PHARMACOVIGILANCE SYSTEMS IN AFRICA

NORTH AFRICA / SUB-SAHARAN AFRICA

Pr. Rachida Soulaymani Bencheikh
R. Ouledghriss / S. Skalli /L. Alj

Moroccan Pharmacovigilance center
ASTMH 2009 Symposium

Adverse Drug Reaction (ADR) Adverse Drug Event (ADE)

❑ Definition:

Any response to a drug that is noxious, unintented and occurs at doses normally used in human for the prophylaxis, diagnosis or therapy of disease. But also any reaction due to:

- ✓ Acceptance and tolerance,
- ✓ Misuse and therapeutic errors,
- ✓ Pharmacodependance,
- ✓ Antibio resistance,
- ✓ Effect on pregnancy and children
- ✓ Failures (drug quality and conterfeits),

❑ Consequences:

- ✓ Morbidity and Mortality
- ✓ Social and economical

Pharmacovigilance

- **WHO Definition**: The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem

- **WHO PV Network 1968 – 2009**:

✓ WHO Geneva
✓ Upsalla Monitoring centre (UMC)
✓ 100 National PV Centres

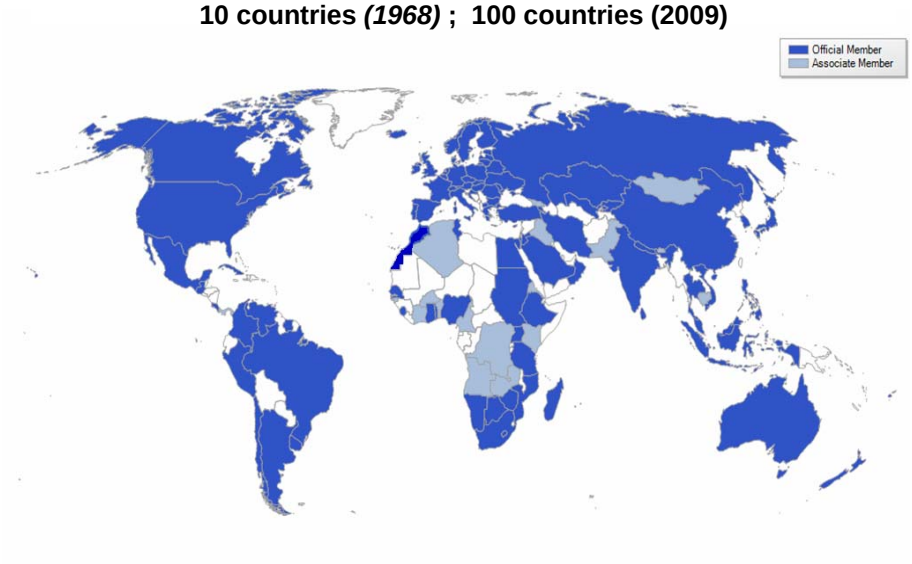
- **PV WHO Tools**

✓ Terminology for ADRs and Drugs classification: WHOART and ATC
✓ Data Management System: Vigiflow
✓ Signal generation

WHO Member Countries

of the Programme for International Drug Monitoring

10 countries *(1968)* ; 100 countries (2009)



What is an efficient PV system

Data about Advers Drug Reaction are:

- ✓ **Gathered**: reporting from health Professionals and the Public to PV centre
- ✓ **Analyzed**: Causality Assessment Processes
- ✓ **Shared**: in the country and reported to UMC / WHO
- ✓ **Processed into Policy:** collaboration with Drug regulatory Authority

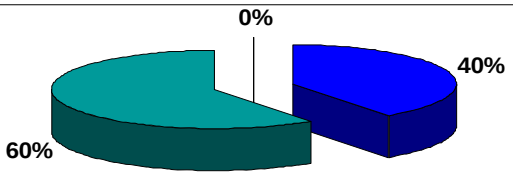
OUTLINE OF THE PRESENTATION

in African countries

- What is the Actual situation of Pharmacovigilance?
- What are the contributing factors for PV development?
- Is there any difference between North African and sub Saharan countries?
- What are the lessons to be learnt?

UNDP 2009 Report
Human Developement in Africa :

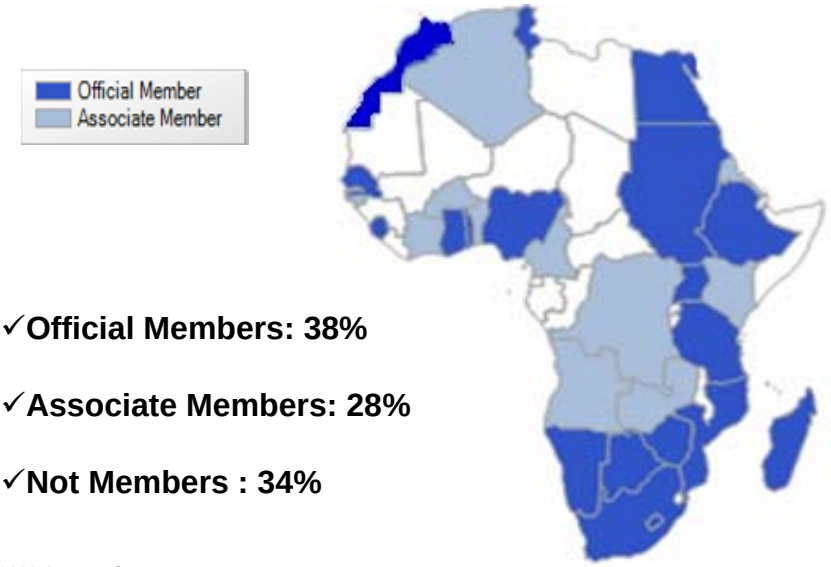
Population : 987 millions
African countries : 50
No country is classified **very high or high Human development**



