



## Caribbean Workshop for Prevention and Combat of Counterfeit Medicines

“Establishing an inter-sectoral partnership and a plan of  
action”

Draft programme

Venue: Kingston (Jamaica) November 23rd -26th 2009.

Promoted by:

PAHO/WHO

Ministry of Health of Jamaica

CARICOM

Caribbean Regional Drug Law Enforcement Training Centre

In collaboration with:

External Affairs Ministry of Argentina



## Acknowledgements/Disclaimer



### European Union

This document has been produced with the financial assistance of the European Community and the technical support of the World Health Organization. The views expressed herein are those of the authors and can therefore in no way be taken to reflect the official opinion of the European Community or the World Health Organization.



## Caribbean Workshop for Prevention and Combat of Counterfeit Medicines

### Background

According to the World Health Organization (WHO) “Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of quality and therefore dangerous to patients’ health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with incorrect ingredients, without active ingredients or with insufficient active ingredients”<sup>1</sup>.

It is a public health problem. The use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance. In some cases, it can lead to death. In some way counterfeit and other substandard medicines can compromise the confidence people have in their Healthcare systems.

A variety of factors contribute to the proliferation of counterfeit drugs, as described by WHO<sup>2</sup>:

- Lack of legislation
- Absence or weak national drug regulatory authority
- Lack of the enforcement of the existing legislation
- Weak penal sanctions
- Corruption and conflicts of interest
- Transactions involving many intermediaries
- Demand exceeding supply
- High prices
- Sophistication in clandestine drug manufacture
- Inefficient cooperation among stakeholders
- Lack of legislation by exporting countries and within free trade zones.

According to Declaration of Rome, *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*<sup>3</sup>.

This activity is part of the work plan of the CARICOM Technical Advisory Group (TAG) Access to Medicines for 2009/2010 and it has the technical support of the Working Group on Prevention and Combat Counterfeit Medicines of the Pan-American Network on Drug Regulatory Harmonization (PANDRH). It is supported by the Pan-American Health Organization/World Health Organization through the EU/WHO ACP Project “Partnership on Pharmaceutical Policies” in collaboration with CARICOM Secretariat, the Ministry of Health of Jamaica, the Ministry of National Security of Jamaica and Caribbean Regional Drug Law Enforcement Training Centre (REDTRAC), with the support of the External Affairs Ministry of Argentina as part of the Triangular cooperation mechanism with PAHO/WHO and Caricom.

<sup>1</sup> <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>

<sup>2</sup> WHO. **Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs**. Geneva: WHO, 1999.

<sup>3</sup> WHO International Conference on Combating Counterfeiting Medicines. **Declaration of Rome**, Rome, 18 of February, 2006.



## Objectives

### General objective

To identify the key elements for improving the control of medicines and for developing an inter-sectoral proposal for prevention and combat counterfeit medicines

### Specific Objectives

- To present and to discuss international recommendations and guidelines;
- To present elements and country experiences related to effective medicines regulation;
- To present national experiences and tools for prevention and combat of counterfeit medicines;
- To identify tools and mechanisms for inter-sectoral collaboration and communication in the Caribbean.
- To design a two year plan of action in the field.
- To build an inter-sectoral task force to implement the plan.

## Methodology

The workshop will be conducted through presentations, roundtable/plenary discussions and working groups.

## Participants

Representatives from:

- Ministries of Health: Chief Medical Officers, Chief Pharmacists, National Regulatory Authorities.
- Customs authorities,
- Police,
- House of Representatives,
- Judicial branch,
- Universities
- Consumers Associations
- Association of pharmaceutical Industry, distributors, importers
- Pharmacists Association
- CARICOM Technical Advisory Group (TAG) for Access to Medicines



## Draft Programme

### Day 1

08:00 - 08:30 Registration

08:30 - 10:00 Opening Ceremony

10:00 – 10: 30 B R E A K

10:30 – 10:35 **Procedural and Other Matters**

- **Define Work Schedule**
- **Adoption of Work Programme**
- **House keeping Matters**

