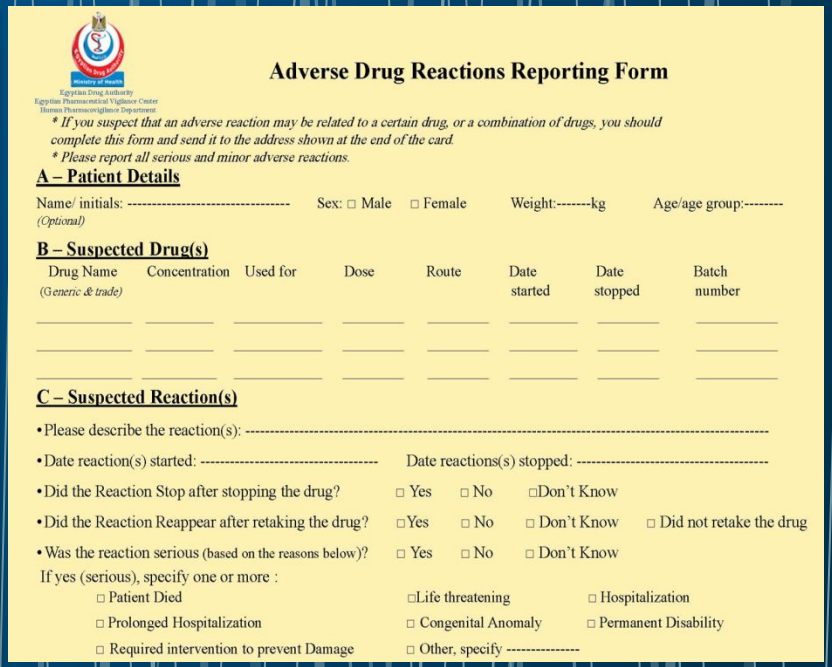
Reporting drug adverse reactions "pharmacovigilance unit"



Egyptian Drug Authority
Egyptian Pharmaceutical Vigilance Center
Human Pharmacovigilance Department

Adverse Drug Reactions Reporting Form

** If you suspect that an adverse reaction may be related to a certain drug, or a combination of drugs, you should complete this form and send it to the address shown at the end of the card.*
** Please report all serious and minor adverse reactions.*

A – Patient Details

Name/ initials: ---------- Sex: □ Male □ Female Weight:-------kg Age/age group:--------
(Optional)

B – Suspected Drug(s)

Drug Name *(Generic & trade)*	Concentration	Used for	Dose	Route	Date started	Date stopped	Batch number

C – Suspected Reaction(s)

- Please describe the reaction(s): ----------
- Date reaction(s) started: ---------- Date reactions(s) stopped: ----------
- Did the Reaction Stop after stopping the drug? □ Yes □ No □Don't Know
- Did the Reaction Reappear after retaking the drug? □Yes □ No □ Don't Know □ Did not retake the drug
- Was the reaction serious (based on the reasons below)? □ Yes □ No □ Don't Know

If yes (serious), specify one or more :

□ Patient Died □Life threatening □ Hospitalization
□ Prolonged Hospitalization □ Congenital Anomaly □ Permanent Disability
□ Required intervention to prevent Damage □ Other, specify ----------

by

Dr. Khaled sobhy

Case Scenario

- Jane J. is a 22-year-old woman who was admitted to Community Hospital on **May 24** with an exacerbation of autoimmune encephalitis and received a 5-day course of high-dose intravenous steroids. Her symptoms rapidly stabilized and improved and she was discharged on May 29. She returned to Community Hospital's outpatient infusion department later on May 30 and May 31, and on June 1 for a 3-day course of XZ Pharmaceutical's IV immune globulin, 90 grams daily.
- On June 6, Jane returned to the hospital emergency room with symptoms suggesting anemia. Lab work showed reticulocytosis, and a positive Coombs test.

