Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No.45 / 2019

15 -09-1440 H

21 -05-2019

TO
ALL THE LOCAL AGENTS
MARKETING AUTHORISATION HOLDERS (MAHs)
LOCAL PHARMACEUTICAL MANUFACTURING COMPANIES

After Compliments,

Sub: Guide for Good Pharmacovigilance Practices in Oman for MAHs/Pharmaceutical Companies
Supplement to Chapter 11- Educational Materials

This has reference to the Guideline for Good Pharmacovigilance Practices in Oman for MAHs/Pharmaceutical Companies issued as per our Circular No. 5/2017 dated 22.1.2017 and Circular No. 75/2018 dated 27.11.2018 regarding submission of online report to Department of Pharmacovigilance & Drug Information via MOH e-portal and Circular No. 33/2019 dated 16.4.2019 regarding our request to incorporate a section titled 'Call for Reporting' in all educational materials.

Herewith we are attaching a '***Supplement to Chapter 11-Education Materials***' and it will become part of the issued Guide for Pharmacovigilance Practices in Oman for MAHs/Pharmaceutical Companies. This will be effective from July 1, 2019.

Yours faithfully

Dr. Mohammed Hamdan Al Rubaie
Director General

Encl: aa

Cc: Director, Office of H.E. The Undersecretary for Health Affairs
Director of Pharmacovigilance & Drug Information
Director of Pharamceutical Licensing Dept.
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Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs & Drug Control

Department of Pharmacovigilance & Drug Information

Guideline for Good Pharmacovigilance Practices in Oman for MAHs/Pharmaceutical Companies

Supplement to Chapter 11- Educational Materials

1. Introduction:

Educational programmes are additional risk minimisation measures and usually include educational material(s) aimed to minimise an important risk and/or to maximise the risk-benefit balance of a medicinal product.

The content of any Educational Material (EM) should be fully aligned with the currently approved product information for the medicinal product, i.e. the summary product characteristics (SmPC) and the package leaflet (PL), and should add rather than replicate SmPC and PL information.

This is supplement to Chapter (11) of the Guideline of Good Pharmacovigilance Practices in Oman provides further guidance for Marketing Authorisation Holders (MAHs) on the submission of EM(s) to the Department of Pharmacovigilance & Drug Information (DPV&DI).

This Supplement consists of:

1. Principles for Educational Materials (EMs)
2. Submission of EMs
3. Format and layout of EMs
4. Content of EMs
5. Timeline for approval of EMs by DPV&DI

2. Principles for Educational Materials (EMs)

- Any EM should be specifically designed to fulfill the risk minimisation objectives.
- It should focus on the specific safety concern(s) and provide clear statements and concise messages describing actions to be taken in order to prevent and minimise these risks.
- The Marketing Authorisation Holders should only submit the national versions of the EM online to the DPV&DI.
- Educational Materials should be drafted in Arabic and English language.
- Educational Material should focus on the risk(s) related to the product and the management of those risk(s) requiring additional risk minimisation.
- Educational Materials should not include or be combined with promotional elements either direct or veiled (e.g. logos, product brand colors, suggestive images and pictures).
- The methods for dissemination and the target audience should be stated.
- Based on the respective target audience, MAH should provide to the DPV&DI a proposal for the EM(s). The target population determines which tool, content, format and language type is appropriate for the EM. Specific efforts in adaptation should be made when targeting patients.
- The DPV&DI will review the EM(s).
- The Marketing Authorisation Holder should disseminate the EM(s) only after approval by the DPV&DI.
- The Marketing Authorisation Holder should exercise version control and ensure that only the latest approved version of the EM is disseminated. *The date of approval by the DPV&DI should be included in the EM*, as reference for healthcare professionals and/or patients.

3. Submission of EMs

The Educational Material should be submitted online (submission type: 'Educational Material') to the DPV&DI with the following information*:

1. Contact details of MAH	
2. Target population(s)	
3. Dissemination method (e.g. paper, email, social media, websites etc...)	
4. Time point when dissemination is anticipated and frequency of further disseminations	
5. Estimated date of launch	
The intended layout and, where applicable, images and graphic presentations of the information (e.g. pictures, charts, diagrams, video)	

* Listed information to be included in the cover letter.

When changes of the risk and/or the need for additional risk minimisation measures have been identified and changes in the key elements and/or in the content of the EM(s) have been agreed by the DPV&DI, the MAH should submit to the DPV&DI revised proposals of the EM for assessment and approval. In the revised EM, the changes to the materials previously approved should be highlighted.

4. Format and layout of EMs

Educational Materials should have an appropriate format and layout. A title line identifying the type of educational material, e.g. administration guide, checklist for prescribing, alert card, educational leaflet for the patient, is recommended.

The format of educational material should include the following:

- The invented name of the medicinal product followed by the name of the active substance(s) and/or therapeutic class in brackets.

The material should be formatted as follows:

- Bullet points should be used wherever appropriate to present the information clearly;
- Materials should be kept as brief as possible; however, if the EM is long, an introductory text summarising the key messages should be added and an index may be included;
- If the MAH`s and/or product`s logo appear, it should appear only once in each EM, preferably on the first or last page, respectively, and should not be larger than the document title;
- For version control, a unique document identifier should be used on each sheet of the EM, and the date of last revision of the text in the format of "<month> <year>" should be provided on the first and the last page, unless the type of EM requires appropriate exceptions (e.g. a video should have the unique document identifier appearing at its beginning and ending).

5. Content of EMs

- The reference documents to be used in the preparation of EMs are the agreed RMP (including its annexes), the product information and the conditions of the marketing authorisation.

- References to other websites for "more information" will usually not be acceptable unless they refer to the SmPC/PL or unless specific circumstances apply.

- Images and graphic presentations of the information should only be used when text alone is insufficient to adequately convey the messages of the key element(s) and should not be promotional (e.g. use of a particular device to administer the medicinal product).

- The scope of the information in the EM should be limited to the agreed key elements. Additional information such as efficacy data, comparisons of safety with other medicinal products or statements which imply that the medicine is well tolerated or that adverse reactions occur with a low frequency should not be included. However, in certain circumstances the DPV&DI might consider the inclusion of efficacy data provided that this is duly justified by the MAH. Referring to other medicinal products outside the scope of the EM is not allowed.

- A statement on "Call for Reporting" which encourages the reporting of any suspected adverse reaction and information on the modalities how to report to the DPV&DI should be included.

6. Timeline for approval of EMs by DPV&DI

The timelines for the approval of EMs by the DPV&DI depends on the additional risk minimisation measures, the kind of requested EMs, or the quality of the submitted EMs. Nevertheless, an average timeline of **60 days** should be considered for approval. However, for an urgent approval, that should be mentioned in the cover letter.

7. References:

1. Guideline for Good Pharmacovigilance Practices in Oman (Version 1).
2. Guideline on Good Pharmacovigilance Practices for Arab Countries (Version 2).
3. Guideline on Good Pharmacovigilance Practices (Module XVI Addendum I- Educational Materials, EMA/61341/2015).