

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

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 procurement agencies for medicines/vaccines
- *Often parallel to regulatory system*

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

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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

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

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

Efforts in regulatory harmonization

ICH (1990)

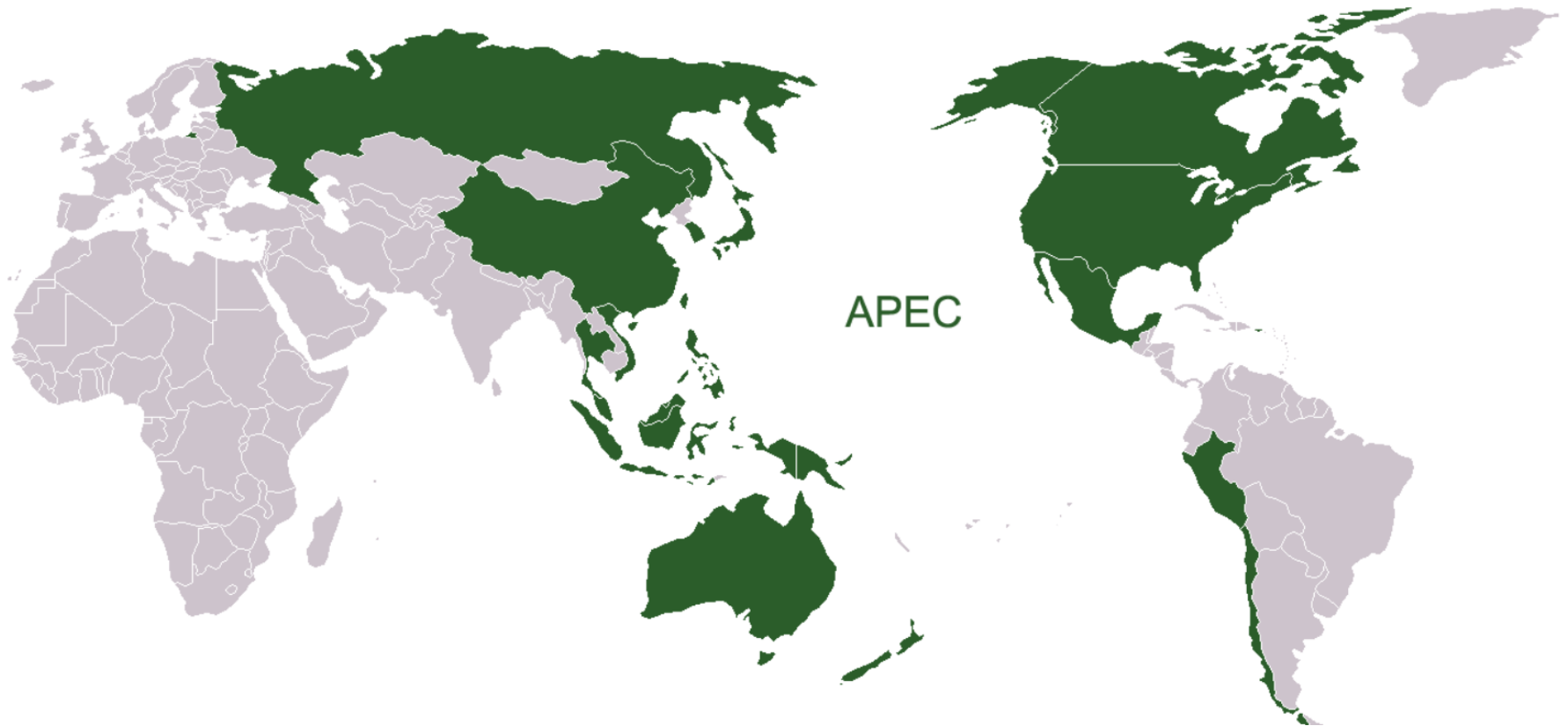
Common guidelines for national regulatory implementation

ICH guidelines provide models for the rest of the world

Standards considered too high → adaptation/regulatory convergence

Fora for regulatory harmonization

Asia-Pacific Economic Cooperation (APEC)



Fora for regulatory harmonization

The African Medicines Regulatory Harmonization (AMRH) Programme



The screenshot shows the AMRH Programme website. At the top, there is a navigation bar with links: Home, About us, Key activities, Partners and participants, Documents, Newsroom, Events, FAQs, Glossary, Related links, and Contact us. Below this is a section with four main categories: Research and knowledge Management, Partnership and Resource Mobilisation, Advocacy, and Monitoring and Evaluation. The main content area features a paragraph about the AMRH Programme's mission, followed by two highlighted sections: 'Latest Highlights' and 'Pool of Regulatory Experts'. The 'Latest Highlights' section mentions the '4 Dec 2013 to 6 Dec 2013 Update on the Third African Drug Regulatory Authorities Conference, Johannesburg, South Africa, 4-6 December 2013'. The 'Pool of Regulatory Experts' section includes a link to 'Apply for selection into the pool of regulatory experts in Africa and diaspora' and a link to 'Click here to create an online profile'. Below these are sections for 'New Documents and Resources', including 'First Scientific Conference December 2013 Book of Abstracts in English' and 'First Biennial Scientific Conference December 2013 Dornpoint'. The footer of the website displays the date 'December 2013'.