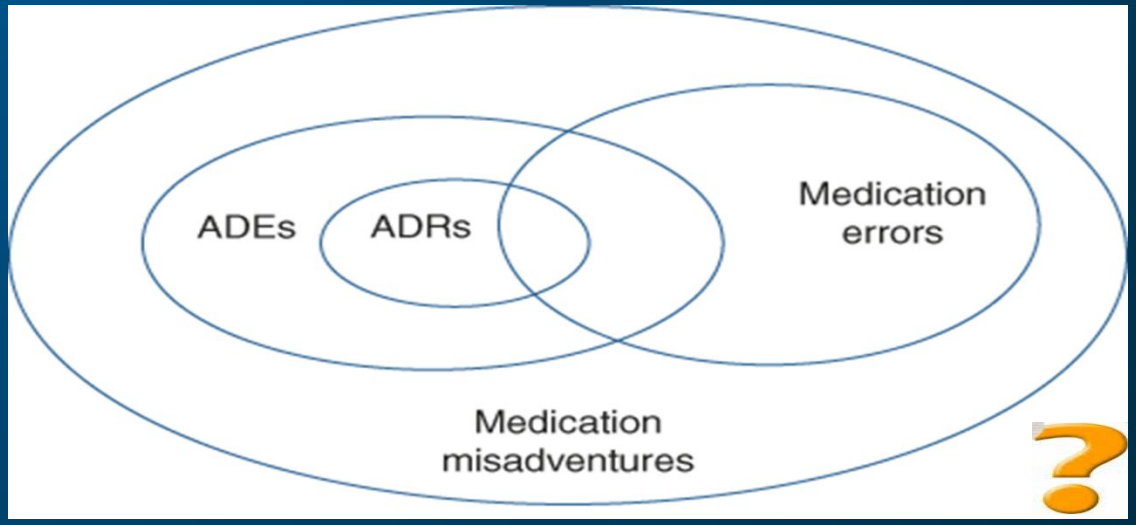
Case Scenario "continued"

- **Her hemoglobin was 6.3 g/dL** (it had been 13.4 g/dL on a previous admission, May 24). She was admitted with a working diagnosis of acute hemolytic anemia. The physician suspects an association between her recent treatment with XZ Pharmaceutical's IV immune globulin and the anemia.

- Jane received two units of packed red blood cells on June 7. Repeat hemoglobin was 9.0 on June 8 and 9.2 on June 9. Past medical history also included diagnoses of obesity and hypertension. She was also taking atenolol, norvasc, folic acid, pantoprazole and felodipine.

Terminology

- Medication misadventure "MS" refers to **any hazard associated** with medications.
- Pharmacists play a pivotal role in reporting MS. Reporting MS is one of the main service of pharmacist in DIC.
- Determination of the type of MS is important in liability issues



