19 February 2021

توضيحات تتعلق بالقرارين الوزاريين رقم ١٨٠ و ١٨١ الصادرين بتاريخ ٢٠٢١/٠٢/٠٣

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

The effective date of decision 180/1 is the date of its issuance.

1. Decision 180/1:

1.1 Article #3

a- Reports should be sent to **ONE** of the following emails: pv@moph.gov.lb **OR** phvg.phar@ul.edu.lb

b- As mentioned in paragraph 2: **ALL** adverse events must be reported. e.g Drug Related Problems and Special Situations (refer to the national Reporting Form, paragraph 7, page 4/5 and to the related instructions section 5, page 3/5) **either associated or not with drug adverse event** (s).

c- All AEs are to be reported no matter the source (spontaneous, non interventional studies, Compassionate use, Pre approval Access programs, Patient Support programs, Market researches etc..) following the 15 and 90 day seriousness timelines in ICH E2B (R2&R3) Format.

d- For Interventional Studies, foreign SUSARs for global interventional trials where Lebanon is part of this study and are submitted to Health Education Department. For such global studies Domestic Serious Adverse Events (SAEs) belonging to Lebanese patients and foreign SUSARs are sent to the MOPH pharmacy Service. **(Article #6 of the Decision 1159/2014).**

Only domestic SAEs for interventional Studies need to be submitted within the 15 day timeline in E2B format to the PV department pv@moph.gov.lb

1.2 Article #5

Good Pharmacovigilance Practice Guideline for Pharmaceutical Companies, Marketing Authorization Holders and their Representatives is under preparation. It will provide guidance on the requirements, procedures, roles and activities in the field of PV and describe the relationship between the MoPH and all the parties mentioned above. It will be supported by a regulation

clarifying how to submit all related documents such as RMP, PSMF, PSUR, PBER, PAA and other document. Just make sure that a person is dedicated 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).

1.3 Reporting form:

An electronic signature should be used to sign the forms (There is a space for electronic signature in the reporting forms, page 5).

2. Decision 181/1:

2.1 Article # 1

The reports should be sent into the format ICH E2B (R2 & R3) as XML file. **No CIOMs nor line listing in excel format are acceptable** as they are not compatible with our data management tool.

2.2 Article #2

Pharmaceutical Companies, Marketing Authorization Holders and their Representatives are requested to re submit all adverse events to the MoPH (from 2018 till today) in this **New format** even if these adverse events have been submitted in hard copy earlier to the Ministry.

This decision 181/1 is effective from the date issued however, the Pharmaceutical Companies, Marketing Authorization Holders and their Representatives will be granted **a 3-month extension (3rd of May 2021)** to submit retrospective adverse events in the new format E2B to allow a system configuration.