Introduction for
SSFFC medical products
Global and regional perspectives

7th PANDRH meeting, Ottawa, September 5-7, 2013

World Health Organization

World Health Assembly Resolution (WHA) 65.19, 2012

Based on recommendations from the *Intergovernmental Working Group on Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit (SSFFC) medical products*

*… "4. DECIDES to establish a **new Member States mechanism** for international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations, regarding "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" in accordance with the goals, objectives and terms of reference annexed to the present resolution;"..*

WHA65.19 (2012) - Annex

Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products

- Goal
- Objectives and
- Terms of reference

General goal

"*In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and the Secretariat, the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products* and associated activities.*"

*The Member State mechanism shall use the term “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” until a definition has been endorsed by the governing bodies of WHO.

Objectives

- "*(1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" in order to strengthen national and regional capacities.*

- *(2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.*

- *(3) To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.*

Objectives

- (*4*) ***To identify actions, activities and behaviours that result in "substandard/spurious/falsely-labelled/falsified/counterfeit medical products"*** *and make recommendations, including for improving the quality, safety and efficacy of medical products.*

- *(5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.*

- (6) *To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of "SSFFC medical products".*

Objectives

- *(7) To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.*

- *(8) To promote cooperation and collaboration on surveillance and monitoring of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products".*

- *(9) To further develop definitions of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" that focus on the protection of public health."*

Structure

- *(1) The Member State mechanism will be open to all Member States.* The Member State mechanism should include expertise in national health and medical products regulatory matters.*
- *(2) The Member State mechanism may establish **subsidiary working groups** from among its members to consider and make recommendations on specific issues.*
- *(3) Regional groups will provide input into the Member State mechanism as appropriate.*
- *(4) The Member State mechanism shall make use of existing WHO structures.*

* And, where applicable, regional economic integration organizations.

The first meeting of the Member State mechanism

- **Held in Buenos Aires, Argentina from 19th-21st November 2012**
- **Chairperson: H.E. Ambassador Umunna Humphrey Orjiako of Nigeria**
- **Vice-Chairpersons:** Iskari Fute of the United Republic of Tanzania, Colin McIff of the United States of America, Ahsan Nabeel of Pakistan, Roland Driece of the Netherlands, Hemant Kotalwar of India, and Ruth Lee Choo Ai of Singapore.

