Guidance Manual for Pharmacovigilance focal points in Healthcare facilities in the Arab Republic of Egypt

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1. Objective

This manual aims to support the pharmacovigilance practice in the healthcare facilities in the Arab Republic of Egypt and ensures its consistency with the international regulations, especially the requirements of the World Health Organization.

2. Scope:

- This manual is concerned with the pharmacovigilance system and processes within healthcare facilities but not the technical knowledge of pharmacovigilance
- For more details about pharmacovigilance, please refer to the official website of Egyptian Drug Authority for the Guidelines for detecting and reporting of adverse reactions for Pharmaceutical products and Medical .

3. Pharmacovigilance role in patient safety

- The pharmacovigilance is one of the major pillars for patient and medication safety in healthcare facilities.
- It falls on the shoulder of the healthcare facility management to assure that all healthcare professionals within the facility are familiar with the principles and concepts of pharmacovigilance and reporting mechanisms. The management should also work towards increasing the awareness of medicine safety, as well as providing the necessary support to the pharmacovigilance focal points to carry out the tasks of monitoring and following up adverse events within the healthcare facility.

4. Nomination and allocation of pharmacovigilance focal point

1) The hospital management shall allocate a qualified pharmacist or more to assume the responsibilities of pharmacovigilance within the healthcare facility. It's preferred for the pharmacovigilance team to include two pharmacists, one as the primary focal point and supervisor of the pharmacovigilance work within the facility and the other shall work as a deputy and a team member, in accordance with the recruitment plan, work load and the size of the health facility.
2) The basic qualifications to be taken into consideration when selecting the focal points:

- The technical competency, those with experience in clinical pharmacy are preferred.
- Good knowledge with the programs (power point, excel and word)
- The focal points needs to receive a qualifying training in pharmacovigilance.
- Effective communication skills.
- Commitment and discipline.

3) An administrative decree shall be issued to designate a focal point in the healthcare institute, that shall be published via the various means of communication among the staff within the facility.

4) The hospital management shall ensure that the focal point is well known to the staff, with a clear and easy routes of communication. The focal point's contact details (phone number, WhatsApp groups… etc.) should be published within the facility and well known among the staff members.

5) An announcement about pharmacovigilance in Arabic and English targeting the healthcare facility could be placed in the drug dispensing area. The announcement shall include: (A simple definition of pharmacovigilance, what, when and how to report adverse drug events).

6) Job performance of the focal point shall be evaluated periodically by the central pharmacovigilance coordinator (if any) or the facility's management. The evaluation result shall be documented.

7) The focal point needs:
   - Computer connected to the Internet;
   - Office; and
   - Printer + papers.

5. Role of the pharmacovigilance focal point in healthcare facilities

5.1. Role of focal point in preparing the PV policy and the standard operating procedures (SOPs)

The focal points for pharmacovigilance shall formulate the pharmacovigilance policy and the pharmacovigilance the standard operating procedures (SOPs) within the healthcare facility. Ideally, the policy shall contain the following:

- The purpose

- Related pharmacovigilance definitions
- The scope
- The mechanism of detection and reporting of adverse events within the facility.
- Who can report?
- When to report?
- Adverse Events cases validation
- How to prevent preventable adverse events and implementing corrective measures when needed.
- Follow up mechanism with healthcare professionals to complete the information of the reported cases when needed.
- A flow chart showing the steps from detecting the adverse event to sending the report to the national pharmacovigilance database in the Egyptian Drug Authority. **(See annex (1))**
- Mechanism for classifying the adverse events to serious and non-serious and how to prioritize the work accordingly.
- The reporting timelines
- How to share the feedback and comments from the Egyptian Drug Authority to the reporters and other health care professionals.
- The policy effective date update date.
- References and resources.
- Appendixes: Contain the forms to work with

5.2. The pharmacovigilance focal point role in the Drug Committee

- The pharmacovigilance focal point or a representative shall attend the drug committee and discuss the topics related to pharmacovigilance and drug safety.
- Documenting of the subject and the resulted recommendations and outcome in the committee meeting minutes.
- A clear communication channel shall be present between the focal point and the Drug Committee.

