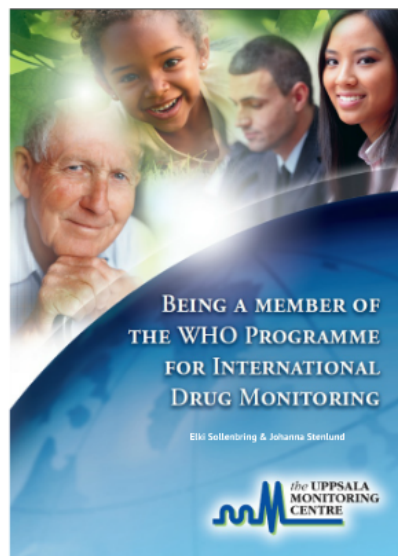


Aim of this session

After the session the students will be able to:

Discuss the benefits and obligations of member countries of the WHO Programme for International Drug Monitoring



Associate? Official member country?



Support and resources -what have you used?



Access to the international network



Which UMC developed software and/or terminologies are you using?

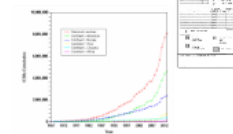


What we expect from you

- Reporting format, compatibility & report quality
- Frequent submissions of ICSRs
- Regulatory information
- Active participation
- Drug terminology



ICSRs in Vigibase



Do you work with signal detection?

If yes:
How do you communicate the outcome?



Frequency of report submission



Why is it important?

What you get from the UMC

- Access to Vigibase™
- Early information about potential safety hazards
- Terminologies and software
- Support, guidelines and resources
- Access to the international network



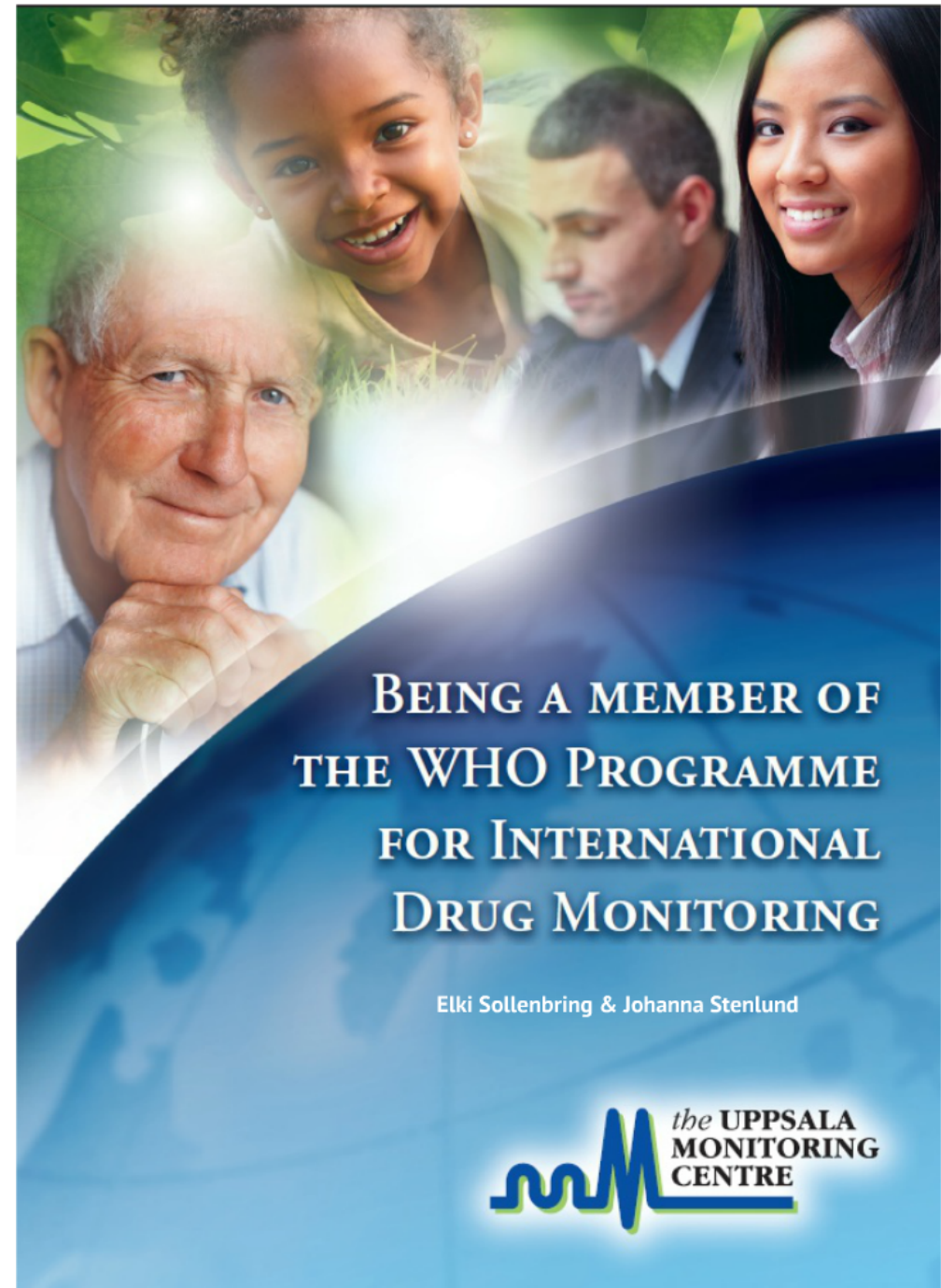
Thank you for your attention!