AMRH African Medicines Regulatory Harmonization

Home | About us | Key activities | Partners and participants | Documents | Newsroom | Events | FAQs | Glossary | Related links | Contact us

Research and knowledge Management | Partnership and Resource Mobilisation | Advocacy | Monitoring and Evaluation

The African Medicines Regulatory Harmonization (AMRH) Programme works with Regional Economic Communities (RECs) to fulfil the vision of the Pharmaceutical Manufacturing Plan for Africa. The overall aim of the AMRH Programme 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.

Latest Highlights

4 Dec 2013 to 6 Dec 2013
Update on the Third African Drug Regulatory Authorities Conference, Johannesburg, South Africa, 4-6 December 2013

The Third African Drug Regulatory Authorities Conference was held in Johannesburg, South Africa from 4-6 December 2013 jointly co-hosted by the World Health Organization (Headquarters) and WHO Regional Office for Africa in collaboration with NEPAD Agency.

[Read more](#)

Pool of Regulatory Experts

Apply for selection into the pool of regulatory experts in Africa and diaspora

Click [here](#) to create an online profile

New Documents and Resources

First Scientific Conference December 2013 Book of Abstracts in English

First Biennial Scientific Conference December 2013 Dornpoint

December 2013

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**

Participating Regional Economic Communities (REC)

1. East African Community (EAC)



2. Southern African Development Community (SADC)



3. Economic Community of West African States (ECOWAS)



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)



African Vaccine Regulatory Forum AVAREF

23 countries

Coordinated by WHO

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

- Meningitis
- Malaria
- Ebola

Fora for regulatory harmonization

- Gulf Central Committee for Drug Registration (GCC)
- Association of South-East Asian Nations (ASEAN)



Fora for regulatory harmonization

Eurasian Customs Union

- Armenia
- Belarus
- Kazakhstan
- Kyrgyzstan
- Russia



Fora for regulatory harmonization

Pan American Network for Drug Regulatory Harmonization (PANDRH)

Coordinated by Pan American Health Organization, PAHO (WPRO)