- The previous articles shall be explicitly stated in the committee's terms of reference or in the pharmacovigilance SOPs .
- Documentation of the subject related to pharmacovigilance and drug safety presented to the committee and decisions taken by the Drug Committee. **(See template (2))**

5.3. The role of pharmacovigilance focal point as a contact point inside and outside the healthcare facility

- The focal point shall receive all reports related to drug and patient safety from various sources (patients and healthcare professionals) within the healthcare facility.
- The focal point shall encourage and motivate patients and healthcare professionals to report drug and patient safety problems.
- The pharmacovigilance focal points shall work to clarify the pharmacovigilance scope within the health facility, which includes, but is not limited to, suspicion of adverse events, quality issues associated with adverse events, lack of drug effect and medication error associated with adverse events.
- Yellow card forms shall be popularized among healthcare professionals and kept after filling them out.
- The focal point shall acknowledge the reporter and work to overcome obstacles or fears that would limit reporting.
- The focal point, in addition to the drug information center (if present), can answer patients and healthcare professionals safety and medicine related inquiries.
- The qualified person for pharmacovigilance shall represent the drug and patient safety file within the Drug and Medicine Committee as well as he shall publish the procedures and activities approved by the committee.
- The qualified person for pharmacovigilance shall deliver the feedback/ comments (including the evaluation of causality) related to the report from the Egyptian Drug Authority to the reporter.
- The focal point shall disseminate EPVC's Newsletters, Safety alert and Direct Healthcare professional communications among healthcare professionals within the healthcare facility.

- The pharmacovigilance focal point shall work to increase awareness of precautions and preventive measures to assure patient safety. This can be achieved by preparing awareness flyers and disseminating it in available communication channels inside and outside the healthcare facility (WhatsApp and Facebook page).
- If the need arises to carry out investigations, the Egyptian Drug authority may request the assistance of the healthcare facility focal point in information collection in accurate and comprehensive manner after the coordination with the central coordinator (if present).
- The pharmacovigilance focal point shall participate in scientific conferences and publish what he deems appropriate based on the healthcare facility's experience in the pharmacovigilance field.

5.4. Role of Pharmacovigilance focal point in the training of Healthcare professionals

5.4.1. The focal point training:

- The pharmacovigilance focal point shall receive adequate training from the General Administration of Pharmaceutical Vigilance-EDA.
- The pharmacovigilance focal point should participate (if feasible) in the events and trainings offered by the Egyptian Drug Authority.
- The pharmacovigilance focal point shall document the trainings received and events attended to keep up with the new developments in the pharmacovigilance field.

5.4.2. Pharmacovigilance focal point role in training of staff members in healthcare facilities:

- The health facility's training plan shall include training on pharmacovigilance concepts and reporting mechanisms within the facility.
- The pharmacovigilance focal point shall prepare an annual training plan targeting all the stuff in the healthcare facility. **(See template (3))**
- All trainings shall include the basic concepts of pharmacovigilance and reporting mechanisms within the health facility, in addition to other topics that health care professional may need.

- Training on pharmacovigilance concepts shall be included in the new employees' training program/induction training and is provided within 1 month of employment.
- The pharmacovigilance focal point shall work in cooperation with the pharmacy team and the health facility management to establish the activities and events that address pharmacovigilance topics and measures that enhance patient safety.
- It's recommended for the healthcare facility to participate in events and activities directed to the community in general (for example: the Patient Safety Week, … etc.).
- The pharmacovigilance focal point shall document all training activities through attendance sheets and photographs and retain them. It is preferable to conduct a pre- and post-training evaluation/test and document its results.

5.5. Follow up and documentation mechanisms

5.5.1. Follow up with the reporter:

- The pharmacovigilance focal point shall follow up with the reporter to complete the case's important information .
- The pharmacovigilance focal point shall update the case reports by the additionally obtained information.
- The pharmacovigilance focal point shall follows up the with the central coordinator (if present) with regard to reported cases.
- The pharmacovigilance focal point shall provide the initial causality assessment to the reporter.

5.5.2. Comprehensive follow-up of progress in pharmacovigilance in the healthcare facility:

- The pharmacovigilance focal point shall create a tracker -an excel sheet- for follow up of reported cases in the healthcare facility. **(See template (4))**
- The tracker shall contain the following:
  - The Case code in the healthcare facility **(See template (5))**.

- The case ID is the national adverse events database of the General Administration of Pharmaceutical vigilance- Egyptian Drug Authority
- The reporter.
- Date of report
- Report type (adverse event, or quality issue, …etc.).
- Report seriousness
- The case narrative (complete sequence and context of the adverse effect).
- The feedback/ comments on the case report including the causality assessment.