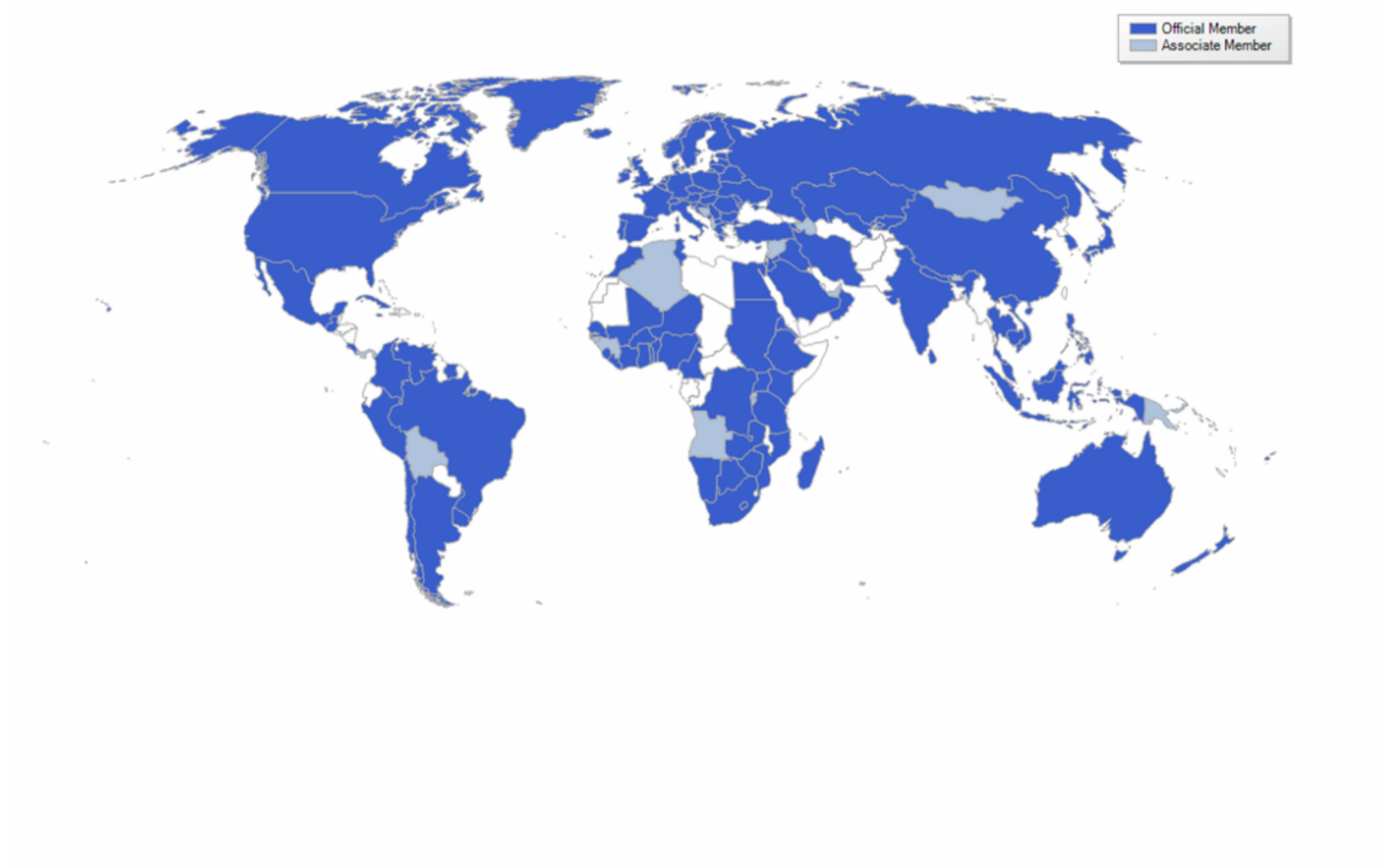
Aim of this session

After the session the students will be able to:

Discuss the benefits and obligations of member countries of the WHO Programme for International Drug Monitoring



Associate? Official member country?



Who has access to VigiBase?



VigiLyze

Search and Analyse VigiBase™ - the WHO Global Database of Individual Case Safety Reports (ICSRs)

Firstname Lastname [Logout](#) [Help](#)

Drug: Carbamazepine x

☒ Exact phrase

Reaction:

☒ Exact phrase

☒ MedDRA ☐ WHO-ART

Search

Reset

Refine by:

Drug

[Clear](#)

Single ingredient

[Clear](#)

- ☒ **Carbamazepine**
☒ **Carbamazepine**
[View all \(112\)](#)

Multiple ingredients

Reaction (MedDRA)

[Clear](#)

- ☒ **SOC: Blood and lymphatic system disorders**
☐ **SOC: Cardiac disorders**
☐ **SOC: Congenital, familial and genetic disorders**
☐ **SOC: Ear and labyrinth disorders**
☐ **SOC: Endocrine disorders**
☐ **SOC: Eye disorders**
☐ **SOC: Gastrointestinal disorders**
☐ **SOC: General disorders and administration site conditions**
☐ **SOC: Hepatobiliary disorders**
☐ **SOC: Immune system disorders**
☐ **SOC: Infections and infestations**
☐ **SOC: Injury, poisoning and procedural complications**
☐ **SOC: Investigations**
☐ **SOC: Metabolism and nutrition disorders**
☐ **SOC: Musculoskeletal and connective tissue disorders**
☐ **SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Country