Terminology

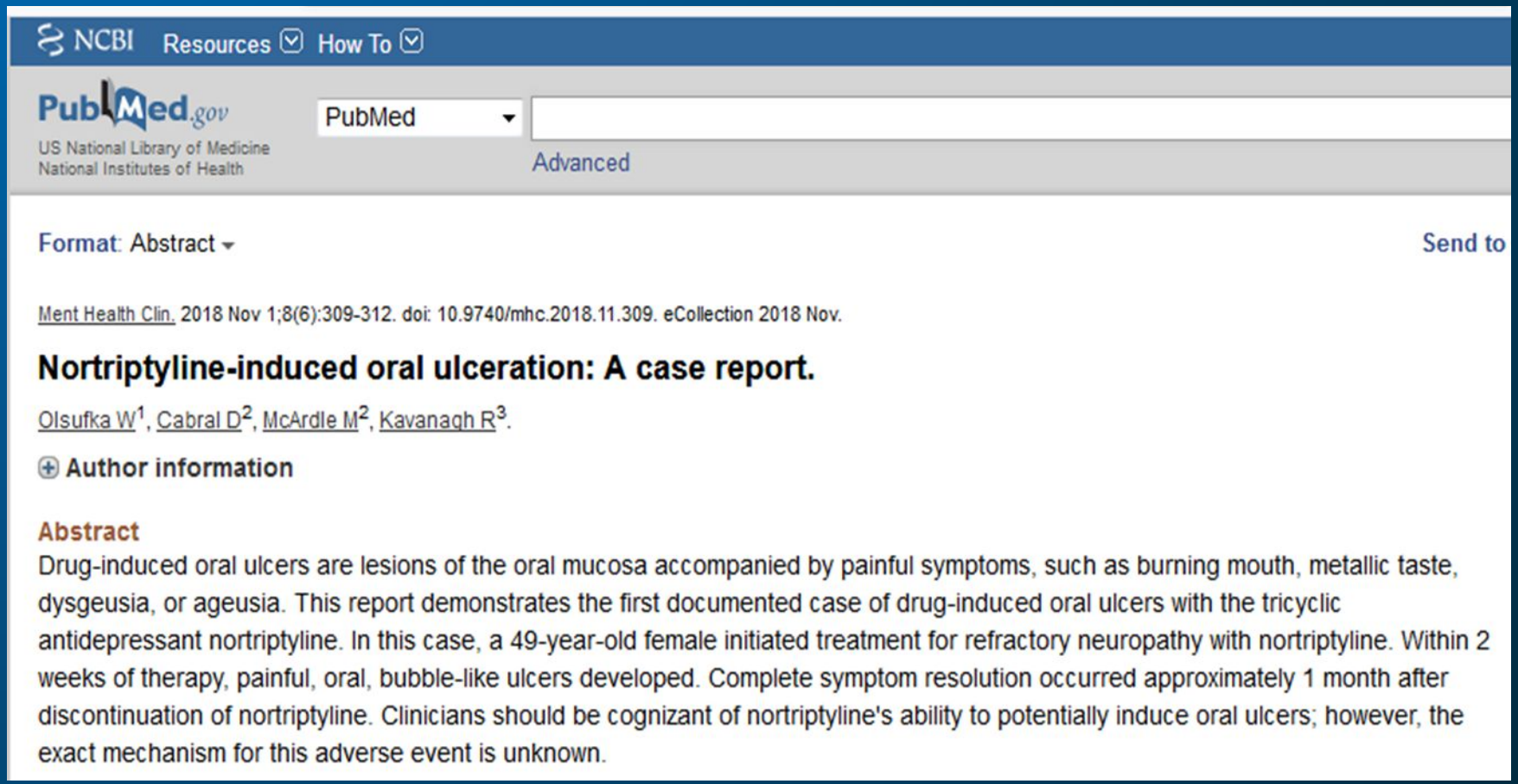
- All adverse drug events (ADEs), adverse drug reactions (ADRs), and medication errors fall under the umbrella of MS.
- The ADE means any body injury caused by a medicine use. It include ADRs that **result in harm to a patient**.
- A medication error is **any preventable event** that has the potential to lead to inappropriate medication use.
- In 1995, ADE-related costs were $76.6 billion annually. It's estimated that 30 to 60% of ADEs are preventable.

Adverse Drug Reactions

- **WHO** defines an ADR as "any unintended response to a medicine which occurs **at doses normally** used in man.
- The ADRs include allergic or idiosyncratic reactions of drugs. Drug-drug interactions can also fall into the category of ADRs.
- Side effect, which is "any unintended effect of drug occurring **at doses normally** used by a patient related **to the pharmacological properties of the drug "2 ry unwanted effects"**

Give the right medical terminology

MR, ADEs, ADRs or SE



NCBI Resources How To

PubMed.gov
US National Library of Medicine
National Institutes of Health

PubMed

Advanced

Format: Abstract

Send to

Ment Health Clin. 2018 Nov 1;8(6):309-312. doi: 10.9740/mhc.2018.11.309. eCollection 2018 Nov.

Nortriptyline-induced oral ulceration: A case report.

Olsufka W[1], Cabral D[2], McArdle M[2], Kavanagh R[3].

Author information

Abstract

Drug-induced oral ulcers are lesions of the oral mucosa accompanied by painful symptoms, such as burning mouth, metallic taste, dysgeusia, or ageusia. This report demonstrates the first documented case of drug-induced oral ulcers with the tricyclic antidepressant nortriptyline. In this case, a 49-year-old female initiated treatment for refractory neuropathy with nortriptyline. Within 2 weeks of therapy, painful, oral, bubble-like ulcers developed. Complete symptom resolution occurred approximately 1 month after discontinuation of nortriptyline. Clinicians should be cognizant of nortriptyline's ability to potentially induce oral ulcers; however, the exact mechanism for this adverse event is unknown.

