Frequently Asked Questions (FAQs) – Regarding the Pharmaceutical Vigilance General Administration (PVGA)

❖ Frequently Asked Questions Regarding Pharmaceutical Vigilance General Administration (PVGA) reception reservation:

☒ What are the advantages of electronic submission?

- Facilitating the submission process for companies and optimizing the use of time and effort.
- Providing an opportunity for a larger number of companies to submit files throughout the week.
- Eliminating the need for physical attendance at the Pharmaceutical Vigilance General administration to submit files.

☒ What is the available number of reservations at the pharmacovigilance reception?

There is no maximum limit for submission on vigilance links, except for the vigilance link specific to Reg/Re-Reg Reception for Human Medicine only, which allows the submission of only 5 files per day.

☒ What are the available days for electronic files submission on PV reception?

The pharmacovigilance reception (all links) operates daily from Sunday to Thursday except the medical device safety reception on Sunday only.

☒ When does the electronic portal open for file submission to be assessed?

The portal opens and file submission is available daily (from Sunday to Thursday) from 9:00 AM and automatically closes at 10:00 AM except Compliance follow up Reception is from 09:00 AM to 11:00 AM and medical devise safety reception from 9:00 AM to 3:00

☒ Why is it required to enter product-specific data in the electronic link?

The purpose of entering this data by QPPV is to ensure proper identification of the submitted documents and their submission context, which positively impacts the receipt and assessment process

☒ What are the consequences of not entering product-specific data in the electronic link?

If the product-specific data is not entered correctly and completely for each product, the file submitted by the company will not be received.

☒ Can I submit files related to DHPCs/emerging safety issues/signals via email?

- Please note that notifying PVGA with such files via email is not considered an official notification, and that PVGA email isn't designated for this purpose. In addition, the PVGA email capacity isn't large enough to receive such files.
- Furthermore, companies must also have a mechanism for classifying the information that needs to be reported to the regulatory authority in writing, according to the criteria related to the principles of Good Pharmacovigilance Practice (GVP) in Egypt.

☒ What are the practices that may hinder the receipt process at the pharmacovigilance reception and may lead to the cancelation of the whole submission process?

- Submission of a different file from the one whose data was entered on the portal.
- Submission of files on a wrong portal.

- Submission/Reservation of more than five files for the same PV system on the Re/Re-reg reception for human medicine only.
- Not entering the full required data
- Entering inaccurate data or "Dummy Data" in the submission form, for example, but not limited to:
    - Entering symbols (such as @#^or ….) or zero in the fields designated for Application Number, The ATC code or any of the other required fields.
    - Selecting an incorrect Procedure Type.
    - Writing the QPPV's name instead of the company's name (PV representative field) in the designated field.
    - Confusion between the name of the MAH and the PV representative.
    - Entering a different active ingredient name or N/A.
    - Entering an incorrect email address in the email address field.
- Sending an electronic link that is empty, non-functional, or in a non-downloadable format.
- Sending a link secured by a password without mentioning the password in the submission form.
- Not submitting all required documents for the reception process according to the latest Checklist for each submission framework.
- Regarding amendments: submission on the deadline day without fulfilling all of the requirements mentioned in the PVGA letter.

Please note that the data entered is for the Submission application, and therefore, accuracy must be exercised in entering the data and its conformity with the submitted documents, Approval Box, or Referral Letter, or the previous PVGA letter, and any contradiction may lead to rejection of submission.

☒ What will be the consequences of non-compliant practices by some companies?

If any non-compliant practices are observed by PVGA from the company, they will be registered as (Non-compliance) in the PVGA database, and their repetition may lead to non-reception.

☒ What should companies do to facilitate the submission process?