The combat against inadequate quality

S

Substandard

S

Spurious

F

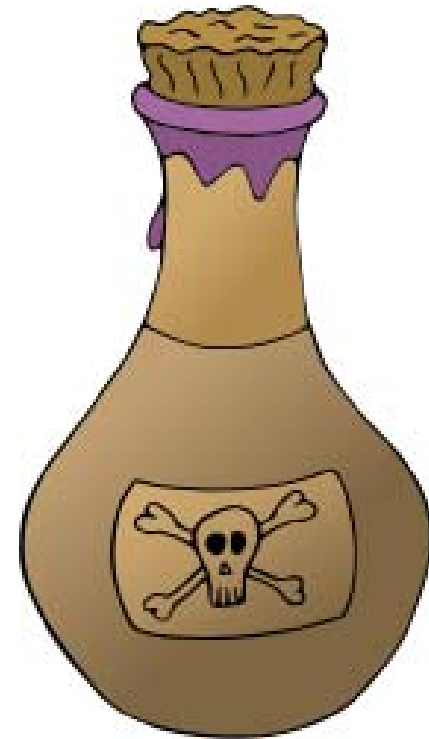
Falsely labelled

F

Falsified

C

Counterfeit



Globalisation = Increased vigilance necessary

September 2013, Paraguay
46 patients hospitalised

WHO Intervention

WHO International Alert

December 2012, Pakistan
50 deaths

WHO Intervention

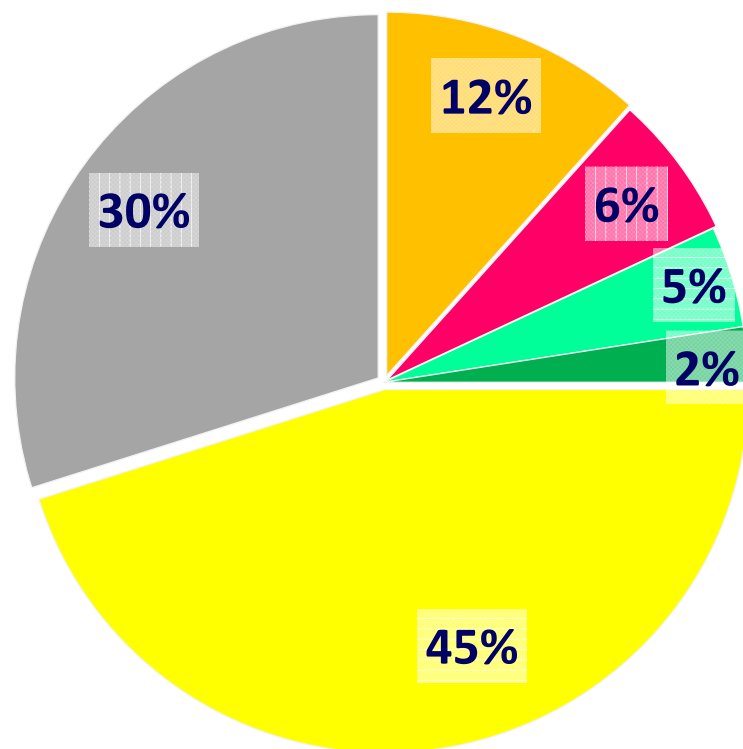
WHO International Alert

Colombia and
Peru trace the API

Global Impact
8 Countries
4 Continents

Dextrometorphan contaminated with levometorphan

Suspect products reported by WHO Region



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

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

ISO/IDMP substances and other information

Suggestion for optimal benefit:

Accessible to and include information from:

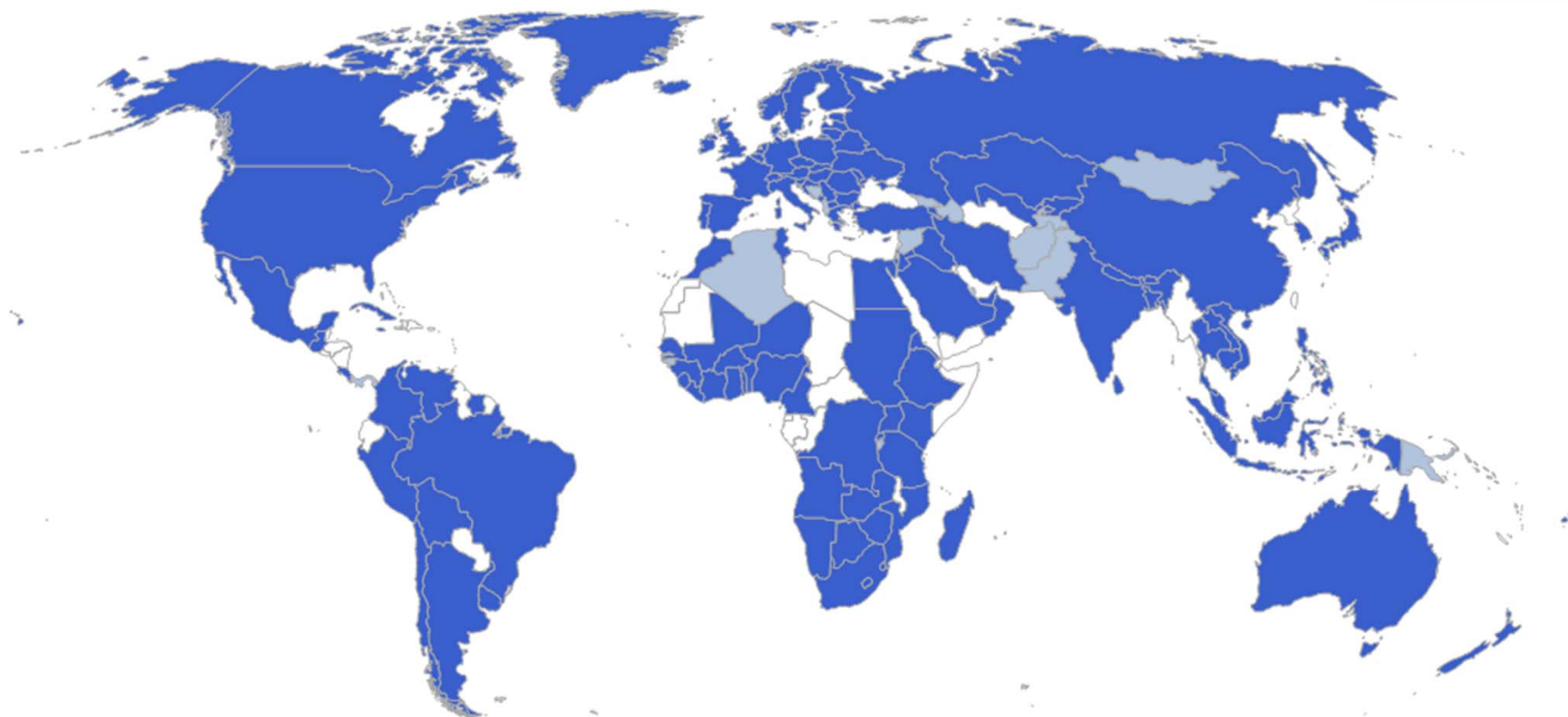
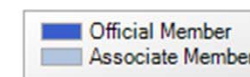
WHO

- Pre-qualification programme
- SSFFC network

MAH in low-and middle income countries

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



Thank you for your attention !

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– Building a global safety culture



– Building a global safety culture

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