[Clear](#)

- ☒ **Asia**
☒ **Armenia**
☒ **Brunei**
☒ **Cambodia**
☒ **China**
☒ **Cyprus**
☒ **India**
☒ **Indonesia**
☒ **Iran**

View: [Statistics](#) [ICSR List](#)

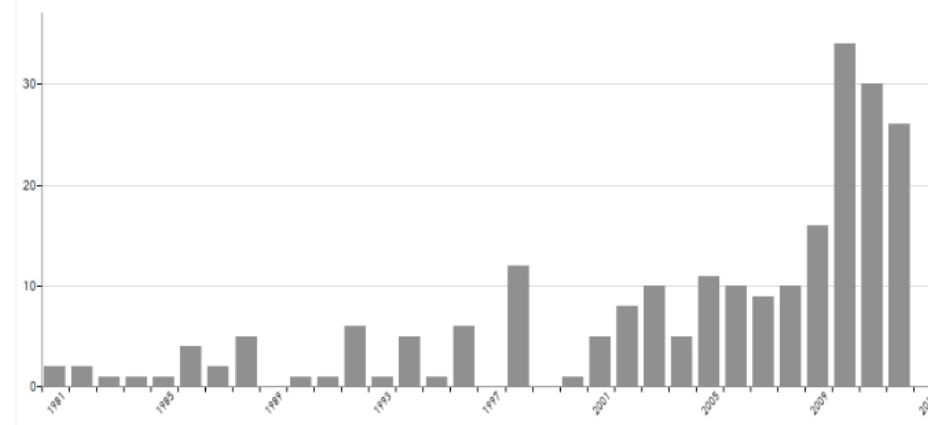
226 ICSRs match your search:

