Benefits of ISO/IDMP for regulatory harmonization within the WHO PIDM

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Country needs

1. **Patient safety**
    - Adverse reactions Type B
    - Hazards from excipients/degradation products etc
2. **Supporting various regulatory processes**
    - Same as in EU/USA

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Country needs

3. Monitoring international trade

- Fragmented distribution chains
- Quality issues (SSFFC)
- Traditional/herbal medicines with less rigorous regulatory framework

4. Public Health Programmes

- National and international procument agencies for medicines/vaccines
  - *Often parallel to regulatory system*

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Well known problems – not resolved

Excipients and additives: hidden hazards

1984

CURRENT REVIEW

Excipients and additives: hidden hazards in drug products and in product substitution

E. Napke,* MD, DPH
D.G.H. Stevens,† MD, FRCP[C]

The excipients and additives in drug formulations have been described as inert because they do not have an active role in the prevention or treatment of particular ailments. This has led to the misconception among physicians, pharmacists, drug manufac-

more than one ingredient, no matter how innocuous the constituents are believed to be. In Canada, drug manufacturers are not even required to share this information with physicians or pharmacists when they introduce a new drug or reformulate a product already being marketed, nor are pharmacists required to disclose the contents of formulations that they prepare in the absence of commercially available products.

déjà, et le pharmacien n'est pas tenu non plus de dévoiler le contenu des médicaments qu'il prépare *secundum artem*.

Most pharmaceutical products are a combination of constituents. In addition to the active or therapeutic ingredients, product formulations contain a number of "inert" materials known as additives or excipients. Classified according to the part they

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A dream come true

Having access to information on excipients when analyzing the cause of Type B adverse reactions

- Extrapolate risks to other products with the same excipients
- Issue warnings to affected individuals
- Preventive PV
- Vaccines and other injectables of particular importance

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International medicine supplies

- **Generic products and APIs in high-income countries often supplied from countries without stringent regulatory systems**

- **Supporting development of those systems is in everybody's interest**
  - Lack of access to reliable information one of the major shortcomings for these NRAs

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Efforts in regulatory harmonization

ICH (1990)

Common guidelines for national regulatory implementation

ICH guidelines provide models for the rest of the world

Standards considered too high → adaptation/regulatory convergence

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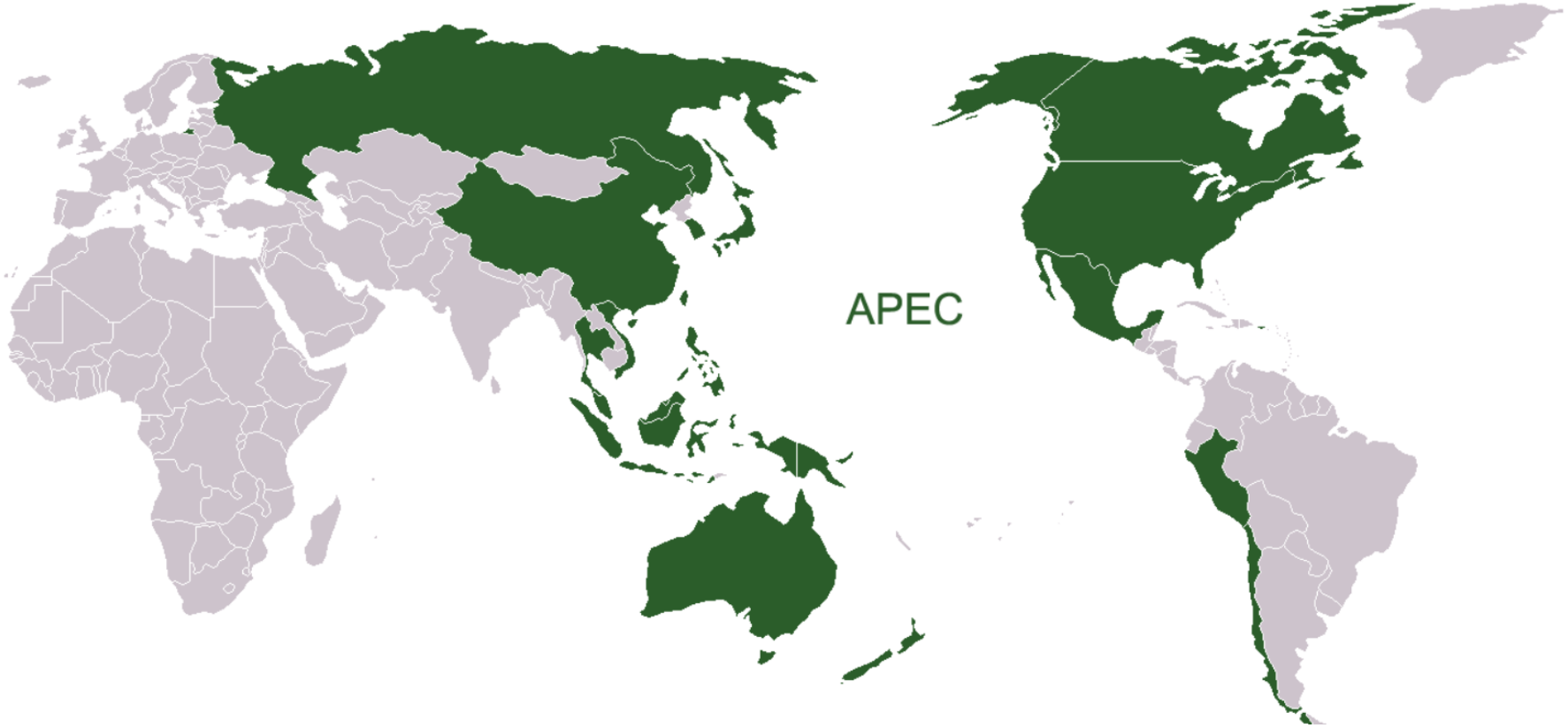
Fora for regulatory harmonization