- Ensure proper planning of work and submit files well before the deadlines.
- Verify that all documents and attachments required for submission are complete.
- Ensure that submitted files are free from viruses.
- Ensure that the required registration/submission data is entered completely, accurately, and only by QPPV. Inaccurate or "dummy" data may result in cancellation of the company's reservation.
- Enter a correct email address, as confirmation of file receipt or rejection will be sent by PVGA to this email.
- Ensure consistency between entered data and the attached documents.
- For amendments, ensure that all requirements stated in the PVGA's letter are fulfilled. Otherwise, the file will be rejected, even if submitted on the deadline date.
- Companies must strictly adhere to submission deadlines (both initial submissions and amendments).
- Regularly refer to the latest Checklist and all documents published on the PVGA registration/ electronic submission page through the following link:
  👉 https://sites.google.com/view/pvcenter/epvc-reception

⚠ **Important Note:**
In case the company receives an email indicating non-completion of the submission process (due to the missing of some requirements), it is considered completely canceled, and the company must re-submit the complete documents before the deadline

(Any previously rejected submission will not be considered, and it is strictly prohibited to submit incomplete files merely to claim submission before or on the deadline).

☒ What are the prescribed fees for files submitted to the Pharmaceutical Vigilance General Administration (PVGA)?

Companies must refer the decision of the Chairman of the Egyptian Drug Authority No. (6) for the year 2021 and No. (99) for the year 2022 regarding the payment of fees for services provided by the Central Administration for Pharmaceutical Care, specifically for files submitted to the Pharmaceutical Vigilance General Administration (PVGA).

☒ What should companies submit regarding payment receipts?

Companies must provide payment receipts showing the following:

- The Central Administration providing the service (Central Administration for Pharmaceutical Care).
- The service applicant (company name).
- The service name.
- The service fee.
- The collective number.
- The individual number used in the submission (each individual number can only be used once).

⚠ *Important Note:* Receipts must be submitted in the name of the Marketing Authorization Holder (MAH).

❖ Frequently Asked Questions Regarding Receiving Letters Issued by the Pharmaceutical Vigilance General Administration

☒ How are issued letters announced?

- Lists of companies for which official letters have been issued are published (one list for companies with letters that include deadlines, and another list for letters without specified deadlines) through the following link:
  ☞ https://sites.google.com/view/pvcenter
- Companies must monitor the lists on a daily basis to ensure not exceeding the stipulated deadline mentioned in some letters, noting that the maximum period allowed for receiving is two weeks.

☒ When are these lists updated?

The lists are updated daily.

☒ What is the designated time for companies to receive their issued letters?

The designated time for companies to receive their issued letters from the Pharmaceutical Vigilance General Administration (PVGA) is from 11:00 AM to 12:00 PM.

☒ What should companies present when receiving issued letters (for files submitted at the PVGA reception with a payment receipt, based on EDA Chairman's Decree No. 6/2021 and Decree No. 99/2022)?

Companies must retain a stamped copy of the payment receipt and present it to the Pharmaceutical Vigilance General Administration (PVGA) when receiving the letter related to the paid receipt.

❖ Frequently Asked Questions Regarding Company Inquiries:

☒ What is the designated time for company inquiries?

Tuesday of each week is designated to answer company inquiries on the administration's telephone line from **12:00 PM to 3:00 PM**.

How can companies contact the Pharmaceutical Vigilance General Administration (PVGA)?

- For communication with the **RMP team**, please call extension **1475**.
- For communication with the **Master File team**, please call extension **1471**.
- For communication with the **post-marketing team**, please call extension **1470**.
- For communication with the **Medical Device team**, please call extension **1476**.
- For communication with the **PV inspection team**, please call extension **1471**

❖ Frequently Asked Questions regarding registration/re-registration dossiers for human medicinal products:

What pharmacovigilance documents are required according to Decree 296 and the approval of the Chairman of the Egyptian Drug Authority dated 02-03-2021?
Companies holding a final license under any of the decisions (296/2009, 370/2006, 645/2012, …) with the Chairman's approval dated 02-03-2021 must submit:

- Final registration license
- Risk Management Plan (RMP) of the product
- Pharmacovigilance System Master File (PSMF) document and its summary

What should be submitted for the registration of imported products in case the Periodic Benefit-Risk Evaluation Report (PBRER) or the Risk Management Plan (RMP) is not available?
The company must provide a justified declaration stating the absence of the document, signed by the Marketing Authorization Holder (MAH) abroad.

What should be submitted for re-registration if the product has not been marketed in the Egyptian market?
The company must provide an official statement confirming that the product has not been

marketed in Egypt and has not been supplied via tenders. This statement must be on MAH official paper and signed by the CEO.

