

# ***Mecanismo de Estados Miembros sobre Productos Medicos Falsificados, de etiquetado engañoso, espurios, de imitacion o calidad substandard.***



Government  
of Canada

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du Canada

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# UNASUR



- Union of South American Nations.
- Uniform position of countries with common interests.
- Importance: Posture block before other international organizations.

Rio Meeting 2010:

Aspects counterfeiting treaty:

- DEFINITION
- INTERNATIONAL APPROACH
- POSITION IN THE AMS 63rd.



# 1. International Approach

Discussion of the status of IMPACT!

- Need to form a new field in the framework of WHO, duly mandated, where issues are discussed from a strictly medical, stripped of outside interests that may prioritize issues of intellectual property and / or encourage the limitation of access to generic drugs by patients.
- Intergovernmental Group composed of representatives from WHO Member States belonging to the field of PUBLIC HEALTH.
- Find consensus with Asian countries, African Union and CARICOM



# TECHNICAL MEETING OF UNIVERSAL ACCESS TO MEDICINES UNASUR

- UNASUR Position Paper.
  - Analysis of terms. Preference "falsified".
  - Differentiation subestándars.
  - Creating a Intergub Group. WHO-mandated.
  - Find consensus on definition.
  - Activities and previous documents may be taken



## WHO GROUP MEETING (OCT-2011)

- GAUMU previous meeting / UNASUR in Rio de Janeiro.
- New position paper UNASUR: Intergovernmental Group.
- Exposure of the proposal: In the Region / In plenary.
- **PROJECT APPROVAL OF RES. THE PROPOSAL WITH UNASUR AMS!**
- Mechanism of EM with government representatives. Ability to summon other players.  
Group Meetings: default in Geneva. Possibility held in another EM



## AMS 65 (Mayo-2012)

- ***APROBACIÓN DE LA RES. POR LA AMS !!!***

**Focus on the seat and not on the Mechanism**

**Premeetig in Geneva (June / July 2012)**

**1st Meeting of MSM in Buenos Aires (November 2012).**

**POSITION UNASUR Foco en la sede y no en el Mecanismo**



***POSICION UNASUR***



# WORKINGO GROUP MEETING

- **July 23-24, 2013, Geneva**
- **Working paper submitted by the delegation of Brazil, "Identification of actions, activities and behaviors that result in medical products SSFFC"**
- **"5 P" on which health authorities should focus: Products, Processes, People, Post-Marketing and Public Health Risk**  
**23-24 de Julio de 2013, Ginebra**

- Manufacturing medical products in establishments that are non authorized by the national and/or regional regulatory authority.
- Manufacturing, importing, distributing, supplying or selling of medical products without registration or authorization of the health authority.
- Substituting the contents of the medical product using the authorized packaging.






Marco Legal  
definido  
claramente

Ciencia  
reguladora  
en la Toma  
de decisiones

Buenas  
Practicas  
regulatorias

- Proposal for the operation group to combat counterfeiting medical products, to replicate the model used in WHO:
- A country that has a document, it leads the group and virtual meetings are held to discuss it, also are forwarded through entries virtual platform of each of the countries. After consolidating the comments, you can perform a physical meeting to consolidate the document



Ventas por internet

Trazabilidad de medicamentos



**MERCI**  
**OBRIGADO**  
**THANKS**  
**GRACIAS**