Low Human Development
Togo, Malawi, Benin, Zambia, Cote d'Ivoire, Ethiopia, Eritrea, Senegal, Rwanda, Gambia, Guinea, Guinea Bissau, Chad, Mozambique, Congo, Mali, Burkina Faso, Central Africa Republic, Niger, Sierra Leone

Medium Human Development
South Africa, Morocco, Egypt, Algeria, Tunisia, Nigeria, Ghana, Namibia, Tanzania, Zimbabwe, Uganda, Sudan, Madagascar, Cameroun, Botswana, Congo, Kenya, Mauritania, Djibouti, Gabon

WHO Member African Countries
of the Programme for International Drug Monitoring

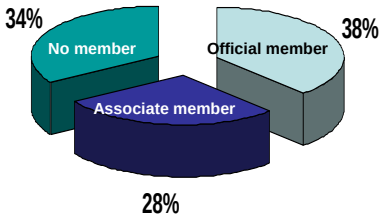


✓**Official Members: 38%**

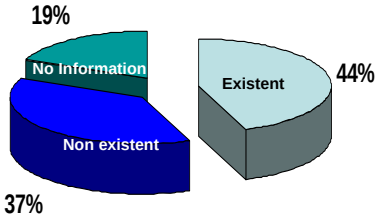
✓**Associate Members: 28%**

✓**Not Members : 34%**

Relation between being WHO member and legislation of Pharmacovigilance in Countries

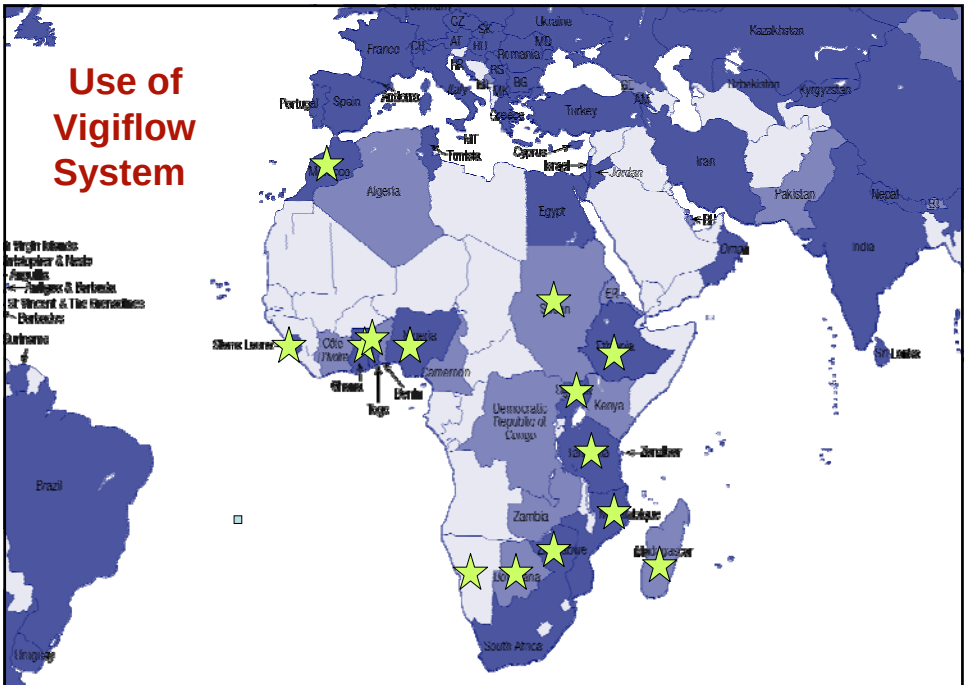


WHO Membership



Regulation in PV

Use of Vigiflow System



The overall growth of the program

- ✓ 1992: earliest African countries joining the program: Morocco and South Africa
- ✓ 1992 to 1998: Tunisia
- ✓ Slow growth in sub Saharan Africa: Zimbabwe (1998); Ghana (2002)
- ✓ Recent spurt of growth and interest in sub Saharan Africa:
  - Training and capacity building
  - Incentives (to retain trained persons)
  - Funds, infrastructure
  - Political commitment