DIC Pharmacist role & ADRs

- 1-updated with recent ADRs of drug in clinical practice & increase medical team awareness of recent updates of ADRs "newsletter publications"
- 2-reporting new ADRs to EPVC and WHO
- 3-sharing in researches "epidemiology for ADRs in community"
- 4-Sharing in programs for prevention of ADRs "adding to drug label"

Resources for updates in ADRs

- The FDA Web **(http://www.fda.gov/Safety/Medwatch)**.
- This online provide FDA's latest safety alerts and recalls.
- The site also provides monthly summaries of changes to drug labeling that the FDA made in response to reports.
- **Lexicomp database** also provide update in FDA safety alerts for drugs.
- This data is Important to be included in DIC newsletters

https://www.fda.gov/Safety/MedWatch/default.htm

Search

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program

MedWatch The FDA Safety Information and Adverse Event Reporting Program

- Subscribe to MedWatch Safety Alerts
- Safety Information
  - Safety Alerts for Human Medical Products
  - Drug Safety Labeling Changes
- Reporting Serious Problems to FDA

Resources for You

- 2018 Safety Alerts for Human Medical Products

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Your FDA gateway for clinically important safety information and reporting serious problems with human medical products.

Report a Problem | **Safety Information** | **Stay Informed**

What's New

- Gilenya (fingolimod): Drug Safety Communication - Severe Worsening of Multiple Sclerosis After Stopping the Medicine is rare but can result in permanent disability.[11/20/2018]
- Implanted Pumps: Safety Communication - Use Caution When Selecting Pain Medicine for Intrathecal Administration that are not FDA approved for use with the implanted pump.[11/14/2018]

Importance of Reporting ADRs

- 1- Postmarketing Surveillance of ADRs using Well-designed **programs** makes it possible to **detect early signals of a developing problem**.
- Postmarketing ADR reporting can cause **changes in prescribing drugs** as well as result in the **withdrawal of various drugs from the market**.
- 2-Pharmacoepidmiology studies: It estimate the ADRs in the community exposed to a given used drug “”

Causality of ADRs

To detect ADR, determine the causality "the probability that a particular drug causes an adverse event".

Assessment tools for causality of ADRs

1-the sequential relationship between drug administration and event.

2-Dechallenge: did the patient improve after stopping the drug

3-rechallenge: the reaction appear after repeated exposure to the drug. Rechallenge is not applicable to all ADRs

4-The response pattern to the suspected drug

5-the event is not explained by patient clinical cases "condition & other concurrent drugs"

Types of probability of Adverse Drug Reactions

1-Definite ADR is a reaction which:

- Follows a reasonable temporal sequence from administration of the drug;
- Follows a known response pattern to the suspected drug; and
- Is confirmed by dechallenge; and
- Could not be reasonably explained by the known characteristics of the patient's clinical state.

Types of probability of Adverse Drug Reactions

2-Conditional ADR is a reaction which:

- Follows a reasonable temporal sequence from administration of the drug;
- **Does not follow a known response pattern to the suspected drug**
- Could not be reasonably explained by the known characteristics of the patient's clinical state.

3-Doubtful ADR is any reaction that does not meet the criteria above.

MedWatch program

- In June **1993**, the FDA developed a new program called **MedWatch.**
- The current MedWatch system allows health care providers to report suspected ADRs using **FDA Form 3500**.
- With this program, the FDA receives reports from **health care team, health organizations and consumers "patients".**
- MedWatch is interested in reports of serious ADRs, which the FDA defines as death, life threatening events, hospitalization, disability, congenital anomaly, or requiring intervention to prevent permanent impairment.

MedWatch

- Once submitted through the MedWatch system, ADR reports are received by a unit of the FDA called **the Central Triage Unit** which screens reports and forwards them to the appropriate **FDA program within 24 hours of receipt**.

- The report becomes **part of a database used by the FDA** to **identify signals or warnings** related to drug safety that require **further study or regulatory action**.

Reset Form

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** — In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)
or Date of Birth *(e.g., 08 Feb 1925)* __ __ – __ __ __ – __ __ __ __

3. **Sex** ☐ Female ☐ Male

4. **Weight** ☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* __ __ – __ __ __ – __ __ __ __
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)*

4. **Date of this Report** *(dd-mmm-yyyy)*

5. **Describe Event, Problem or Product Use Error**

6. **Relevant Tests/Laboratory Data, Including Dates**

(Continue on page 3)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

(Continue on page 3)

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 – Name and Strength	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Manufacturer/Compounder	#2 – Lot #

3. **Dose or Amount** | **Frequency** | **Route**

#1

#2

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __ __ – __ __ __ – __ __ __ __ #2 __ __ – __ __ __ – __ __ __ __

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** | 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** | **Lot #**

