Counterfeit Medicines Toolkit

4. Information about the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

IMPACT

International Collaboration: A Request of Medicine Regulatory Authorities

- Various WHO resolutions **since the 80's**
- **1994-2004:** The International Conference of Drug Regulatory Authorities (ICDRA) recommended actions to be taken, at the WHO level, to tackle counterfeiting
- **Madrid 2004:** ICDRA requests WHO to work towards international convention
- **Seoul 2006:** ICDRA endorses establishment of IMPACT
- **Bern 2008:** ICDRA requests WHO to develop harmonized definition, based on 1992 definition with focus on public health and protect legitimate generics
- **2006: Rome conference recommended the establishment of an international taskforce.**

Declaration of Rome (extracts)

- “Counterfeiting of medicines (…) is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems”
- “Combating counterfeit medicines requires the coordinated effort of all the different public and private stakeholders that are affected and are competent for addressing the different aspects of the problem”
- Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary(…)
- The WHO should lead the establishment of an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of governmental, non-governmental and international institutions (…)”

Signed by the participants at the Rome Conference, 2006.

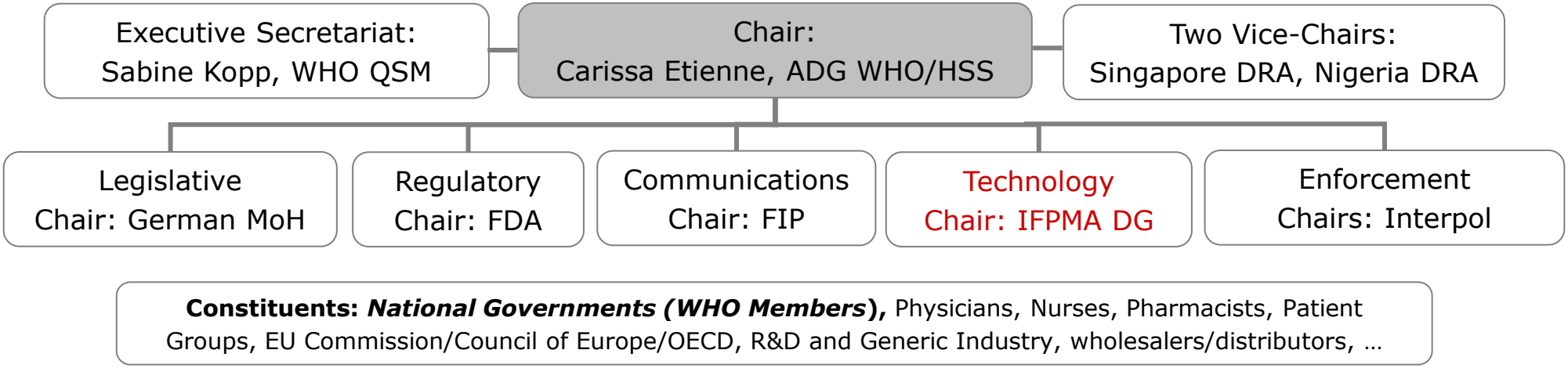
http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf

IMPACT Materialized Multi-stakeholder Collaboration

- **I**nternational **M**edical **P**roducts **A**nti-counterfeiting **T**ask **F**orce
- Launched at WHO Conference in Rome, 2006
- Call for political engagement to **act now**
- Call for **collaboration** among regulators, enforcement, judiciary, private sector, health professionals, patients
- **First global taskforce of its kind specific to medicines**
- Hosted by the WHO, but **not a WHO organization**
- Set an example to be followed in regions: IMPACT Italy, IMPACT Philippines…

IMPACT's Structure

IMPACT International Medical Products Anti-Counterfeiting Taskforce



- The **IFPMA supports IMPACT**
  - IFPMA experts contribute to all IMPACT working groups
  - IFPMA DG chairs technology WG

IMPACT's Work

Key IMPACT guidelines in development	Status
Principles and Elements for **National Legislation** against Counterfeit Medical Products	✓Completed- in consultation at WHO
Comparative study on existing legislation used to combat counterfeiting of medical products	✓In process
A **data collection tool** to identify regulatory and legislative gaps in national situations	✓Pilot phase
Sampling strategy guidelines for Regulators	✓In process
Guidelines for rapid response plan for national drug regulatory authority for signal of suspect counterfeit	✓Completed
Good security practices for printed packaging material for pharmaceutical products	✓Completed
Counterfeit-oriented revision of the **WHO guidelines on good distribution practices** (GDP)	✓Completed
Guidance for ways to adapt current **pharmacovigilance systems** for counterfeit reporting	✓In process
A **guide to investigate** counterfeit medical products and pharmaceutical crime	✓Completed
Model for a **Network of Single Points of Contact** (SPOC)	✓Completed
Communication campaigns tailored to diverse audiences	✓In process
Review of existing anti-counterfeiting technologies	✓Completed
Review of existing and new field-testing models	✓In process

IMPACT's Work

An outlook at IMPACT's future agenda of work	
Guidance on **Internet** trade of medicines	Not started
Review national strategies regarding **exports** of pharmaceuticals and develop guiding principles for Regulators	Not started
Revised WHO **Rapid Alert System** (global)	Not started
Assessment of serialization as a tool for safeguarding the pharmaceutical supply chain	Not started

Only some of the guidelines developed by IMPACT are accessible online. To find more information go to:

www.who.int/impact

Further background information about IMPACT has been prepared by the WHO and can be found here:

http://www.who.int/medicines/services/counterfeit/open_forum/en/index.html

IMPACT Definition of Counterfeit

"The term counterfeit medical product describes a product with a false representation (1) of its identity (2) and/or source (3). 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(4), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting"

Agreed by IMPACT General Meeting- Hammamet - Tunisia, Dec. 3-5

Notes:

(1) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed

(2) This includes any misleading statement with respect to name, composition, strength, or other elements

(3) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution

(4) This refers to all components of a medical product