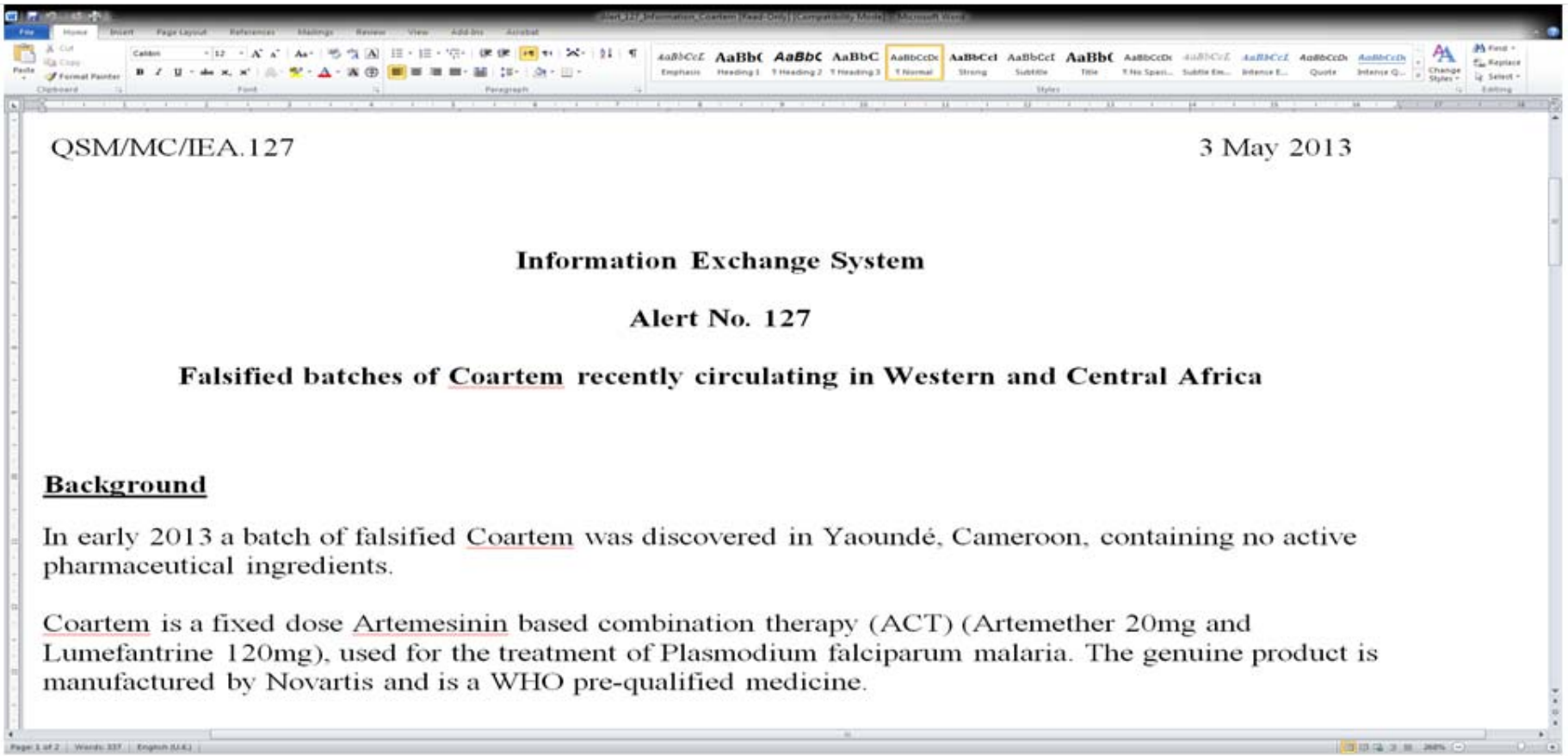
First meeting of the Member State mechanism

- Attended by delegates from 65 Member States and 1 Economic Integration Organization
- Discussed:
  - the scope of the Member State mechanism,
  - areas of work and workplan,
  - structure and governance,
  - funding, and
  - dates of the next meeting.
- Reported to the 66th WHA in May 2013 (document A66/22) through the EB in January 2013 (document EB132/20)

SSFFC Member state mechanism 2013

- **July 23-24 : Open-ended working group to identify the actions, activities and behaviours that result in SSFFC medical products, chaired by Brasil**
- **July 26 : Steering Committee completed the proposed plan of work for the SSFFC Member State Mechanism**
- **November 28-29, second meeting SSFFC MS Mech**

Recent case of "SSFFC" medical product



QSM/MC/IEA.127 3 May 2013

Information Exchange System

Alert No. 127

Falsified batches of Coartem recently circulating in Western and Central Africa

Background

In early 2013 a batch of falsified Coartem was discovered in Yaoundé, Cameroon, containing no active pharmaceutical ingredients.

Coartem is a fixed dose Artemesinin based combination therapy (ACT) (Artemether 20mg and Lumefantrine 120mg), used for the treatment of Plasmodium falciparum malaria. The genuine product is manufactured by Novartis and is a WHO pre-qualified medicine.

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Rapid Alert – Coartem – West Africa

(Artemether /Lumefantrine)

- Anti- Malarial Medicine
- Zero active pharmaceutical ingredient
- WHO prequalified product
- Global Fund AMFm programme medicine
- Millions of doses seized at Borders
- Found in several West and Central African markets
- Subject of WHO Drug Alert May 2013

http://www.who.int/medicines/publications/drugalerts/drugalertindex/en/index.html

Rapid Alert - Postinor 2 – African Region

(Levonogestrel)

- Emergency Contraceptive
- Zero Active Pharmaceutical Ingredient
- WHO Pre Qualified Product
- Genuine version supplied through UN Programmes
- 150,000 doses seized in Nigeria
- Reports of product in other African Countries
- Drug Alert being prepared, pending further laboratory analysis

Project on SSFFC surveillance

- Facilitate COOPERATION between Member States
- Inform policy makers of the ACCURATE THREAT
- Enable EVIDENCE-BASED policy making
- RECOMMEND proportionate action based on strong, reliable evidence
- Assist Member States to determine PRIORITIES and use of RESOURCES