Catalog # | **Expiration Date** *(dd-mmm-yyyy)* __ __ – __ __ __ – __ __ __ __

Serial # | **Unique Identifier (UDI) #**

5. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* __ __ – __ __ __ – __ __ __ __

7. **If Explanted, Give Date** *(dd-mmm-yyyy)* __ __ – __ __ __ – __ __ __ __

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

(Continue on page 3)

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

Last Name: | First Name:

Address:

City: | State/Province/Region:

Country: | ZIP/Postal Code:

Phone #: | Email:

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: http://www.fda.gov/medwatch/report/consumer/instruct.htm

Report adverse events, product problems or product use errors with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Combination products *(medication & medical devices)*
- Human cells, tissues, and cellular and tissue-based products
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics
- Food *(including beverages and ingredients added to foods)*

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Other methods of reporting:

- 1-800-FDA-0178 - To FAX report
- 1-800-FDA-1088 - To report by phone
- www.fda.gov/medwatch/report.htm - To report online

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves a serious adverse event with a vaccine, call 1-800-822-7967 to report.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

-Fold Here-

-Fold Here-

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail to the left.

OMB statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (10/15) (Back) **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

Reset Form

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

FORM FDA 3500 (10/15) *(continued)*

(CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

Back to Form

B.5. **Describe Event or Problem** *(continued)*

Back to Form

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Form

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Back to Form

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(continued)*

Good Vigilance Practice (GVP)

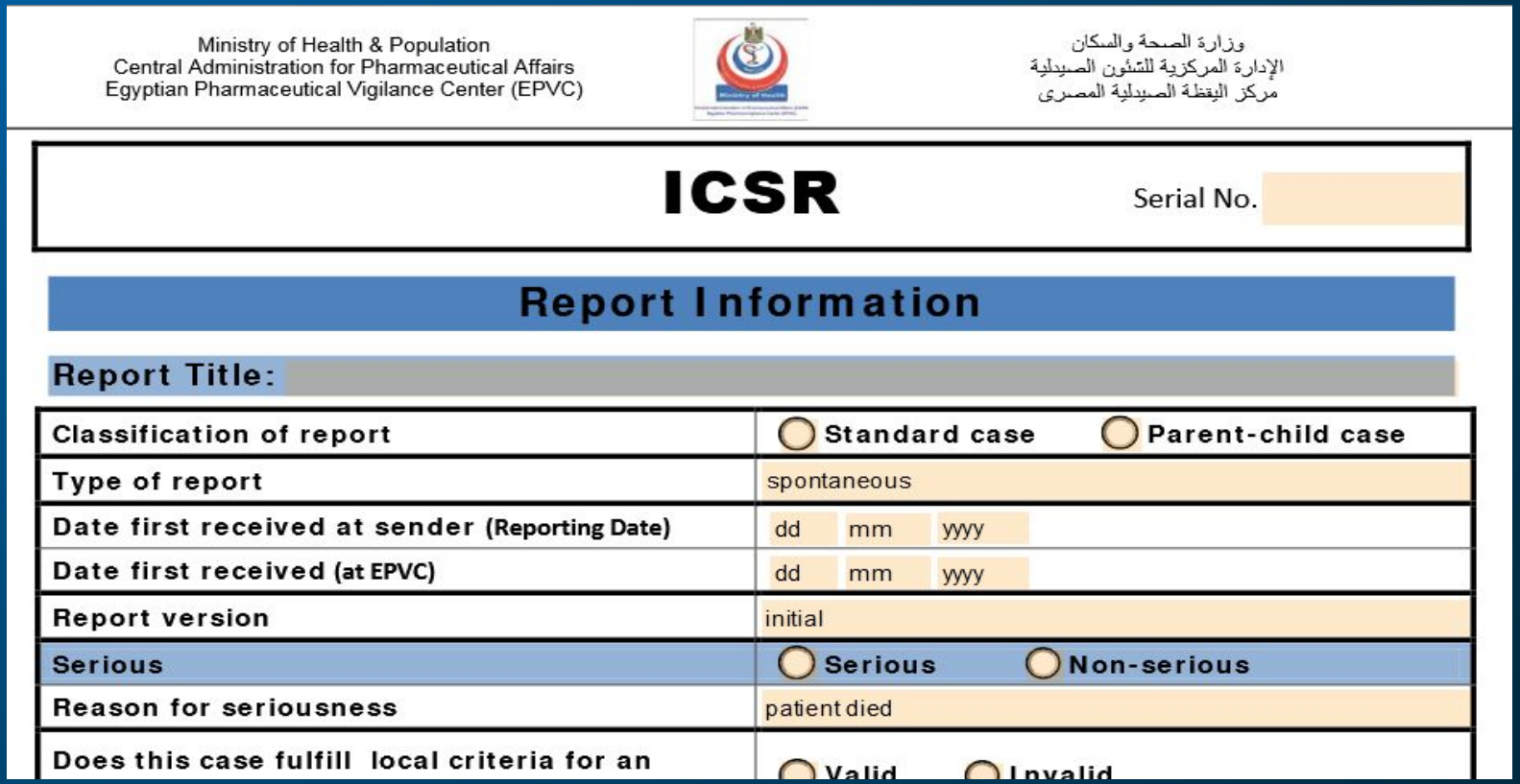
- WHO stated for **any company to be qualified** for drug **manufacturing and exporting**, this require 6 steps (licence for factory, registeration for drugs, clinical trials if needed, inspection, laboratory analysis, pharmacovigilance reports).

