An Effective National Pharmacovigilance System

Anna Hegerius, MSc Pharm
Team Leader, Education & Training

the UPPSALA MONITORING CENTRE

UMC/WHO guidelines (2000)

Available in:

English
Spanish
French
Russian
Italian
Korean
Portuguese

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Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

World Health Organization

Minimum Requirements for a functional Pharmacovigilance System

Introduction

Pharmacovigilance (PV) is defined as the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems"[1]. It is a very important medical discipline to prevent drug-related adverse effects in humans, ensure patient safety and promote the rational use of drugs.

PV is well established in most industrialized countries but its practice in low and middle income countries is variable with some countries having absolutely no systems at all whilst a few have systems comparable to the best in industrialized countries. In view of the importance of pharmacovigilance to all countries, the World Health Organisation, upon request from the Global Fund against AIDS, TB and Malaria (Global Fund) and key multilateral and technical agencies, has embarked upon an extensive and wide ranging consultative process to produce a Pharmacovigilance Strategy for use by all countries that are seeking to advance PV systems, through the Global Fund and similar health initiatives. The process includes the identification of (and the specifications for) the minimum requirements for PV.

http://www.who.int/medicines/areas/quality_safety/safety_efficacy/saf_pub/en/

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Success factors

- Mandate
- Funding
- Organization
- Scope
- Resources
- Routine operations
  - Data collection
  - Data analysis
  - Communication
  - Actions/Results
- Partnerships

Mandate

❑ A political mandate with a legal framework

- National pharmacovigilance policy

Nigeria adopts national policy

Adeline Osakwe

Nigeria joined the WHO international collaboration on monitoring of adverse drug reactions and other medicine-related problems in 2004. Its national database as of February 2013 holds a total of 12,400 documented Individual Case Safety Reports, which, with a population of over 167 million [illegible] ximately 5% of what is expected.

was generated after three rounds of committee meetings while the Expert Consultant Committee reviewed the zero draft to produce a 1st draft. The Final draft of the document was adopted in September 2010 and reverted to FMoH for government approval. The document has recently been [illegible] ved by the Federal Executive Council.

A holistic approach is being put in place in the National Pharmacovigilance Policy to cover the entire scope of pharmacovigilance products at all tiers of the healthcare system. To achieve the goal and objectives the various stakeholders in the healthcare system are in the process of being adequately engaged.

- Voluntary or mandatory reporting?

Mandatory Reporting for HPs

- ✓ Austria
- ✓ Bulgaria
- ✓ Croatia
- ✓ Czech Republic
- ✓ France
- ✓ Greece
- ✓ Hungary
- ✓ Italy
- ✓ Lithuania
- ✓ Mongolia
- ✓ Morocco
- ✓ Norway
- ✓ Oman
- ✓ Russia
- ✓ Slovak Republic
- ✓ Spain
- ✓ Sweden
- ✓ Switzerland

Disease areas
Transparency
Releasing clinical-trial data
Antimicrobial resistance
Safety monitoring of medicines
2010 pharmacovigilance legislation
Medicines under additional monitoring
Medication errors
Medicines for

Medicines under additional monitoring

The European Union (EU) has introduced a new process to label medicines that are being monitored particularly closely by regulatory authorities. These medicines are described as being under 'additional monitoring'.

Medicines under additional monitoring have a black inverted triangle displayed in their package leaflet and in the information for healthcare professionals called the summary of product characteristics, together with a short sentence explaining what the triangle means:

▼ This medicinal product is subject to additional monitoring.

The black triangle will be used in all EU Member States to identify medicines under additional monitoring. It will start appearing in the package leaflets of the medicines concerned from the autumn of 2013. It will not appear on the outer packaging or labelling of medicines.

What does the black triangle mean?

All medicines are carefully monitored after they are placed on the EU market. If a medicine is labelled with the black triangle, this means that it is being **monitored even more intensively** than other medicines. This is generally because there is less information available on it than on other medicines, for example because it is new to the market or there is limited data on its long-term use. It does not mean that the medicine is unsafe.

Mandatory Reporting for MAHs

ICH-countries and many others:

- Expedited reporting
  - Serious, unexpected reactions within 15 days
- Non-serious in Periodic Safety Update Reports

New EU legislation in July 2012

Funding

- A designated budget for routine operations

Affiliation

- **Where to establish the National Centre?**

- Drug regulatory authority
- Poison information or drug information centre
- University institution
- Hospital department
- Independent foundation/organization

Where do you find competent and dedicated people?