Drug: Carbamazepine

Reaction: SOC Blood and lymphatic system disorders

Country: Asia

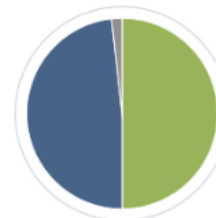
NUMBER OF ICSRs PER YEAR



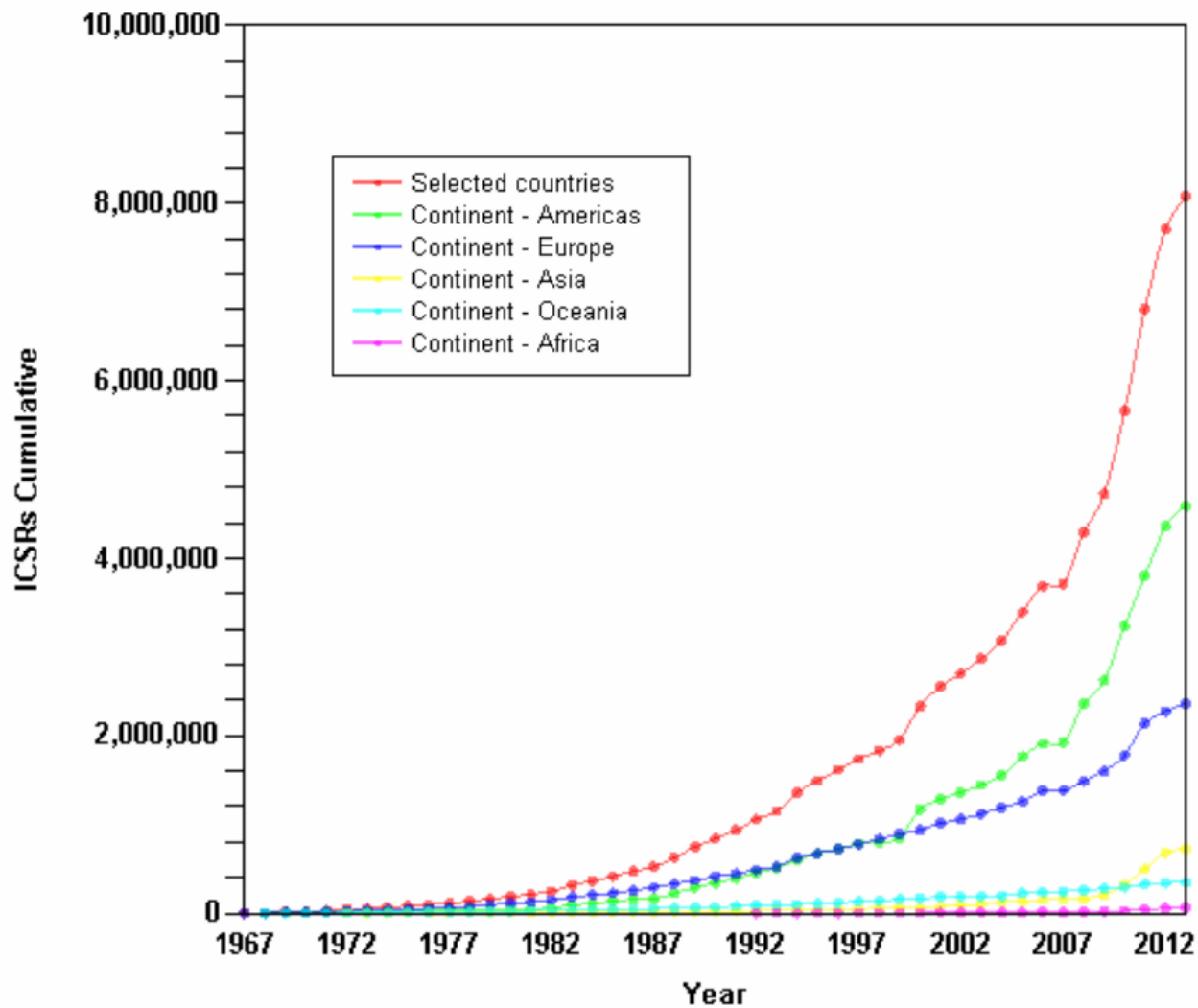
PATIENT AGE



PATIENT SEX



ICSRs in Vigibase



DO NOT WRITE IN SHADED AREAS

USE TYPEWRITER 12 PITCHES PER INCH, SINGLE SPACING

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING

COUNTRY	COUNTRY CASE IDENTIFICATION NO.	Source of data	Country of origin	ADR	BSI	REPORT OF SUSPECTED DRUG REACTION	STRICT DESIGN	Start of reaction	RECORD NUMBER
1-1	1-10	2	3	4-5	6-7	8-9	10-11	12-13	14-15

-16 FOREIGN REPORT

ADVERSE REACTION PREFERRED TERMS

1-16

ICD-CODE

20-29

18

OUTCOME:

A RECOVERED WITHOUT SEQUELAE
 B RECOVERED WITH SEQUELAE
 F NOT YET RECOVERED
 D DIED - DUE TO ADVERSE REACTION
 C DIED - DRUG MAY BE CONTRIBUTORY
 N DIED - UNRELATED TO DRUG
 U UNKNOWN

19-20

IF ADVERSE REACTION IS DEATH,
CAUSE OF DEATH ICD**

21-26

**INDICATE ICD VERSION

DRUGS: Trade name if available

1-15

DOSAGE: REASON

3-11

19-20

AMOUNT

UNIT

21-26

27-28

29-30

31-32

33-34

35-36

37-38

39-40

41-42

43-44

45-46

47-48

49-50

51-52

53-54

55-56

57-58

59-60

61-62

63-64

65-66

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79-80

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83-84

85-86

87-88

89-90

91-92

93-94

95-96

97-98

99-100

DRUG ADMINISTRATION***

3-11

19-20

AMOUNT

UNIT

21-26

27-28

29-30

31-32

33-34

35-36

37-38

39-40

41-42

43-44

45-46

47-48

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97-98

99-100

101-102

103-104

105-106

WHO PHARMACEUTICALS NEWSLETTER

prepared in collaboration with the
WHO Collaborating Centre for
International Drug Monitoring,
Uppsala, Sweden

No. 4, 2010

The aim of the Newsletter is to disseminate information on the safety and efficacy of pharmaceutical products, based on communications received from our network of "drug information officers" and other sources such as specialized bulletins and journals, as well as information in the form of resumes in English, full texts of which may be obtained on request from:

Quality Assurance and Safety:
Medicines, EMP-HSS,
1211 Geneva 27, Switzerland.
E-mail address: psd@who.int

This Newsletter is also available on our Internet website:
<http://www.who.int/medicines>

Further information on adverse reactions may be obtained from the
WHO Collaborating Centre for
International Drug Monitoring
Box 1051
751 40 Uppsala
Tel: +46-18-65 60 60
Fax: +46-18-65 60 80
E-mail: sten.olsen@who-umc.org
Internet: <http://www.who-umc.org>

Contents

Regulatory matters
Safety of medicines
Features

The US FDA has recently uncovered fraudulent Tamiflu sold over the internet, which put many patients at risk for anaphylaxis. Read about this and other alerts in our regular sections, Safety of Medicines and Regulatory Matters.

This June, representatives from the pharmaceutical industry and regulatory authorities gathered in Beijing to discuss pharmaceutical development on paediatric formulations. This event was the fourth workshop organized by the Prequalification of Medicines Programme (PPQ), which provided an open forum for information exchange on the development, formulation and manufacturing of paediatric medicines. The discussions covered technical, safety and ethical topics with an overall positive feedback from the participants.

Around the same time, Singapore's Health Sciences Authority (HAS) hosted the first pharmacovigilance training for ASEAN countries. The 5-day training was a collaboration with WHO and UMC, and aimed to strengthen pharmacovigilance awareness and capabilities in ASEAN nations and to build future collaborations for medicines safety in the region.