- Later on, WHO mandate that vigilance should be not only in companies but also in independent center.

- Role of pharmacovigilance centers is to ensure good vigilance practice (GVP) and to adhere **standard performance** in vigilance practice.

ICSR Form

ICSR: Individual Case Study Report (ICSR) is an adverse event report for an individual patient by pharmaceutical company as source of data in pharmacovigilance.



Ministry of Health & Population
Central Administration for Pharmaceutical Affairs
Egyptian Pharmaceutical Vigilance Center (EPVC)

وزارة الصحة والسكان
الإدارة المركزية للشئون الصيدلية
مركز اليقظة الصيدلية المصرى

ICSR Serial No.

Report Information

Report Title:

Classification of report	◯ Standard case ◯ Parent-child case
Type of report	spontaneous
Date first received at sender (Reporting Date)	dd mm yyyy
Date first received (at EPVC)	dd mm yyyy
Report version	initial
Serious	◯ Serious ◯ Non-serious
Reason for seriousness	patient died
Does this case fulfill local criteria for an	◯ Valid ◯ Invalid

Pharmacovigilance

- Pharmacovigilance is the **science and activities relating** to the **detection, assessment, handling and prevention of adverse drug reactions**

- Egyptian Pharmaceutical Vigilance Center (EPVC) is established within the Ministry of Health (**MOH**) which has a direct contact with **WHO**.

- This EPVC collect and evaluate Information about the harms associated with the use of medicines in Egypt.

yellow card

- a unified form used to facilitate the reporting ADRs.
- The EPVC adapted this from the international Yellow Card (UK). This yellow card is to be used by the healthcare professionals and the patients.
- it is designed in English and Arabic forms, you can submit it to the center by one of the following means: fax, post, over the phone, email, or online submission.
-

How to obtain the reporting form

- A web based dynamic reporting module is available at EPVC website to be completed and submitted online. (www.epvc.gov.eg).

- **Signal detection**: if new side effect reported in the yellow card or in the ICSR "Individual Case Study Report (ICSR)" exceed specific number, the MOH or the WHO make signal detection for this new SE and make the required action

- The action may be withdrawal, add to warning drug leaflet , or more studies)

Egyptian Drug Authority
Egyptian Pharmaceutical Vigilance Center
Human Pharmacovigilance Department

Adverse Drug Reactions Reporting Form

** If you suspect that an adverse reaction may be related to a certain drug, or a combination of drugs, you should complete this form and send it to the address shown at the end of the card.*

** Please report all serious and minor adverse reactions.*

A – Patient Details

Name/ initials: ---------- Sex: □ Male □ Female Weight:-------kg Age/age group:--------
(Optional)

B – Suspected Drug(s)

Drug Name *(Generic & trade)*	Concentration	Used for	Dose	Route	Date started	Date stopped	Batch number

C – Suspected Reaction(s)

- Please describe the reaction(s): ----------
- Date reaction(s) started: ---------- Date reactions(s) stopped: ----------
- Did the Reaction Stop after stopping the drug? □ Yes □ No □Don't Know
- Did the Reaction Reappear after retaking the drug? □Yes □ No □ Don't Know □ Did not retake the drug
- Was the reaction serious (based on the reasons below)? □ Yes □ No □ Don't Know