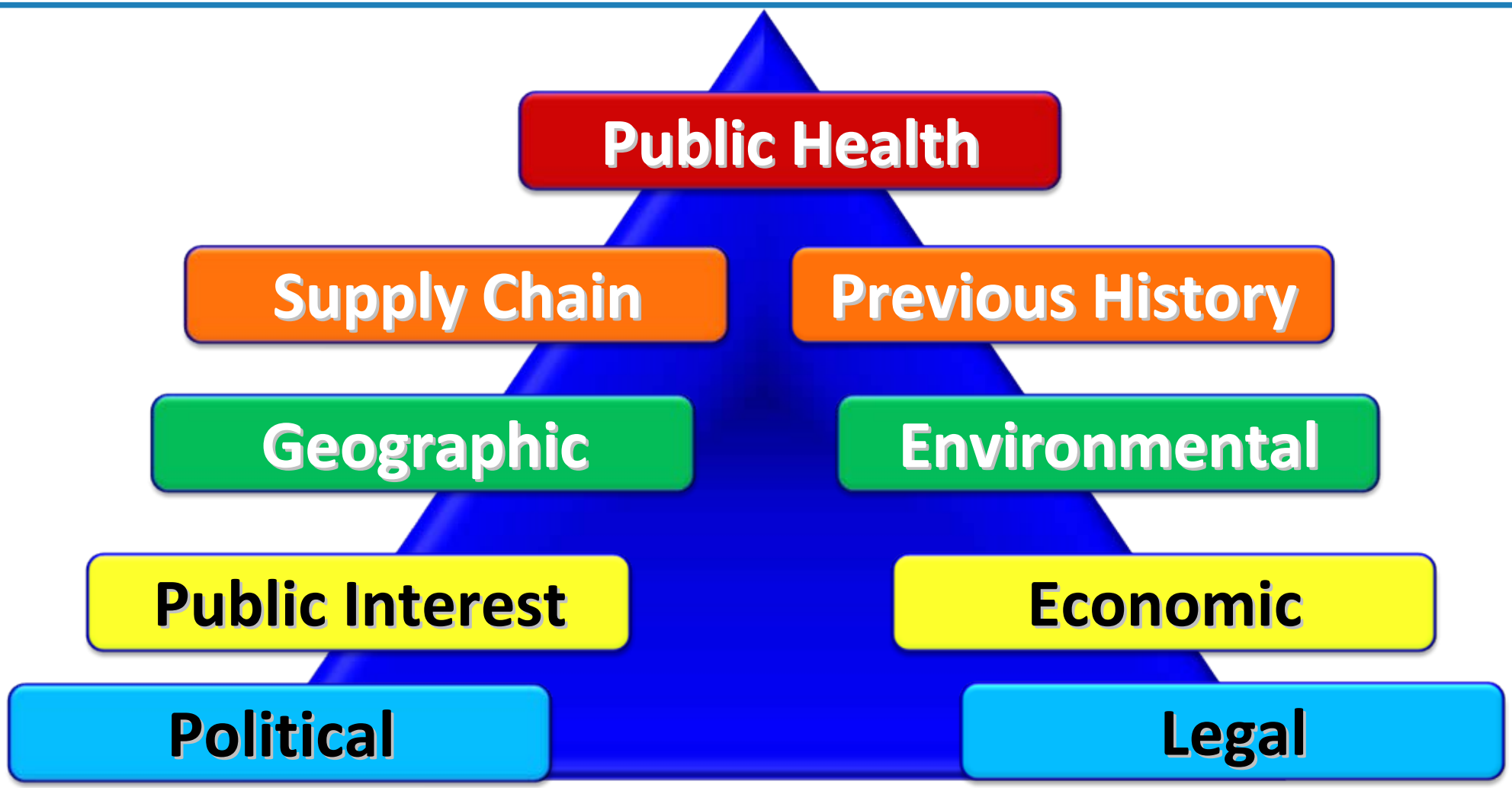
MISSION

- SCALE OF THE PROBLEM
- VULNERABILITY SUPPLY CHAIN
- GEOGRAPHIC SPREAD
- SIZE OF THE MARKET
- WHAT PRODUCTS INVOLVED
- DAMAGED CAUSED