10:35 – 11:00 Plenary: Presentation of the objectives and methodology, participants and their expectations  
**Moderator: Maria Jose Sanchez and Tiago Lanius**

11:00 – 11:20 **Presentation- Medicines Regulation in the Caribbean: Constraints, Challenges and Opportunities**  
Adriana Ivama PAHO/WHO on behalf of TAG

11:20 – 11:40 **Presentation - International Initiatives: IMPACT/ PANDRH /PAHO – Strategies for prevention and combat of counterfeiting of medicines**  
**PAHO/WHO**

11:40 – 13:00 **Round Table-** Vision, Operational Structure, Action Strategies and Experiences of regional and National Authorities  
**Moderator(s): Maximiliano Derecho**

13:00 – 13:30 Discussion

13:30 - 14:30 L U N C H

14:30 – 15:00 **Presentation/Plenary - Counterfeit Medicine: Concept and Identification.**  
**Maria Jose Sanchez**

15:00 – 15:45 **Working Group - Identifying Counterfeit Medicines.**  
**Coordinator(s): Maria Jose Sanchez and Maximiliano Derecho**

15:45 – 16:30 **Presentation/Plenary-** Technology for Prevention and Combat of Counterfeiting of Medicines  
**Tiago Lanius Rauber**

16:30 – 16:45 B R E A K

16:45 – 17:30 **Presentation/Plenary - Strategies for Education of Society.**  
**Maximiliano Derecho**

17:30 17:45 Closing Exercise – Day 1



## Day 2

**8:30 – 10:00 Presentation/Plenary** - Sanitary Control of the Medicines Chain: The importance of the Medicines Registry and Good Manufacturing Practices, Good Distribution Practices and Good Transportation Practices.  
Presentation of videos (regular company and counterfeiting)  
**Tiago Lanius Rauber**

**10:00 – 10:15 B R E A K**

**10:15 – 12:00 Presentation/Plenary** - Essential components to be considered in national legislation for combating counterfeiting of medicines.

Argentinean experience on legislation

**Maximiliano Derecho**

Brazilian Experience on legislation

**Tiago Lanius Rauber**

**12:00 – 13:00 Presentation/Plenary** - Operational Unit and Critical path (drug regulatory authority's actions in case of suspicious counterfeit drug)  
**Maria Jose Sanchez.**

**13:00 - 14:00 L U N C H**

**14:00 - 14:40 Presentation/Plenary** - Information systems and access to information resources.

**14:40 - 15:40 Presentation/Plenary** - Example of practical application: The Case of Counterfeited Iron Supplement  
**Maximiliano Derecho**

**15:40 - 16:00 B R E A K**

**16:00 - 16:30 Presentation/Plenary** - Guidelines for investigation on counterfeit medicines and other pharmaceutical crimes.  
**Tiago Lanius Rauber**

**16:30 - 16:45 Closing Exercise**



### Day 3

**8:30 – 10:30 Working Groups - Case Studies.**

***Facilitators: TBD***

**10:30 – 10:45 B R E A K**

**10:45 - 12:30 Working Groups - Continuation of Case Studies.**

***Facilitators: TBD***

**12:30 – 13:30 L U N C H**

**13:30 – 14:30 Plenary Session - Presentation of Conclusions on Case Studies.**

***Moderators: Francis Burnett (OECS/PPS)***

**14:30 - 15:15 Presentation/Plenary - Actions, Planning and Assessment of Results: The use of Indicators.**

***Tiago Lanius Rauber***

**15:15 – 15:30 B R E A K**

**15:30 – 16:30 Working Group**

- Establishing effective protocols for prevention and combat against counterfeit medicines;
- Summary of elements constituting the Work Plan

**16:30 – 17:00 Closing exercise**

### Day 4

**8:30 – 11:00 Plenary Session**

Preparation of effective proposals for prevention and combat against counterfeiting of medicines, and summary of elements constituting the work plan

**10:45 – 11:00 B R E A K**

**11:00 – 11:30 Composition and Review of Conclusions**

**11:30 – 12:00 Presentation of Conclusions and Closing Remarks**

**14:00 – 18:00 Meeting of Technical Advisory Group and National Regulatory Authorities**