24 March 2021

توضيحات تتعلق بالقرارين الوزاريين رقم 180 و 181 الصادرين بتاريخ 2021/02/03

Clarifications regarding the Ministerial Decisions #180 & 181 released on 03/02/2021

When to Report

The report should be sent to **ONE** of the following emails:

pv@moph.gov.lb **OR** phvg.phar@ul.edu.lb

Drug Related Problems /Special Situations

- ✓ Any adverse events, Adverse Reactions, Side effects, Drug related problems should be reported.
- ✓ Drug related problems /Special Situations: medication errors, off-label use, misuse and abuse of drugs, Quality defects, medication errors, counterfeit products, interaction of medicines and lack of efficacy should be reported associated or not with Adverse Events.
- ✓ Special Situations with or without adverse events to be reported according to their seriousness timeline (15 or 90 days)
- ✓ In this situation when an adverse events is not associated, the reporting timelines of non-serious cases i.e. 90 days is to be respected

NB: As for the lack of efficacy cases, there is no need for reporting when there is an evidence and confirmation that the LOE is related to the disease progression (e.g. oncology cases).

Drug Registration

- ✓ Reporting of Adverse Events related to Registered and Marketed Products in Lebanon is to be done.
- ✓ In some cases such as donations, products supplied for personal use or any other source of non-registered products used in Lebanon where the patient has had an adverse event should be reported.

- ✓ A medicine having a local MA used by a patient in foreign country and where the patient has had an adverse event in this country should be reported.
- ✓ Since MAH needs to process and assess AEs prior to submitting them to the PV department/LNPVC, hence the 15 and 90 day rules apply to them. As per Article 4, the "immediate reporting" stated in article 3 - paragraph 4 concern all parties but mainly for HCPs to report cases immediately.

Interventional Studies

- ✓ **Foreign SUSARs** for Global interventional trials (WWSUSARs) where Lebanon is part of this study are submitted to Health Education Department and to the MoPH pharmacy Service. **(Article #6 of the Decision 1159/2014). The calendar days of submission depends on the requirements of the above mentioned department.**
- ✓ Domestic Serious Adverse Events (SAEs) arising from these global interventional studies are to be submitted to the MoPH pharmacy Service. **The calendar days of submission depends on the the department requirements.**
- ✓ For such Global interventional studies, Domestic Serious Adverse Events (SAEs) are to be submitted within 15 days timeline to the PV department pv@moph.gov.lb in ICH E2B R2 or R3 XML format. No worldwide SAEs need to be submitted. The SAE in question are these related to the Investigational Product.
- ✓ You should submit retrospectively (for years 2018, 2019 & 2020) all the domestic SAEs that occurred in Lebanon to the PV department pv@moph.gov.lb

Other type of Studies

- ✓ All AEs are to be reported no matter the source: Non interventional studies, Compassionate use, Pre approval Access programs, Patient Support programs, Market researches by following the 15 and 90 day seriousness timelines in ICH E2B R2 or R3 XML Format.

Reporting Timeline

- ✓ Serious Adverse Events should be reported within 15 days of the **date of reception of the report** (90 days for Non serious) means the **company received date** (Day 0) i.e. once the company was aware of the AE.

Follow up Reports

- ✓ Any type of Follow up should be reported even if these follow up reports do not include an Adverse Events. It could include event outcome or other relevant information
- ✓ A new form is to be sent mentioning that it is a follow up of a previous patient (Refer to our national form where there is a mention if it is a first or follow up report)

Submission format XML Files

- ✓ The reports should be sent into the format ICH E2B (R2 or R3) as XML file. It is a XML Folder (Electronic Submission using a Folder Structure) NOT a Gateway Solution
- ✓ No CIOMs nor line listing in excel format are acceptable as they are not compatible with our data management tool Vigiflow.
- ✓ Up to 99 ICSRs could be included in each XML file and one XML file in each email containing 99 ICSRs.
- ✓ You will receive "ackLog" documents or acknowledgments of the submitted reports at the end of each month

Good Pharmacovigilance Practice Guidelines

- ✓ Good Pharmacovigilance Practice Guideline for Pharmaceutical Companies, Marketing Authorization Holders and their Representatives is under preparation.
- ✓ MNC with Scientific Local Office in Lebanon: A Quality Person Representative for Pharmacovigilance (QPPV) is to be nominated to communicate and to coordinate with the PV at the MoPH. It will be supported by a regulation clarifying how to submit all related documents such as RMP, PSMF, PSUR, PBER, PAA and other documents.
- ✓ No Scientific Local Office in Lebanon: Local safety Representative (LSR) is to be nominated is to be nominated to communicate and to coordinate with the PV at the MoPH.

- ✓ You are requested to continue submitting RMPs and other documents to the pharmacy service at MoPH until the issuance of the guideline and related regulation.

Additional Information

You may visit the link below for all necessary clarifications related to the minister 'decisions 180/1 & 181/1 (2021):

https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/PV%20Clarifications%20-%20Ministerial%20Decisions%20180%20and%20181.pdf

If you have any additional queries, do not hesitate to contact us via the same email: pv@moph.gov.lb