WHO Collaborating Centre for
International Drug Monitoring

RESTRICTED

SIGNAL

Analyses of Reports in the WHO Global ICSR Database – VolBase • September 2010



Signals in this issue

- Abacavir – Vasoitis
- Doxepin – Acute Renal Failure and Decreased Creatinine Clearance
- Sumatriptan/Ergotamine – Spinal stenosis
- Vimovone – Toxicity

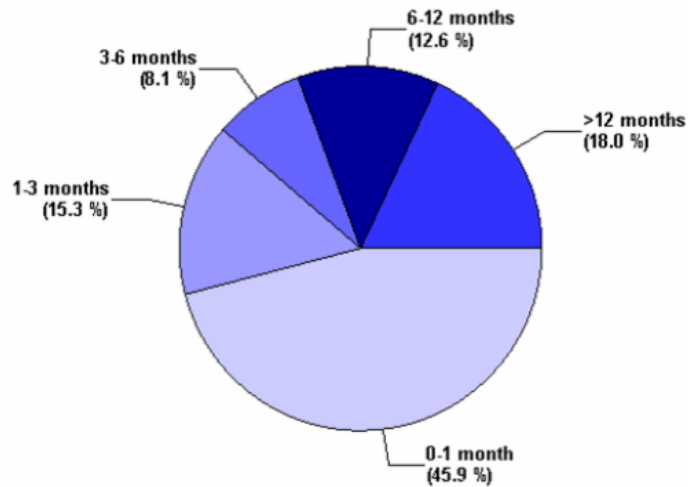
Also with this issue

- Overview of reporting for over-the-counter drugs
- Doxepin: an antidepressant in overdose



There shall be no publication of reports generated in the database to the Uppsala Monitoring Centre

Frequency of report submission



Why is it important?

Do you work with signal detection?

If yes:

How do you communicate the outcome?



EDA
Egyptian Drug Authority
Central Administration of Pharmaceutical Affairs (CAPA)

Part I of II

EPVC

Newsletter 5
Volume 3
May 2012

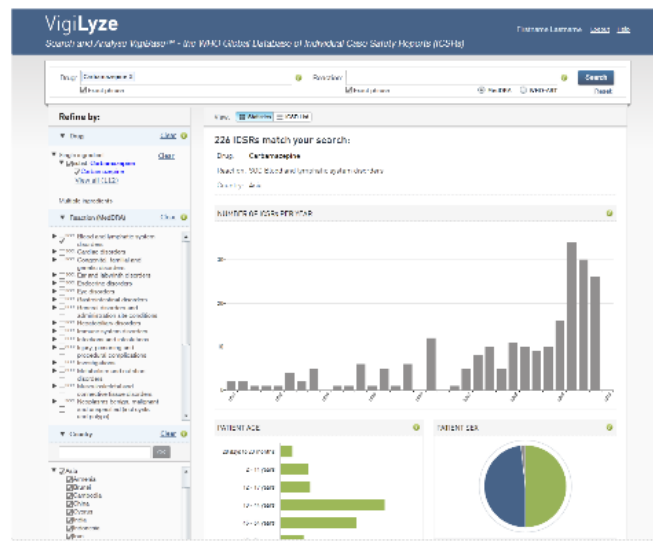
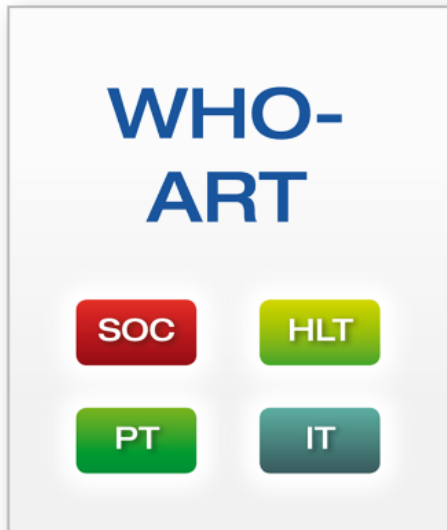
Egyptian Pharmacovigilance Center (EPVC)

Tel: 25354130 Fax: 23610497 Email: pv.center@eda.mohealth.gov.eg

- [Nicotinic acid-- Label Update](#)

In reference to the clinical trial called the Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global

Which UMC developed software and/or terminologies are you using?



WHO-
ART

SOC

HLT

PT

IT

WHO
DDE

Support and resources -what have you used?



www.who-umc.org

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[COMMERCIAL SERVICES >](#)

[RESEARCH >](#)



SEARCH



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To Improve Worldwide Patient Safety

The Uppsala Monitoring Centre (UMC) is an independent foundation and a centre for international service and scientific research.

Our priorities are the safety of patients and the safe and effective use of medicines in every part of the world.

We meet these priorities by innovative research and development, and by providing data, reference, consultative and training resources to medicines regulatory agencies, health professionals, researchers and the pharmaceutical industry all over the world.

UMC's Vision is to improve worldwide patient safety and welfare by reducing the risk of medicines.

News

23 April 2013

VigiBase reaches 8 million reports

The Uppsala Monitoring Centre has now entered 8 million adverse drug reaction (ADR) reports from countries contributing to the WHO Global Individual Case Saf...

PV Consulting





You are here: Home

Welcome to the UMC-A website!

If you are involved in healthcare in any role in Africa, there's something here for you.

Our job at UMC-A is to help ensure the safety of patients and the safe and effective use of medicines in Africa.

We are here to support and work with everyone who shares that ambition.

If patient safety is your priority, for your country, your public health programme or your hospital or clinic, take a look through this website and see what we may be able to do together.

Your enquiries or reactions will be welcome: do get in touch!

Search

Go

Our social media pages



What's New?

1 2



UMC-A visits Liberia

Liberia is a country located in the western coast of Africa with a population of about 3.5 million. The country has sh...



A change blowing over Africa

Pharmacovigilance in Africa is going through a rapid phase of growth and development thanks to several initiatives from ..