What documents are required for submission according to decree 600/2018 "From to tentative to final license"?
The company must submit:

- Final registration license
- Tentative registration license
- Addendum to Clinical Overview (ACO)
- Risk Management Plan (RMP)
- Pharmacovigilance System Master File (PSMF) document and its summary

What should be submitted if the company exceeds the deadline for submitting re-registration documents?
The company must submit:

- Appeal letter
- Registration license
- Re-registration action letter
- Corrective and Preventive Actions (CAPA)
- Root Cause Analysis (RCA)
- Evidence of CAPA implementation

What documents are required to fulfill the license PV condition for products under additional monitoring (i.e., products with an inverted black triangle in the leaflet) or in case of the Chairman's approval dated 02-03-2021?
The company must submit:

- Registration license that includes the pharmacovigilance requirements condition
- Risk Management Plan (RMP)
- Pharmacovigilance System Master File (PSMF) document and summary

What is required in case of product ownership transfer?
The following must be provided:

- From the previous MAH: Certificate/statement confirming transfer of ownership, on MAH paper, signed by the CEO of the Marketing Authorization Holder (MAH).
- From the new MAH: Certificate/statement confirming receipt of ownership, on MAH paper, signed by the CEO of the Marketing Authorization Holder (MAH).
- Registration license
- Approval from the concerned department within the EDA for transfer of ownership

Is there an official website or link to follow up pharmacovigilance-related regulations?
Yes. For updates, alerts, guidance, announcements, and FAQs, use the following link: https://drive.google.com/drive/folders/1i5N62hbEJ3RD1B4W1x0QZQY59bnisDZc?usp=sharing

❖ Frequently Asked Questions regarding registration/re-registration dossiers for biological medicinal products:

How should companies submit pharmacovigilance requirements for biological products during registration?

- For first-time submissions: Reserve an appointment at the Administration of Registration to submit the full dossier (including PV requirements).
- For PV amendments requests issued by the PVGA, the company must respond electronically before the deadline stated in the letter.

What are the applicable fees for PV requirements in the context of registration?
Companies must refer to EDA Chairman Decisions No. 6/2021 and 99/2022 regarding service fees payable to the Central Administration for Pharmaceutical Care. Payment receipts must include the product name and company name.

How can companies follow up on the PV Department's evaluation of PV requirements in registration?

- After submission, the PV Department evaluates the documents and issues an official reply letter.
- If further requirements are needed by the PV department, the reply specifies a deadline for submission. The company must comply within the stated deadline and submit via the Biological product safety unit reception portal.

- If a final evaluation is issued, the PV Department sends an internal report to the Administration of Registration and issues a final assessment letter to the company (no deadline, no response required).

How should Pharmacovigilance System Master File (PSMF) document requirements be submitted in registration and re-registration?

In accordance with EDA Chairman Decision 6/2021, companies must submit the PSMF assessment report, or the Pharmacovigilance System Master File (PSMF) document requirements and pay the applicable fees. They must then attach the confirmation email issued by the PV System reception to the PV documents included in the registration/re-registration dossier. The Biological product safety unit will not accept PV documents without this confirmation email.

❖ Frequently Asked Questions regarding PV system:

Why is it necessary to provide Pharmacovigilance Agreements / Safety Data Exchange Agreements (SDEA / PV), and what are the requirements?

- The need to provide SDEA / PV agreements lies in the accurate definition of the responsibilities of each party in a way that ensures the performance and implementation of all pharmacovigilance activities and requirements, thereby ensuring proper follow-up of the product's safety profile.
- The requirements of any agreement are divided into two parts:
    1. Technical Part: Specifies in detail the pharmacovigilance activities to be performed by each party.
    2. Legal Part: Subdivided into two aspects:
        - Signature of the responsible and authorized signatory from each party involved in any pharmacovigilance activity.

- Authentication of the signatures by a legal entity (Bank, Embassy, Egyptian Drug Authority, etc.).

What is the importance of the Pharmacovigilance System Master File (PSMF)?

The PSMF is a descriptive document that reflects the robustness and effectiveness of the company's pharmacovigilance system in monitoring all its products (registered or under registration). It also demonstrates the company's ability to carry out all activities related to the safety of its products and to monitor any updates or changes related to them.

Why must the Pharmacovigilance Officer have sufficient authority in the company, and why must they be fully dedicated?