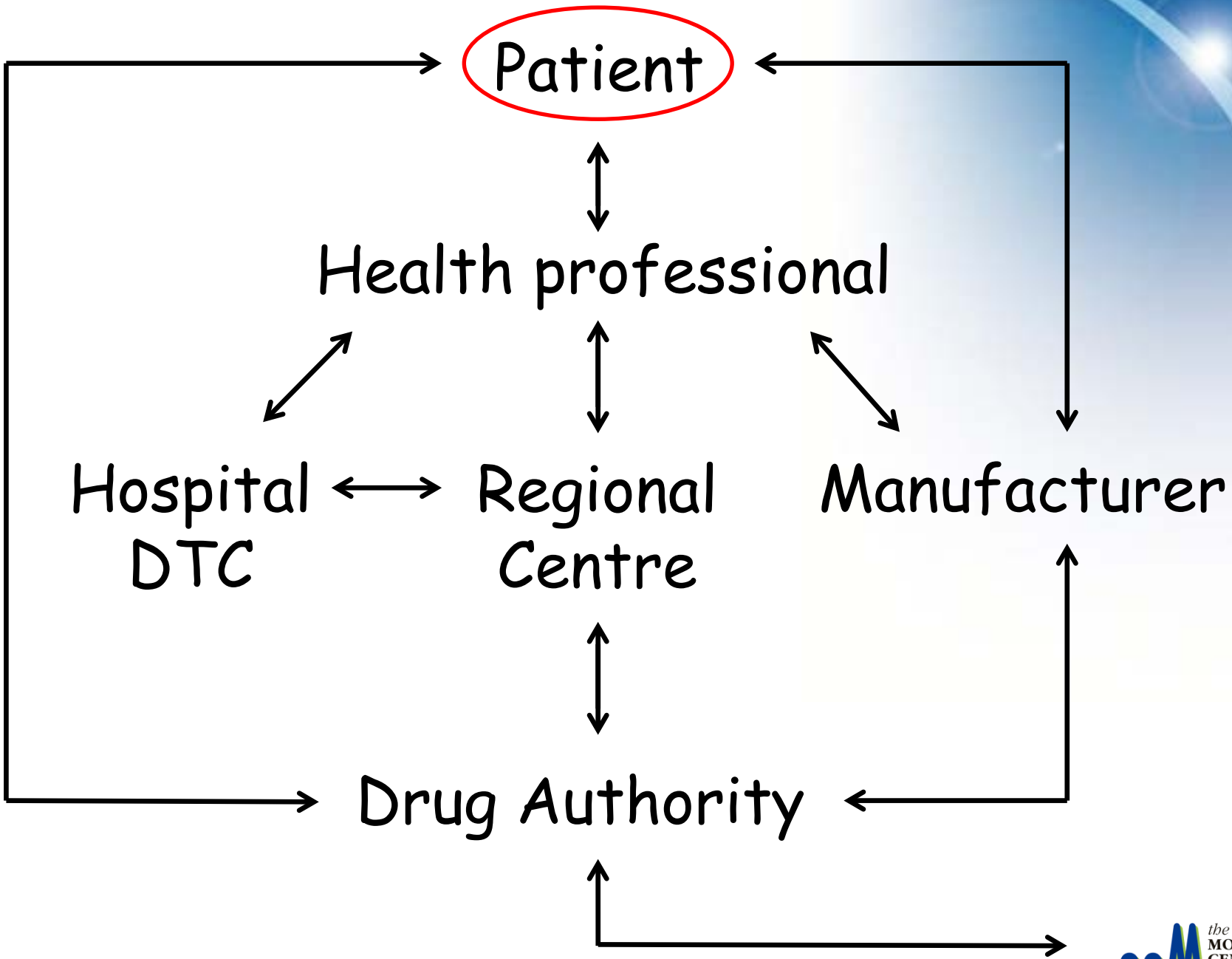
Organization

- **How to organize the PV system?**

- Centralized
- Network of regional centres
- Sentinel sites

Countries with regional network

- ✓ Argentina
- ✓ Brazil
- ✓ Canada
- ✓ China
- ✓ Cuba
- ✓ France
- ✓ Ghana
- ✓ Italy
- ✓ India
- ✓ the Netherlands
- ✓ Nigeria
- ✓ Norway
- ✓ Poland
- ✓ Portugal
- ✓ Russia
- ✓ Spain
- ✓ Sweden
- ✓ Switzerland
- ✓ Thailand
- ✓ Uganda
- ✓ United Kingdom