Pharmacovigilance in Eritrea – promise and potential

Iyassu Bahta and Mulugeta Russom The Eritrean National Pharmacovigilance Centre (ENPC) was established in 2003 in which...

www.umcafrica.org

Pharmacovigilance Toolkit

This **Pharmacovigilance (PV) Toolkit** is a collection of resources and information needed for the practice of pharmacovigilance. The main aim of its development is to ensure that PV practitioners in low- and middle-income countries get access to information on the processes and activities involved in PV from a trusted source. The Toolkit contents are endorsed by the WHO Advisory Committee on the Safety of Medicinal Products after the original text has been written and reviewed by global experts.

In addition to this website, the Toolkit is available on USB drives in a similar format to this website, for use in areas with poor internet connectivity. The Toolkit is currently available in English, and efforts are underway to have it translated into other languages, although this is dependent on availability of volunteers and/or funding. The Toolkit will be reviewed periodically to ensure that it is abreast with developments in PV.

The Toolkit Management Team is keen to have your feedback such as what you think can be added, removed or modified in order to make its use more beneficial.

Disease-specific Toolkits

Although this PV Toolkit covers all the basics required for PV work, there are peculiarities when carrying out PV for certain diseases and subgroups of people. This has led to the development of the **Malaria** and **HIV** PV Toolkits, with a **TB** Toolkit currently being developed in addition. These disease-specific toolkits should be used in combination with the main PV Toolkit.

What's New?

Definition and Application of Terms for Vaccine Pharmacovigilance



Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance. ...

The World Medicines Situation 2011: Pharmacovigilance and Safety of Medicines



The World Medicines Situation 2011: Pharmacovigilance and Safety of Medicines ...

Supporting PV in Developing Countries. The Systems Approach



Supporting Pharmacovigilance in Developing Countries. The Systems Approach. ...

Toolkit is managed and maintained by
WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance, University of Ghana Medical School, Accra, Ghana



Toolkit content reviewed by



WHO (Safety of Medicines Programme)

WHO Advisory Committee on Safety of Medicinal Products (ACSoMP)

www.pvtoolkit.org

Alertes

L'eau de javel ambulatoire العبار
: Un prix bas mais des
risques élevés - Jalal Ghyslaine
[Plus de détails](#)

Diluant : danger à domicile -
Hardouz Houria
[Plus de détails](#)

"Lkina elkhadra" الكينة الخضرا vendue
en épicerie! - Benabdallah Ghita
[Plus de détails](#)

[Archive des alertes](#)

Evénements

17/06/2013 au 28/06/2013
7ème cours francophone de
pharmacovigilance
Rabat
[Plus de détails](#)



Pour une vie meilleure

من أجل حياة أفضل

المركز المغربي لمحاربة التسمم و لليقظة الدوائية هو معهد تابع لوزارة الصحة
يقوم بوظيفتي اليقظة و الإنذار الصحي. هدفه الرئيسي هو تحسين صحة
المواطنين عن طريق خفض معدلات الاعتلال والوفيات والتكاليف الاقتصادية
المرتبطة بالتسممات والأعراض الجانبية للأدوية و المواد الصحية الأخرى.

بلغوا ،
نتصرف

استفسروا ،
نحيب

اتصلوا ،
نستمع

فضاء للعصوم
Espace pour le Public

فضاء لمهنيي الصحة
Espace Professionnel de Santé

Le Centre Anti Poison et de Pharmacovigilance du Maroc (CAPM) est un
institut du Ministère de la Santé, assurant une fonction de vigilance et
d'alerte sanitaire. L'objectif étant l'amélioration de la santé de la population
marocaine par la diminution de la morbidité, de la mortalité et des dépenses
économiques liées aux intoxications et aux effets indésirables des
médicaments et des autres produits de santé.

Appelez,
nous écoutons

Demandez,
nous répondons

Déclarez,
nous agissons

طبيب مختص رهن إشارتكم طيلة الأسبوع و على مدار الساعة

Le numéro économique :

N° Eco 0801 000 180

Prix d'une communication locale

Un médecin spécialiste est à votre disposition 7 j/7, 24 h/24

www.capm.ma



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Medicines

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[About us](#)

[News and events](#)

[Areas of work](#)

[Medicines publications](#)

[Medicines topics](#)

[Training resources](#)

Norms and Standards: Quality, safety and efficacy of medicines



WHO's mandate is to "develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products" (Article 2, WHO Constitution). WHO Member States rely on WHO for expertise and guidance in regulation, safety and quality assurance of medicines through development and promotion of international norms, standards, guidelines and nomenclature.

— [Guidance on Norms and Standards](#)

WHO provides relevant expertise and technical assistance through various activities in the areas of Quality Assurance, Regulation and Legislation, Safety and Efficacy.

Activities comprise guideline development, workshops and training courses, coordination and promotion of pharmacovigilance for global medicine safety, regulatory and other information exchange, and review of narcotic and psychotropic substances.