5.5.3. The importance of documentation:

- In general, it is necessary and fundamental in the pharmacovigilance policy to document all pharmacovigilance related details, procedures, activities and events.
- The pharmacovigilance focal shall monitor and document how the pharmacovigilance activity participate in rationalizing the pharmaceutical practices in the healthcare facility.

5.6. The Role of Pharmacovigilance focal point in data analysis

- It is recommended for the pharmacovigilance focal point to conduct an initial analysis of the reported cases at the facility level using the available files and template to answer the following questions:
  - Number of serious cases reported monthly and annually.
  - Number and classification of reports submitted monthly and annually.
  - Number of reports that have already been sent to the national database of pharmacovigilance.
  - Number of reports that have not been sent and the reasons for that.
  - Number of communication with the General Administration of Pharmaceutical vigilance and the used mechanisms.

- The number of inquiries received regarding the safety of the medicine and patient monthly and annually.
- The pattern/trends of recurring problems, analysis of their causes and the possibility for prevention.

- The pharmacovigilance focal points shall review the results and proposals produced by this analysis of collected data and shall present those during the Drug Committee meetings on a periodic basis or upon request.
- Proposing preventing and corrective measures for problems raised to the Drug Committee along with methods and mechanisms for implementing those measure in order to enhance patient safety.

6. Required documents

Accordingly, the pharmacovigilance focal point at the healthcare facility is required to have the following documents ready when required:

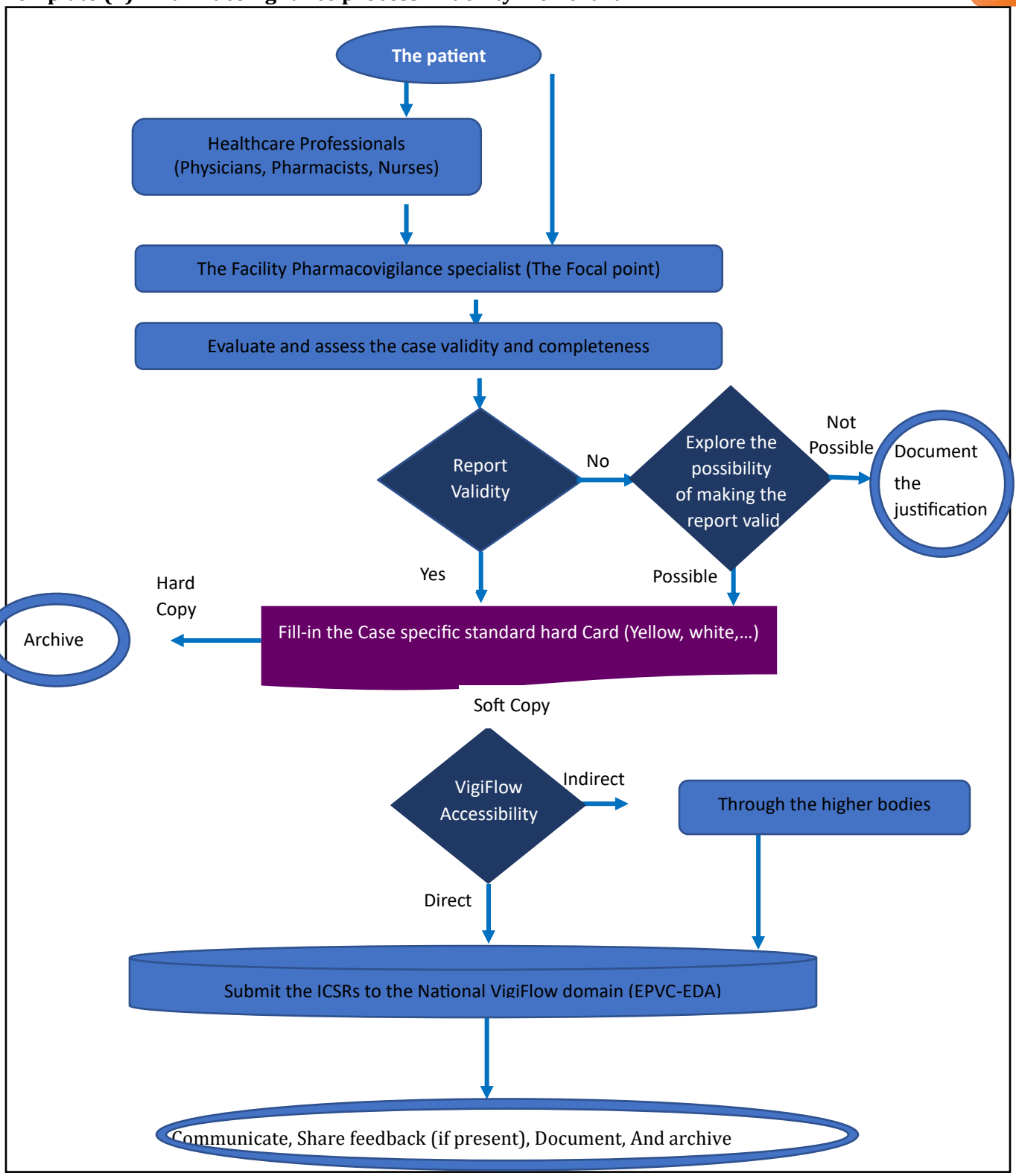
- pharmacovigilance focal point CV.
- The administrative decree assigning the focal point to work in pharmacovigilance.
- Certificates, training records and evidence proving that the focal point received the required training.
- The Pharmacovigilance policy within the healthcare facility.
- A flow chart for pharmacovigilance activities in the healthcare facility.
- Keeping/archiving the yellow cards after filling them out.
- The tracker (Excel) for tracking reports at their various phases.
- The terms of reference of the Drug Committee.
- Meeting Minutes of Drug Committee meetings that discussed medicine safety in the healthcare facility.
- Health facility's pharmacovigilance training plan.
- The new employees' training program/induction training .
- Awareness flyers.
- A combined file of the inquiries received and answered by the focal point at the healthcare facility. **(See template (6))**