Scope of pharmacovigilance

- **Adverse reactions**
- **Inadequate/incorrect use**
  - Medication errors
  - Dependence, abuse and poisoning
  - Antibiotic resistance
- **Product quality problems**
  - Failing GMP
  - Lack of efficacy
  - Counterfeiting
- **Other safety challenges**
  - Immunization programmes
  - Other public health programmes

Scope of pharmaceuticals

- **Include or exclude?**
  - Traditional medicines
  - Biologicals incl. vaccines
  - Blood products
  - Medical devices
  - Cosmetic/hygiene products
  - Functional food
  - Veterinary medicines

Resources (human)

- **Pharmaceutical** competence
- **Medical** competence
- **Administrative** assistance
  - *Dedication*
  - Education
    - Formal training
    - Visit established centre

Resources (technical)

- **Computer** with printer and scanner
  - Standard office software
  - ICSR management system
    - » VigiFlow
- **Literature** sources
- **Internet** access, e-mail
- **Telephone**, fax
- **Photocopier**

Routine operations (data collection)

- **How to aquire data - reporting form?**
  - Main vehicle for information
  - Spend time and resources on it!
  - Ask for the important items
  - Attractive and simple design
  - Be inspired by what others have done
  - Make a pilot form and test it

Design of form depending on scope

Routine operations (data collection)

❑ Who should be requested to report?

- Physicians
- Traditional therapists
- Pharmacists
- Nurses
- Dentists
- Manufacturers
- Public health managers
- NGOs
- Patients/care takers
- General public

Consider amount of info versus quality of data and work required

Routine operations (data analysis)

- **Coding system?**
  - WHO-ART or MedDRA
- **Method of causality assessment?**
  - WHO/UMC or Naranjo (most commonly used)
  - Root-cause analysis for medication errors
- **Method of signal detection**

Advisory Committee

- **National Centre**
  - Preliminary case assessment
  - Case follow-up
  - Case recording
  - Carry out actions
- **Advisory Committee**
  - Final case assessment
  - Promote reporting
  - Analyze problems
  - Provide recommendations
  - Propose actions

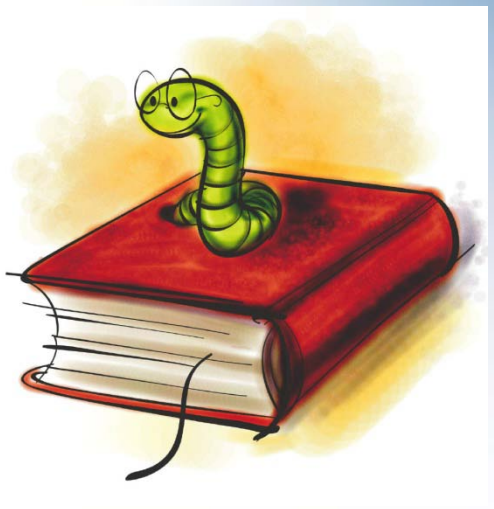
Routine operations (communication)

- **Feed-back** routines
  - Individual response
  - Adverse reactions newsletter
  - Website
  - Social media

- **Promotion**al/educational activities

Actions / results (use of PV data)

- Drug information
  - Individual
  - Formulary/SPC
- Drug Regulation
- Essential Drugs List
- Therapeutic guidelines
- Teaching
- Research



Partnerships

- Drug regulatory authority
- Public health/immunization programmes
- Pharmaceutical companies
- Academic institutions
- Professional associations
- Consumer and patient organizations
- Media
- Pharmacovigilance centres in other countries
- WHO-UMC

International PV network

- Share your
  - ICSRs
  - Experience
  - Knowledge
  - Enthusiasm
  - Challenges
- Receive
  - VigiBase access
  - Medicine safety information
  - Terminologies and software
  - Support and guidelines
  - Publications

Join the WHO Programme for International Drug Monitoring!

Summary

Functions of PV system

- Data collection
- Data management
- Signal detection
- Safety issue assessment
- Decision-making
- Action and Communication


Thank you for your attention!
anna.hegerius@who-umc.org