Asia-Pacific Economic Cooperation (APEC)



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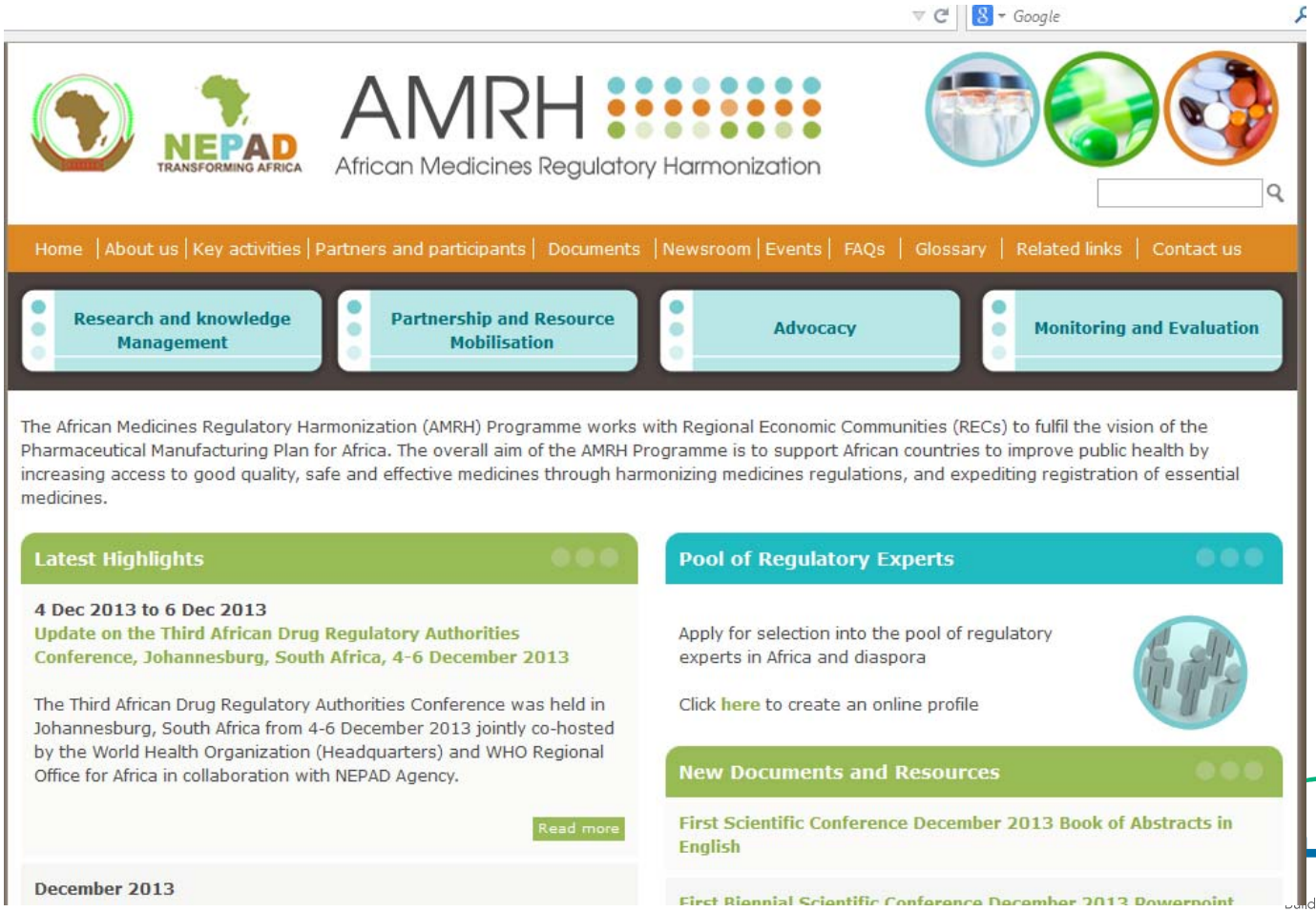
Fora for regulatory harmonization