- The Pharmacovigilance Department must have a high level of authority that enables it to take any decision or action promptly, without delay or conflict with the views of other departments within the company.
- The Pharmacovigilance Officer must be fully dedicated to PV tasks only, in order to ensure effective, accurate, and proactive monitoring of products and safety updates, and to avoid conflicts of interest that may arise when making decisions aimed at ensuring the safe use of medicines and protecting public health.

Why is it necessary for a company, including small entities and toll manufacturers, to have a Quality Department?

The importance of having a Quality / Quality Assurance Department in the company lies in ensuring the monitoring of performance indicators across all departments, including Pharmacovigilance, in a way that guarantees compliance with applicable and mandatory standards issued by regulatory authorities. It also helps identify deficiencies, provide guidance for improvement, and monitor the implementation of corrective actions taken in this regard.

Frequently Asked Questions Regarding Pharmacovigilance Inspection:

What are the submission requirements related to pharmacovigilance system inspection?

The required submission documents vary depending on the type and reason for the inspection as specified in the official communication addressed to the Marketing Authorization Holder **(MAH)** or the **third-party** service provider by the General Administration of Pharmacovigilance.

The company is required to submit pre-inspection requirements (RFIs) as communicated by the General Administration of Pharmacovigilance. The submission should include the following:

1. **Cover letter** (on the company's official letterhead), listing all attached documents, including submission date. It must be:
    - Signed by hand by the responsible pharmacovigilance officer.
    - Stamped with the official company seal.
2. **Copy of the official inspection notification letter** issued by the Pharmacovigilance Department (titled: " Inspection PV Notification ").
3. **Pre-inspection requirements (RFIs):**
    - All requested lists must be submitted in Excel format, ensuring that they are searchable and navigable.
    - Sheets must be numbered according to the RFIs checklist provided.
4. If any required document is unavailable, the company must clarify this in the cover letter.

How are the inspection results received?

Lists of companies that have received official letters are published at the following link:

👉 http://sites.google.com/view/pvcenter

Companies must check the list daily to ensure they do not miss any deadlines specified in the letters.

Frequently Asked Questions Regarding PBRER:

1. **In case the product is registered but not marketed what is the requirement regarding the submission of the Periodic benefit risk evaluation report (PBRER)?**

   The PBRER document should be submitted according to the submission date stated in the EURD list or the EDA supplementary list in addition to recently dated **statement signed (on MAH official paper) by CEO declaring** that the product is not launched yet, never been marketed or sold by any tenders.

2. **In case the active ingredient or the combination of active ingredient are not stated in EURD list or the EDA supplementary list what is the requirement regarding the submission of the Periodic benefit risk evaluation report (PBRER)?**

   In case the active ingredient or the combination of active ingredient are neither present in the EURD list nor in the EDA PBRER supplementary list the MAH should submit a PBRER cycle proposal according to the nearest active ingredient or the combination of active ingredient to be approved by PVGA, then PVGA will add the approved PBRER proposal cycle in the EDA PBRER supplementary list.

3. **In case the active ingredient is stated in both the EURD list and the EDA supplementary list what is the PBRER cycle that the MAH should follows?**

   The MAH should follows the PBRER cycle stated in the EDA PBRER supplementary list.

4. **What is the method of calculation of estimate patient exposure?**
   MAH can use the following equations as guidance:
   - Patient treatment days = no. of mg sold / No of mg per day (defined daily dose)
   - Patient treatment years =Patient treatment days /365.25

   Note: Patient treatment days/patient treatment years is the most common unit to calculate exposure, but for some products this might not apply and the exposure can be calculated by other means

   MAH should calculate the estimate patient exposure during the PBRER reporting interval (Interval) and since the marketing date of the product till the DLP of the submitted PBRER document (Cumulative).

5. **What is the data that should be included under section "Changes to reference safety information"?**
   - According to the guidelines this part MAH should state:
   - The reference of their approved SPC and its approval date.
   - The significant changes made to the Reference Information (RI) for your own product during the period covered by the PBRER. **A track changes version of the document identifying the changes made should be included.**
6. **What is the data that should be included under section "Benefit risk context medical need and important alternatives"?**

   According to Egyptian GVP, this section should provide a brief description of the medical need for the medicinal product in the authorized indications and summarized alternatives (medical, surgical or other; including no treatment).