Activities and Services

Quick links

- [Counterfeit medicines](#)
- [Drug Alerts](#)
- [ICDRA](#)
- [International Pharmacopoeia](#)

Areas of work

Quality assurance of medicines

- [More information](#)

Regulation and legislation

- [More information](#)

Medicines publications



[Search "Medicines publications"...](#)

[Browse "Just published"...](#)

Latest News and Events



[The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences](#)

For everyone concerned with the issues of pharmacovigilance | UPPSALA REPORTS | April 2012

MUR57

Ser miembro del Programa
Internacional de Farmacovigilancia
de la OMS



ESSENTIAL READING
IN DRUG SAFETY

the UPPSALA
MONITORING
CENTRE

Viewpoint

Watching for safer medicines

Part 1
second edition

sies and
arch for
ational

BEING A MEMBER OF
THE WHO PROGRAMME
FOR INTERNATIONAL
DRUG MONITORING

the UPPSALA
MONITORING
CENTRE

SAFER MEDICINES,
SAFER USE OF MEDICINES,
SAFER PATIENTS

What UMC is doing to help it happen

the UPPSALA
MONITORING
CENTRE

Support and resources -what have you used?



Access to the international network



Education & Training







Vigimed ▸ Home

Online Collaboration Site for members of the WHO Programme for international drug monitoring

[Home](#) [Vigimed](#) [VigiFlow](#) [UMC-A](#) [UMC Portal Support](#) [VigiLyze Users](#)

Discussion Forum

[Regulatory status](#)[Product warnings](#)[Pharmacovigilance issues \(including early signals\)](#)[Meetings, courses, events](#)[Other](#)[Planning and information](#)[Calendar](#)[Announcements](#)[Links](#)

Library

[Vigimed Documents](#)[Newsletters](#)[Global Vaccine Safety Initiative](#)[2013 NC meeting](#)[2012 NC meeting](#)[2011 NC Meeting](#)[Vigimed Users](#) All Site Content

Welcome to Vigimed

Vigimed is the restricted forum site set up to stimulate discussion and facilitate rapid exchange of information between representatives of National Centres participating in the WHO International Drug Monitoring Programme. A list of the current Vigimed users is available as a link (on the left in Quick Launch).



You can add items to Vigimed, but not edit or delete. Please contact us at info@who-umc.org if you have any comments or queries.

Before you start a new discussion *please check* if a thread on the same question already exists by doing a search for the subject in the search square (top right).

- To start a new discussion thread:
 - click on the topic area related to your comment (in the quick launch to the left),
 - click [+Add new discussion](#),
 - type Subject and message,
 - complete with Save.

[Link to FAQ](#)



Last item in Regulatory status

 Subject	 Created By	Replies	Last Updated
Diphenhydramine and ethanol	Shynar Baidullayeva	2	04/05/2013 15:46
1 - 1 ▶			

Last item in Product warnings

 Subject	 Created By	Replies	Last Updated
proveron	Maytham Hadi	0	20/12/2012 15:26
1 - 1 ▶			

Last item in Pharmacovigilance issues (including early signals)

 Subject	 Created By	Replies	Last Updated
Injection paracetamol (acetaminophen)	Rokiah Isahak	4	12/04/2013 05:45
1 - 1 ▶			

Education & Training



Spontaneous adverse reaction monitoring

How do we monitor for adverse reactions?
What are the signs and symptoms?
How do we report them?







Hem

Filmer

Kanaler

Live

Logga In



Pharmacovigilance

Kontaktperson: MedfarmDoIT

63 videor



Prenumerera

Spontaneous adverse reaction monitoring

Part of category: ADR reporting

Lecturer: Sten Olsson

Click the link for copyright information: <http://www.who-umc.org/graphics/25569.pdf>



What we expect from you

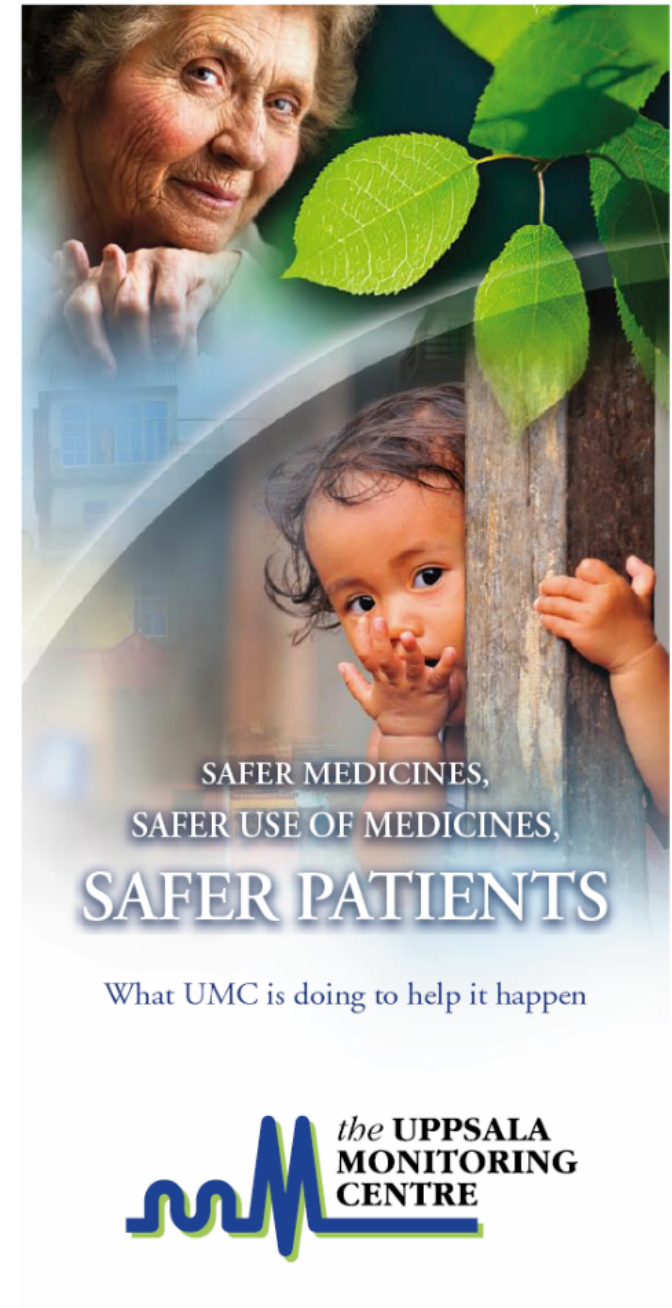
Reporting format compatibility & report quality