The African Medicines Regulatory Harmonization (AMRH) Programme



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Aims of the AMRH

- Works with **Regional Economic Communities (RECs)** to fulfil the vision of the Pharmaceutical Manufacturing Plan for Africa
- Overall aim is to support African countries to improve public health by increasing access to good quality, safe and effective medicines **through harmonizing medicines regulations**, and expediting registration of essential medicines

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Participating Regional Economic Communities (REC)

1. East African Community (EAC)

2. Southern African Development Community (SADC)

3. Economic Community of West African States (ECOWAS)

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Participating Regional Economic Communities (contin.)

4. Economic and Monetary Comm. of Central Africa (CEMAC)

5. Community of Sahel & Saharan States(CEN-SAD)

6. The Arab Maghreb Union (AMU)

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African Vaccine Regulatory Forum
AVAREF

23 countries

Coordinated by WHO

Regulatory requirements e.g. for introduction of vaccines against e.g.:

- Meningitis
- Malaria
- Ebola

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Fora for regulatory harmonization

- Gulf Central Committee for Drug Registration (GCC)

- Association of South-East Asian Nations (ASEAN)

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Fora for regulatory harmonization

Eurasian Customs Union

- Armenia
- Belarus
- Kazakhstan
- Kyrgyzstan
- Russia

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Fora for regulatory harmonization

Pan American Network for Drug Regulatory Harmonization (PANDRH)

Coordinated by Pan American Health Organization, PAHO (WPRO)

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The combat against inadequate quality