7. **In case different concentrations or dosage forms for an active ingredient or combination of active ingredients should be submitted is it required to submit a separate the Periodic benefit risk evaluation report (PBRER) document for each dosage form or different concentration with a separate receipt?**

   All the dosage forms or concentration of an active ingredient or combination of active ingredients that are stated in the same entry in the EURD list or the EDA PBRER supplementary list should be submitted in one PBRER document with one receipt.

8. **In case the registration license of a product is expired is it required from MAH to submit a Periodic benefit risk evaluation report (PBRER) document?**

   MAH is required to submit a PBRER document even if the registration license is expired as long as there is no official cancelation released from EDA for the product.

9. **In case the dates (DLP and submission date) stated in the EURD list or the EDA PBRER supplementary list changed before the DLP of the active ingredients, is it required that MAH should submit the PBRER document on the old dates of submission?**

   MAH is required to submit the PBRER document on the new dates of submission such that the submitted PBRER document should include the data from the DLP stated in the previous submitted PBRER document till the new DLP stated in the EURD list or the EDA PBRER supplementary list.

Frequently Asked Questions Regarding Emergency Safety Issues:

1. What documents are required for each type of safety communication that companies must notify the Pharmaceutical Vigilance General Administration?

Safety communication types	Required documents
1- Examples of Emerging Safety Issues (ESI) (not limited to the following): ▪ Major safety issues identified in the context of ongoing or newly completed studies, e.g. an unexpectedly increased rate of fatal or life-threatening adverse events. ▪ Major safety issues identified through the spontaneous reporting system or publications in the scientific literature, which may lead to considering a contraindication, a restriction of use of a pharmaceutical product or its withdrawal from the market. ▪ Major safety-related regulatory actions outside Egypt, e.g. a restriction of use of a pharmaceutical product or its suspension. ▪ Major safety issues may be foreseen due to shortage or lack of supply of products or raw materials. ▪ Validated /Confirmed signals (of carcinogenicity or teratogenicity/life threatening). ▪ Confirmed signals (if it meets the criteria of ESI after being assessed by the MAH).	▪ Cover letter signed by QPPV (template of it found on EPVC Portal) ▪ Notification Letter: The document should indicate the following: * Whether it was spotted in Egypt or not. * MAHs' proposed action in Egypt regarding this safety issue based on the information collected from Egypt and Globally. * MAHs' evaluation of this safety issue and its impact on the Egyptian market. ▪ Reference of safety notification as PDF or active link (translated to English if needed). ▪ The most recent SmPC accredited (Stamped) as searchable PDF.
2- Direct Health Care Professional Communication (DHPC)	▪ Cover letter signed by QPPV (template of it found on EPVC Portal) ▪ Reference of DHPC as PDF (translated if not in English form) ▪ Company proposed action from DHPC distribution ▪ Company DHPC draft ▪ Communication plan including 1. Distribution list 2. Distribution mechanism

	3. Distribution time frame
3- Examples of Other Safety Issues (OSI) (not limited to the following): ▪ Label update which will be / newly added in certain sections *Warnings & Precaution *Adverse events *Drug interaction with specified risk *Contraindication *Restriction of use ▪ Safety Notification published by another Reference Regulatory Authorities regarding a safety issue which is already included in the label due to increase in reporting as in this situation EDA may take regulatory action suits with this safety issue. ▪ Quality issues (Impurities / Counterfeit / falsified) with adverse events only unless they meet the definition of ESI. N.B: All safety-related changes requested by Other Reference Regulatory Authorities to the product label that are classified as OSIs require submission to the PVGA (Safety Issues unit) , regardless whether MAH agree with the conclusions or recommendations of the regulator and any justification for no further action in Egypt should be included with the OSI notification to the PVGA	▪ Cover letter signed by QPPV (template of it found on EPVC Portal) ▪ Source or the Reference of this safety Issue as hyperactive link or searchable PDF. (translated to English if needed) ▪ The most updated SmPC approved by the Egyptian Drug Authority, along with searchable PDF/word of SmPC (Not PIL) ▪ Assessment report (for OSI) regarding the safety issue referring to PVGA assessment report template (For local MAHs).