Capacity building in Pharmacovigilance

- ✓ Basic principles of pharmacovigilance
- ✓ Reporting systems
- ✓ ADR database
- ✓ Tools for ADR data management (WHO-ART, WHO DD, ATC/DDD)
- ✓ Causality assessment
- ✓ Signal detection
- ✓ Preventing and managing ADRs

- ✓ Workshops in countries
- ✓ Pharmacovigilance training courses
  - WHO course (English language): Upsalla Sweden since1993
  - WHO course (French language): Rabat Morocco since 2007
- ✓ Pharmacovigilance Training in well establish PV centres

Reasons for recent PV growth

- ✓ Strategies from WHO to introduce PV through the PHPs in Africa: collaborations with malaria, HIV, TB, neglected diseases
- ✓ Collaborations between WHO and donors such as BMGF, GFATM, UNITAID, EC
- ✓ WHO's focus on improving services to French-speaking Africa (eg, three successive years of training courses in basic PV at the Moroccan center)
- ✓ WHO commitment to support sub Saharan countries with relevant tools: Vigiflow (progress in growth from 2008 to 2009; please use the two PPTs from 2008 and 2009)

Current Status of PV in Africa

Source : Uppsala Monitoring Centre analysis

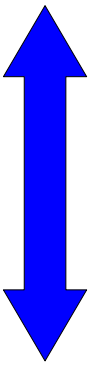
Group 1: Data are Gathered, Analyzed, Shared and Processed into Policy
South Africa, Morocco, Algeria, Nigeria, Ghana,Tunisia

Group 2: Data are Gathered, Analyzed, Shared
Namibia, Tanzania, Zimbabwe

Group 3: Data are Gathered
Mozambique, Sierra Leone, Uganda, Madagascar, Togo

Group 4: May have an office or a person, A reporting form, but minimal or no activity
Cameroun, Ethiopia, Eritrea, Kenya, Senegal, Sudan, Zambia and all other African countries

Strong
Pharmacovigilance capacity



Weak
Pharmacovigilance capacity

OUTLINE OF THE PRESENTATION

in African countries

- What is the Actual situation of Pharmacovigilance?
- **What are the contributing factors for PV development?**
  - ✓ **Human development?**
  - ✓ **Language?**
  - ✓ **Health system development?**
  - ✓ **Pharmaceutical industry development?**
  - ✓ **Proximity to developed countries?**
  - ✓ **Position of PV center in the country**
- Is there any difference between North African and sub Saharan countries
- What are the lessons to be learned

Source : UMC analysis

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South Africa, Morocco, Algeria, Nigeria, Ghana,Tunisia

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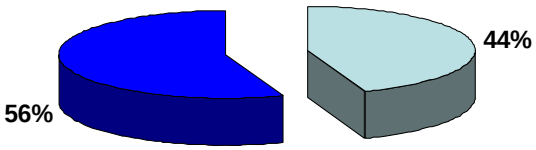
Pharmacovigilance in Africa Depending on Languages



French
- ✓Official member: 20%
- ✓Associate member: 35%
- ✓**Non member: 45%**

English
- ✓Official member: 55.5 %
- ✓Associate member: 27.8%
- ✓**Non member: 16.7%**

Health system development

- Total of Health expenditure in percentage of PIB: from 2.7 in Mauritania…. to 12.2 in Malawi
- Number of Health professionals per 1000 inhabitants:

  From 0.03 Niger to 2.3 in Djibouti

Is essential for PV development but not enough

National Pharmaceutical Industry Development / drugs manufactured within the country

- Morocco, Egypt and South Africa : More than 85%
- Tunisia: 40%
- Algeria: 33%
- Other African countries: 0 to 10%

Source : UMC analysis

Group 1: Data are Gathered, Analyzed, Shared and Processed into Policy
Morocco, Tunisia

Group 2: Data are Gathered, Analyzed, Shared
Egypt

Group 3: Data are Gathered
Algeria

Group 4: May have an office or a person, A reporting form, but minimal or no activity
Libya

North African countries

Morocco, Algeria, Tunisia, Libya, Egypt

- ✓ Classified as Medium Human development
- ✓ Good Development in Health system
- ✓ Powerful pharmaceutical industry (Morocco, Egypt and Tunisia), Medium development in Algeria, None in Libya
- ✓ Proximity to Europe
- ✓ Independent PV from Drug Regulatory Authority

Lessons learnt

PV development is correlated with country development, health systems development, Pharmaceutical development

There is a good progress in all African countries

But

Concept and Principles of PV need time to be fully understood

- ✓ Leadership and dedicated personnel is essential
- ✓ Advocacy and continuity are a *sine qua non* condition for PV Viability
- ✓ Minimum established staff is essential
- ✓ Linkages with international network are essential
- ✓ Need for PV to be recognized by PHP and Regulators
- ✓ Government and international support is needed
- ✓ Networking with international groups must continue

Recommendations

- ✓ Culture of reporting ADRs must be stimulated
- ✓ Data on ADR should be centralized at international level (UMC)
- ✓ Integration with other PHPs should be coordinated by National PV Center
- ✓ Bilateral collaboration and support are needed
- ✓ Different stakeholders and WHO should collaborate and communicate and harmonize their efforts