Substandard

Spurious

Falsely labelled

Falsified

Counterfeit

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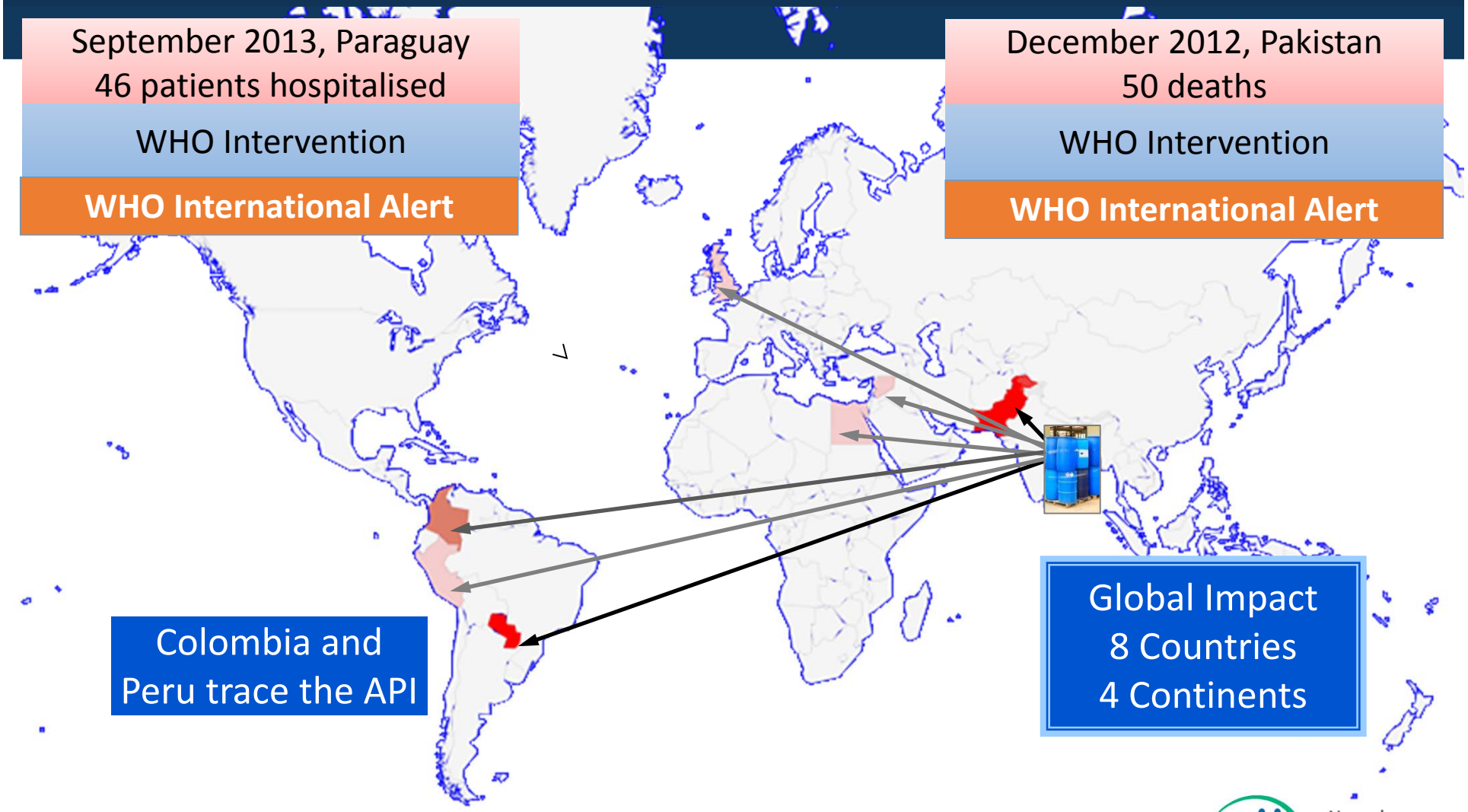
Globalisation = Increased vigilance necessary



Dextrometorphan contaminated with levometorphan

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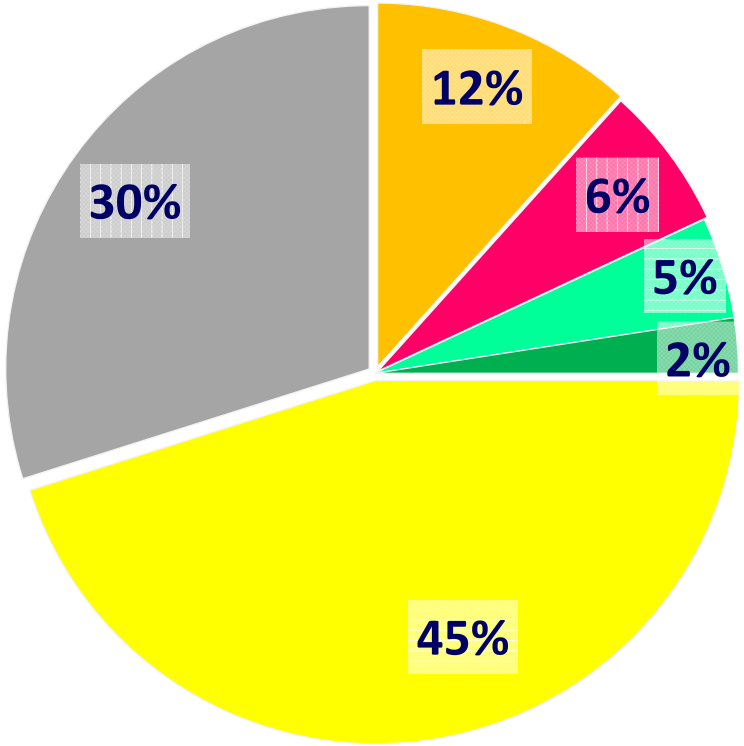
Suspect products reported
by WHO Region



- African region
- European region
- Western Pacific region
- Region of the Americas
- Eastern Mediterranean
- South East Asia region

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Public health programmes

WHO pre-qualification programme functioning as the regulatory body

- International procurement agencies only buy pre-qualified products
- Huge amounts of medicines and vaccines for LMICs