If yes (serious), specify one or more :

□ Patient Died □Life threatening □ Hospitalization

□ Prolonged Hospitalization □ Congenital Anomaly □ Permanent Disability

□ Required intervention to prevent Damage □ Other, specify ----------

D – List of other drugs taken (Please list any other drugs taken during the last month prior to the reaction- *other than the suspected drug/s*)

Drug Name (*Generic & trade*)	Concentration	Used for	Dose	Route	Date started	Date stopped	Batch number

E – Reporter Details

The One who fill in this form: □ Patient □Physician □ Pharmacist □ Nurse □ Other, specify_____

Name: ---------- Specialty *(if physician)*: ----------

Professional address(institution/ clinic): ----------

e-mail: ---------- Telephone/ mobile :----------

Signature: ---------- Date of reporting: ----------

F- Any More Comments:----------

- *The information in this report is confidential and totally protected including both the Patient and Reporter identity.*
- *You can send voluntarily the Adverse Drug Reactions (ADRs) Reports to the Egyptian Pharmaceutical Vigilance Center as per the contact details below.*
- *Reporting for ADRs is Vital for Safely usage of drugs . Enough information will help the Center to evaluate the Safety of the Drugs marketed in our Country.*

Head quarter: Human Pharmacovigilance Department – Egyptian Pharmaceutical Vigilance Center (EPVC)- Egyptian Drug Authority (EDA)

21 Abd Elaziz Al Souad st. – Manial El-Roda – Cairo, PO Box: 11451

Tel: +2 02 23648046 / +2 02 23640368 / +2 02 23684381

Extension (Tel): 1303 **Extension (Fax):** 1300

Fax: +2 02 23684194

Website: www.epvc.gov.eg

e-mail: pv.center@eda.mohealth.gov.eg

- **Alexandria Regional Center:** San Stefano for Family Health Centre, 2 Elkazino st, El-Awkaf building, San Stefano , Alexandria
  Tel-Fax: +2 03- 5845004 **e-mail:** alex.epvc@eda.mohealth.gov.eg
- **Cairo Regional Center:** Al-Azhar new specialized hospital 6th district Nasr City-Cairo
  Tel: +2 01014300013 **e-mail:** cairo.epvc@eda.mohealth.gov.eg
- **Sohag Regional Center:** The old building of the Health Affairs Directorate- 2nd floor- next to the security directorate building- Nasser city- Sohag
  Tel: +2 01063081606/ 01126540893 **e-mail:** sohag.epvc@eda.mohealth.gov.eg

Steps for Implementing a Program "ASHP Guidelines for P&TC"

1. **Develop definitions** for ADRs and its seriousness
2. Assign responsibility for the ADR program within the pharmacy.
3. Develop forms for data collection and reporting "yellow card"
4. **Promote awareness** of the program "workshop, seminars" how to deal with the yellow card.
5. Develop policies and procedures for handling ADRs reports being sent to the FDA or EPVC.
6. Report all findings to PTC or MIH

Report this ADRs to Yellow Card

- Jane J. is a 22-year-old woman who was admitted to Community Hospital on **May 24** with an exacerbation of autoimmune encephalitis and received a 5-day course of high-dose intravenous steroids. Her symptoms rapidly stabilized and improved and she was discharged on May 29. She returned to Community Hospital's outpatient infusion department later on May 30 and May 31, and on June 1 for a 3-day course of XYZ Pharmaceutical's IV immune globulin, 90 grams daily.
- On June 6, Jane returned to the hospital emergency room with symptoms suggesting anemia. Lab work showed reticulocytosis, and a positive Coombs test.

Practical Example "continued"

- **Her hemoglobin was 6.3 g/dL** (it had been 13.4 g/dL on a previous admission, May 24). She was admitted with a working diagnosis of acute hemolytic anemia. The physician suspects an association between her recent treatment with XYZ Pharmaceutical's IV immune globulin and the anemia.

- Jane received two units of packed red blood cells on June 7. Repeat hemoglobin was 9.0 on June 8 and 9.2 on June 9. Past medical history also included diagnoses of obesity and hypertension. She was also taking atenolol, norvasc, folic acid, pantoprazole and felodipine.