2. **What are the required timelines for notifying each type of an Emerging Safety Issue (ESI)?**

- **Emerging Safety Issues:** Within **5 working days** from the date of publication by the reference authority.
- **Direct Healthcare Professional Communications (DHPC**): **Within 5 working days** from the date of publication by the reference authority.
- **Other Safety Issues (OSI):** Within **45 Calendar days** from the date of publication by the reference authority

3. **What are the daily hours for submitting files on ESI reception?**

Files are accepted daily on the EPVC portal from **9:00 AM** to **10:00 AM.**

Frequently Asked Questions Regarding ICSR:

1. What are the official channels for submitting ICSRs to pharmaceutical vigilance general administration (PVGA)?

- Email: Pv.report@edaegypt.gov.eg
- Online portal: https://sites.google.com/view/epvc-reporting/pharmaceutical-company-adverse-drug-event-reporting

2. What are the reporting timelines for ICSRs?

- Serious cases: within 15 calendar days from first awareness.
- Non-serious cases: within 90 calendar days from first awareness.

3. What are the reporting timelines for products approved under Emergency Use Authorization (EUA)?

The company is committed to monitoring and collecting local adverse effects and reporting them to the pharmacovigilance department promptly — within a maximum of 24 hours for serious adverse effects and 7 days for non-serious adverse effects — including cases of lack of efficacy, medication errors, and follow-up with the reporter using the Targeted Follow-Up Questionnaire (Mandatory ICSRs Follow-Up).

4. What is the minimum information required for a valid ICSR?

An ICSR is valid if it contains at least:

1. An identifiable patient
2. An identifiable reporter
3. A suspected product
4. An adverse event/reaction

5. Should suspected cases be reported even if causality is unconfirmed?

Yes. All suspected ADRs must be reported, whether or not a causal relationship has been proven.

6. Are "lack of efficacy" cases reportable?

- Yes, if the lack of effect results in a serious outcome (e.g., hospitalization, death).
- Yes, even if non-serious, when the product is critical (e.g., antimicrobials, vaccines, life-saving drugs).

7. Are medication errors, misuse, abuse, overdose, or off-label use reportable?

Yes, when associated with an adverse reaction.

8. Are special situations reportable (e.g., pregnancy, breastfeeding, pediatrics, geriatrics)?

Cases of exposure during these special situations should be reported only if there's adverse reaction occurred, otherwise those cases should be recorded to allow proper follow-up and inclusion in PBRER

9. Is narrative writing mandatory?

Yes. Each ICSR must include a clear narrative describing:
- Event chronology
- Patient history
- Concomitant medications
- Relevant test/lab results

10. How should follow-up information be submitted?

- As a follow-up report, clearly referencing the original case number.
- Highlight new or updated information (using follow-up CIOMS form or XML).

12. Are ICSRs identified from scientific literature reportable?

Yes. If a literature source describes a domestic and valid ICSR, it must be reported within the same timeline of the spontaneous reports according to Egyptian GVP

13. What formats are accepted for ICSR submission?

- CIOMS form
- XML format (preferred for electronic submission)

14. Which XML standard should be used?

- E2B (R2) or E2B (R3) (latest and preferred).

15. Is submission of follow-up reports mandatory?

-Yes. If significant follow-up data are obtained, a follow-up report must be submitted.

Frequently Asked Questions Regarding Signal:

1. **Do I have to receive a confirmatory email for the received submissions in signal reception?**
   - Regarding standalone signal notifications (signal reception-1), referring to the new Egyptian GVP guidelines, MAHs/PV representatives should not expect to receive a confirmatory email in case of completed submission; only keep the Google reply form received at the time of submission. Only email sent to MAHs/PV representatives in case of not completed submission within 5 working days.
   - Regarding signal reception-2 (inquiry reception), MAHs/PV representatives should expect to receive a confirmatory email in case of completed/ not completed submissions within 5 working days

2. **As an inquiry from the inspection unit to submit a CAPA for the signal notifications not submitted to signal reception-1. Should we resubmit a standalone signal notification in signal reception-1/ or as an inquiry reply in signal reception-2?.**

As a response to the PVGA inquiry or inspection team, the MAH could submit a CAPA with a list of signals not notified to PVGA in the Signal Reception-2. However, according to the new Egyptian GVP, the MAH only notifies the signal management unit of any validated/confirmed signals (within 45 calendar days) in PVGA's Signal Reception 1 (standalone signal notifications) as a routine PV activity.