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ISO/IDMP substances and other information

Suggestion for optimal benefit:

Accessible to and include information from:

WHO

- Pre-qualification programme
- SSFFC network

MAH in low-and middle income countries

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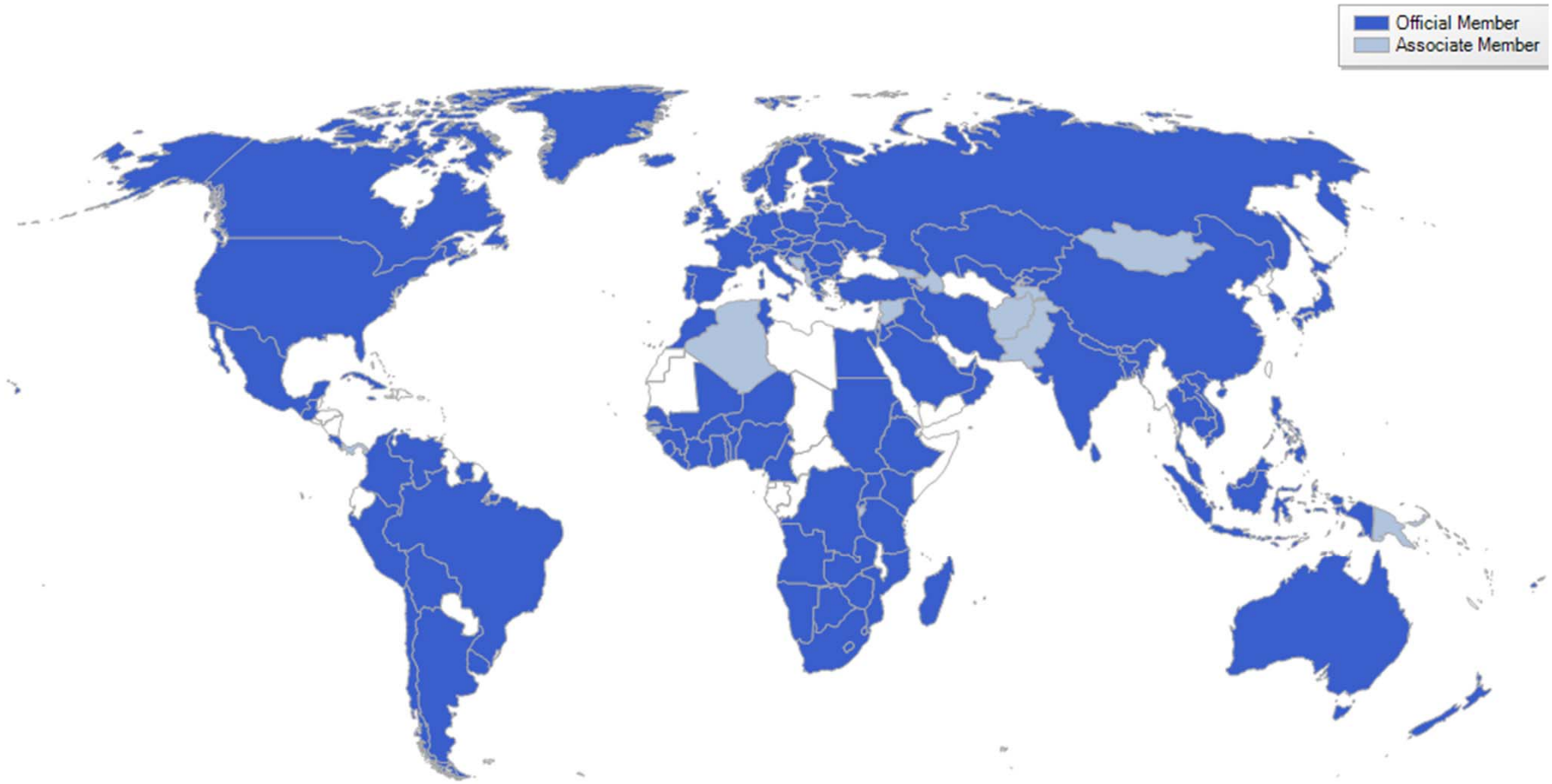
WHO Programme for International Drug Monitoring

Members August 2015



UMC services to countries...

...include:

- **Patient safety data, signals, tools**
- **Information on pharmaceutical products**
  - Drug Dictionary Enhanced
- **Training**

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Thank you for your attention !

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