), Zambia Revenue Authority (ZRA) and Zambia Police Service under Ministry of Home Affairs, Not very active, lack of funding
- PRA provides limited logistical support
- Producing some positive results, cases in court;
- Plans to establish a national Quality Control Laboratory with Regional office on the Copperbelt and major border posts, for more effective monitoring of imports.

Kyrgyzstan



- DRA established registration, certification, and licensing procedures, limited capacity to conduct quality control activities,
- MeTA and the quality/ counterfeit problem:
 - Quality control mini-lab
 - DRA website will include and update a list of all registered medicines.
- Pharmaco-vigilance to monitor adverse drug reactions and understand better the situation with counterfeits in the country.
- Data base all relevant information

Peru



- Est \$40 million in 2002 , \$66 million in 2006,
(Association of Pharmaceutical Laboratories of Peru)
- In Lima 200 outlets in 2002 to 1,800 today.
General Directorate of Medicines, Supplies and
Drugs seized 460,000 counterfeit or expired
medicines in 2005.
- The Department of Health, established the
Medicines National Politics to guarantee
security, efficacy and quality of all medicines
Multisectorial participation in fight against illegal
trade and to apply penal measures
- Media campaigns

Ghana



- Big problem (10-30%) Big response
- STRATEGIES ADOPTED
 - ❑ Law enforcement
 - ❑ WHO workshop
 - ❑ Post marketing surveillance
 - ❑ Quality control laboratory
 - ❑ Intensification of regulatory practices
 - ❑ Public education
 - ❑ Government's support, extra budget legal framework, penalties
 - ❑ Human resource capacity building
 - ❑ Import and export control

MeTA experiences, initiatives

- MeTA is a multi-stakeholder platform
 - Industry, DRA inspectors, watchful eyes / surveys of civil society and the media work together
 - Multi-stakeholder process examines all barriers to access.
- Transparency around quality of locally manufactured vs. imported drugs
 - Collection and dissemination of available data
 - Substandard drugs
 - Counterfeit drugs
- Data disclosure tool training and implementation
- Identifies where capacities need to be strengthened.
- No workplans working on counterfeits per se.

The way forward



- Public Awareness/Education
- Strong inter - sectoral collaboration
- Strengthened DRAs and QC Labs
- Regional co-operation
- Funding
- Local manufacture
- Stiffer penalties

Working together



- **Governments**

- ❑ Ensure quality of medicines
- ❑ Alert professionals and public
- ❑ Enforce Legislation
- ❑ Impose penalties

- **Disclosure**

- ❑ Pharma responsibility to inform DRAs of suspicion of counterfeits
- ❑ CSOs are the eyes and ears, find cfs and inform DRA.
- ❑ Inform international authorities

Working together



- **Pharma**

- ❑ Agreement on clear definition of cfs in country
- ❑ Good quality affordable generics are not cfs

- **Private sector**

- ❑ Collaboration in framing new Laws, eg inspection of Purchase records, Control of middlemen and outlets.
- ❑ Promote better management
- ❑ Adopt a licensing system (using WHO Good Distribution Practices as a criterion)

Working together



- **The media**
 - ❑ Maintain public awareness

- **International Organizations**
 - ❑ Data,
 - ❑ Advocacy
 - ❑ Security
 - ❑ Funding and capacity strengthening

Thank You !