Frequent submissions of ICSRs

Regulatory information

Active participation

Drug formulary






22 oktober 2012

☐ Förklara svåra ord



Gå till
Min Fass 

SÖK 

Läkemedelsnamn

 SÖK

Substans

 SÖK

Överdoserings-

 SÖK

☒ Läkemedel

☐ Substans

☐ ATC-kod

Överdoserings-

information >>

Sök i FASS-text

 SÖK

Avsnitt:

-Alla 

Läkemedels-

grupper (ATC) >>

Skyddsinformation >>

Miljöinformation >>

Tablett-

identifiering >>

Företag >>

	PRODUKTFAKTA Naturläkemedel Läs om naturläkemedel och växtbaserade läkemedel  LÄS MER
	PRODUKTFAKTA FASS 2012 Årets bokutgåva kan beställas från vår webbshop.  LÄS MER
	PRODUKTFAKTA Högekostnadsskydd Fr.o.m. 2012-01-01 gäller höjda belopp i förmånstrappan.  LÄS MER
	PRODUKTFAKTA Överdoserings- information Sök i vår databas med överdoseringsinformation.  LÄS MER

De senaste uppdateringarna av läkemedel på Fass.se

Läkemedel	Uppdatering
Divina@ Plus	Biverkningar
Divina@ Plus	Varningar och försiktighet
Divina@ Plus	Kontraind...
Divina@ Plus	Dosering
Divina@ Plus	Indikationer

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[Prenumerera på RSS-flöden](#)

Användare på Fass.se

Aktiva användare på Fass.se just nu: 1626

[Geografisk fördelning](#)

What you get from the UMC

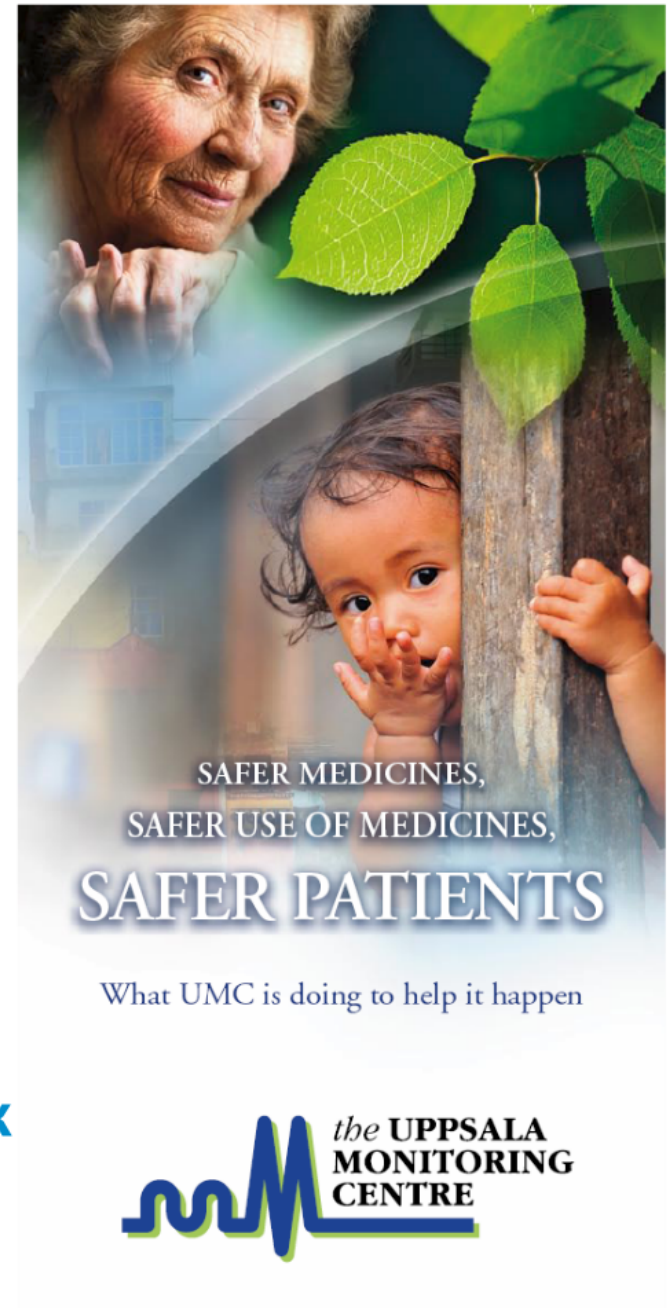
Access to VigiBase™

Early information about
potential safety hazards

Terminologies and software

Support, guidelines and resources

Access to the international network





GLOBAL LEADERSHIP FOR THE SAFER USE OF MEDICINES

Thank you for your attention!