REPORTING TOOL: RAPID ALERT FORM

World Health Organization

RISK ASSESSMENT



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PROGRAM DEPLOYMENT

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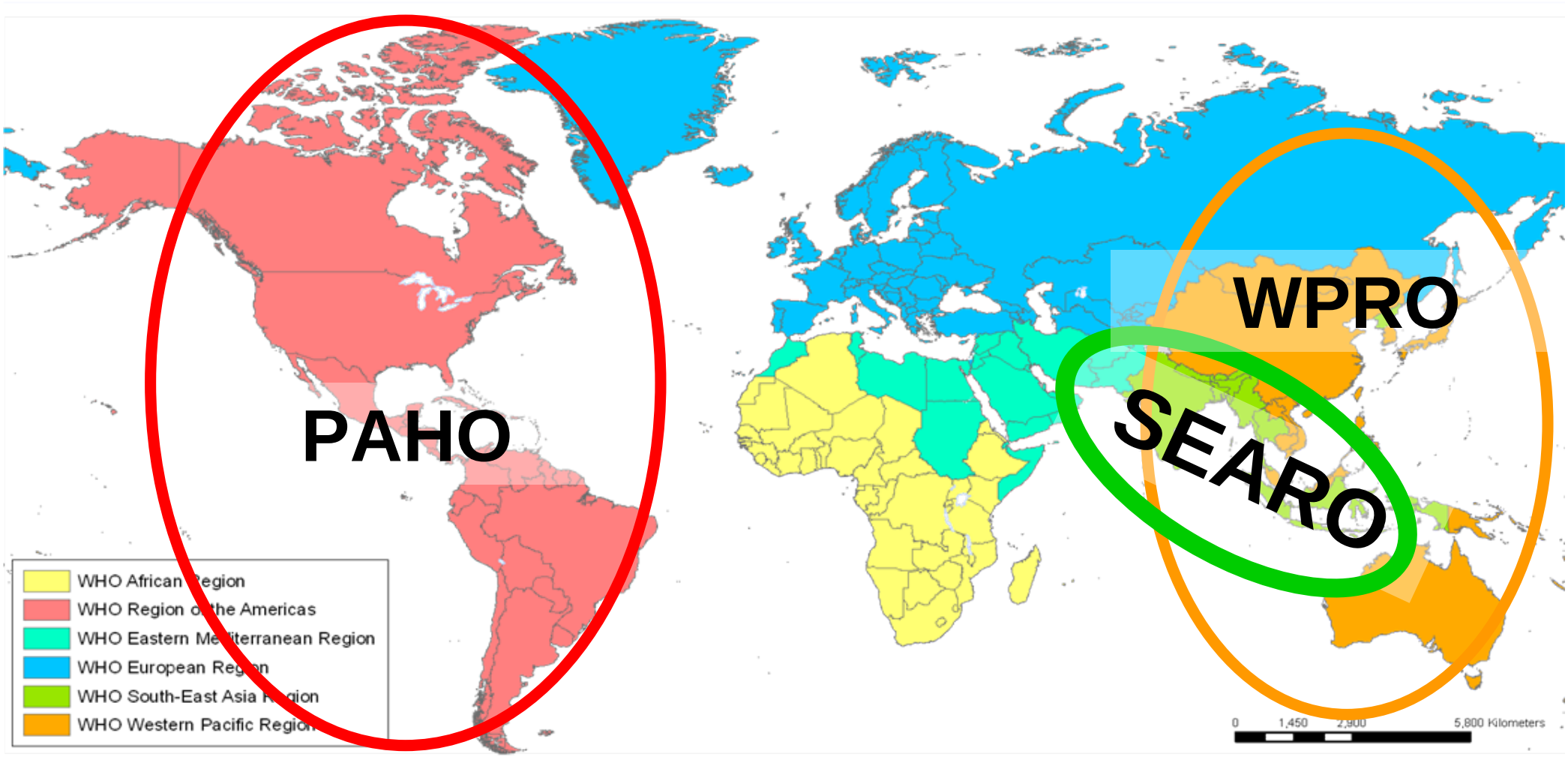
NEXT STEPS



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