- Training records/ list of attendees and evidence of training plan implementation in a combined file showing the trainees and their specializations. **(See template (7)).**
- Photographs documenting activities and events.

References:

WHO: Interim manual for the performance evaluation of regulatory authorities seeking the design as WHO listed authorities

Template (1): Pharmacovigilance process – Facility Flowchart



Template (2) DTC pharmacovigilance-related activities documentation form:

No.	Date	Kind of activity	Purpose of activity

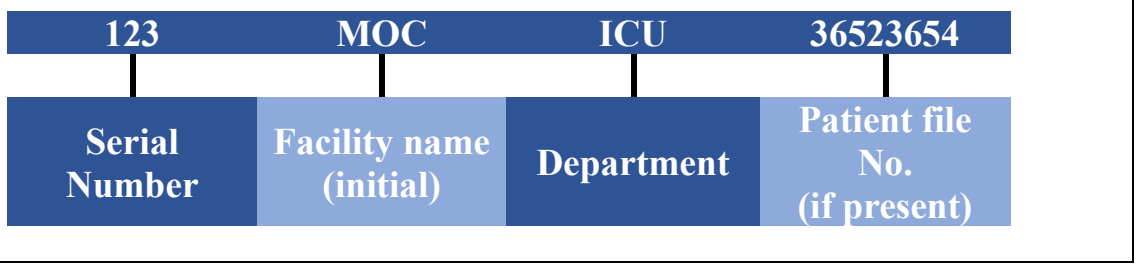
Template (3) PV Unit Annual training plane

Plan set before beginning of the year						Filled during proceeding and implementing the plan		
Month	**Subject**	**Targeted audience**	**Trainer**	**Training mechanism** (lecture or awareness session)	**Expected date for implementation**	**Actual date for implementation**	**Number of attendees**	**Documentation and notes**
January	**Vigilance concepts & reporting mechanism**	**Physicians & Pharmacist**	**Focal point**	**Lecture**	**During the first week of the month**	**Jan. 3rd, 2023**	**15 Physicians & Pharmacist**	**records of attendees attached**
	Vigilance concepts & reporting mechanism	**Nurses**		**Awareness session**	**During the second week of the month**	**Jan. 9th, 2023**	**7 intensive care nurses**	**records of attendees attached**
February								
March								
April								
May								
June								
July								
September								
August								
October								
November								
December								

Template (4) Reporting Tracker:

Report internal code	Vigi. Flow ID	Initial Reporter	Date of report	Report type (ADRs/ Quality/ ME)	Report Seriousness	Case Narrative	Feedback (Yes / No)	Causality Assessment