Frequently Asked Questions Regarding Active surveillance:

1. **Steps for Conducting Active Surveillance?**

- The company must submit the study's protocol for review and approval by the Vigilance Committee.
- After the protocol has been approved, the company is required to obtain all necessary ethical approvals before beginning the study.
- The company must submit interim study reports during the study, as well as a final report with the results upon completion.

2. **What is a Communication Mechanism with the PVGA regarding Active Surveillance and Post-Marketing Studies?**

- Communication is to be conducted via email at: PV.activesurveillance.edaegypt.gov.eg

3. **Steps for Submitting a Meeting Request and Required Fees?**

- A meeting request must be submitted on company paper and signed by the QPPV and stamped.
- A payment receipt for the meeting fee must be submitted. The fee is EGP 1000 for local companies and EGP 2000 for international companies. The receipt must include the company's name and be stamped by the Pharmaceutical Care Department stamp.

Frequently Asked Questions Regarding compliance /follow up unit :

1) **In case of any obstacles during the distribution Process of educational materials, or the need to make change in the approved distribution plan (e.g. distribution method, the number of physicians)??**

A request must be submitted through the google link of the Compliance Unit, clearly indicating the required amendment in the distribution plan (with justification). This request should be submitted before the deadline for submitting the Progress Report.

If the request is submitted at the same day of deadline of the Progress Report, it will be recorded as a non-compliance in the Pharmacovigilance General Administration database.

2) **If the distribution of educational materials to healthcare professionals is not completed within the specified deadline and the required target percentage for the Progress Report is not achieved, what steps should be taken?**

The company must submit an Initial Progress Report covering the period from (the approval of the distribution plan by the concerned Unit to the Progress Report deadline), clearly stating the percentage achieved by that date.

An additional period will be granted by the Follow-up Unit to complete the distribution and submit the Final Progress Report based on the remaining percentage and the product's risk profile.

It should be noted that the minimum acceptable Percentage is 90% of the total approved distribution list.

3) **In case the distribution of educational materials is carried out by company medical representatives, and some of the physicians refuse to sign as proof of receipt, does this affect the company's compliance with pharmacovigilance requirements?**

When distribution is done by company medical representatives, collecting physicians' signatures is not mandatory. If a physician refuses to sign, it should be noted in the Excel sheet submitted with the Progress Report as "refused to sign."

The absence of proof of delivery does not affect the acceptance of the Progress Report when distribution is done via representatives. However, providing proof of delivery is mandatory in cases of distribution via WhatsApp (screenshot), post (acknowledgment receipt), or courier companies.

4) **Are companies still required to submit the Quarterly Oncology Report?**

No. However, companies must adhere to the Criteria established by the Pharmacovigilance General Administration for monitoring oncology and immunosuppressive products, as follows:

- For products which Periodic Benefit-Risk Evaluation Report (PBRERs) from 6 months up to 5 years:
Submission of the Periodic Benefit-Risk Evaluation Report (PBRER) is sufficient, with an attached annex including the list of hospitals where distribution took place, under the National Appendix (applicable to both local and international companies).

-For products PBRERs frequency (more than 5 years):
The PBRER frequency will be submitted every 5 years.
These products will also be added to the EDA Supplementary List, which companies must immediately comply with.

5) **What is required from the company in case of any non-compliance, such as failure to submit a document or late submission?**

The company must submit a CAPA Plan within the specified timeframe.
The CAPA Plan must:
- Be on company official paper and signed by both QPPV and Quality Department,
- Include the Root Cause of the issue,
- Detail the Corrective Actions (with evidence of implementation),
- Preventive Actions to avoid recurrence (with evidence of implementation).

6) **When a production line in a factory is Closed, a notification is issued to companies by the Follow-up Unit. What actions are required from the company?**

The main objective is to collect any adverse events related to products manufactured on this line (whether for the company itself or toll manufacturing).
A causality assessment must be conducted to determine whether the adverse events (particularly lack of efficacy) are linked to quality issues in the closed line or not.
The company must also submit the Plan and corrective actions to be taken until the production line can be reopened.