Template (5) Health facility – Report internal code structure (guide):



Template (6): Drug information safety-related request (collective Form)

Requester (HCP or Patients)	Phone Number	Department	Date	The Question	The answer	References

Template (6): Training Tracker sheet (for HCPs)

No.	Date	Training topic	Training Purpose	Target audiences	Number of attendees	Presented by

Template (8): the yellow card for reporting adverse events

Central administration of Pharmaceutical care
Egyptian Pharmaceutical Vigilance Center

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

Patient 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
- Patient Condition (Outcome): □Recovered □ Not recovered □Recovering □ Recovered with sequelae □ Fatal
- 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 while (concurrently) administered *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 (Medical history "eg: chronic diseases", other diseases, allergies):

- *The information in this report is confidential and totally protected including both the Patient and Reporter identity.*
- *Contact details required to complete the case information if necessary.*
- *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: 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 25354100/ (+2)02 23684288/ (+2)02 23648046/ (+2)02 23640368/ (+2)02 23648769
Extension (Tel): 1409 **Extension (Fax):** 1300
Fax: +2 02 23684194
Website: www.edaegypt.gov.eg
e-mail: pv.report@edaegypt.gov.eg
eReporting: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=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:** pv.alex@edaegypt.gov.eg
- **Cairo Regional Center:** Al-Azhar new specialized hospital 6th district Nasr City-Cairo. **e-mail:** pv.cairo@edaegypt.gov.eg
- **Sohag Regional Center:** The old building of the Health Affairs Directorate- 2nd floor- next to the security directorate building- Nasser city- Sohag
  e-mail: pv.sohag@edaegypt.gov.eg

Template (9): template for reporting adverse events following Immunization

Adverse Events following Immunization form

Month **Year**
Governorate: …… Administration**:……**
Vaccination Unit: …… Reporting date: ……

Case name:	Local No.:
National ID:	(by EPI for serious cases only)
Address:	
Sex :	
Birth date: / /	Age:
Date of symptoms onset: / /	
The symptoms:	

Suspected vaccine	Batch No.	Expiry date	Date of last dose

Reporting entity: Tel. No.:
Name of reporter: E-mail:

Template (10): Template of reporting medical device incidents

Central Administration of Pharmaceutical Care
Medical Devices Safety Department

Medical Device Incident User Report Form

I. Patient Information			
Name/Initials:	Sex: □ Male □ Female	Weight: KG	Age:
II. Medical Device Information			
Name of Medial Device:		Type of Medical Device (e.g. Pacemaker):	
Manufacture Date:		Expiry Date:	
Reference/Registration No.:		Code/Model No.:	
Catalogue No.:	Lot/Batch No.:	Serial No.:	
Manufacturer Name: Address: Phone:		Supplier Name: Address: Phone:	
Quantity Defective (Number):		Current Location:	
Has the manufacturer/supplier been contacted? □ Yes □ No (Keep the device till be requested by the supplier - Please Do Not Discard the device or related consumables & packaging - Do not send medical devices to MDSD/EDA unless you have been specifically requested to do so)			
III. Incident Information			
Incident Description/Nature of Device Defect (includes any action by patient, carer or healthcare professional, or by the manufacturer or supplier):			
Action Taken:			
Type of Injury: □ Death □ Serious □ Non-serious □ None		Date of Incident:	

Central Administration of Pharmaceutical Care
Medical Devices Safety Department

Medical Device Incident User Report Form

IV. Reporter Information (Will Be Kept Confidential)	
Reporter's Name:	Position/Occupation:
Organization:	Address:
Phone/Mobile No.:	Email:
V. Other Comments:	

Head Quarter:
Medical Device Safety Department (MDSD)
Pharmaceutical Vigilance Administration
The Egyptian Drug Authority (EDA)

Address: 21 Abdel Aziz Al Soud Manial Al Roda, PO Box: 11451, Cairo, Egypt
Tel: +202 – 23684288 +202 - 23640368 **Ext.:** 1311
Fax: +202 - 23684194 +202 -23610497

Website: www.edaegypt.gov.eg
E-mail: pv.md@edaegypt.gov.eg

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Cairo Regional Center:
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E-mail: pv.cairo@edaegypt.gov.eg

Sohag Regional Center:
Address: Health Affairs Directorate, the old building, 2nd floor next to the Security Directorate, Nasir City, Sohag
Email: pv.sohag@edaegypt.gov.eg