



Circular No. **118 / 2023**

18-11-1444 H
07-06-2023

To:
Marketing Authorization Holders & Pharmaceutical Companies
QPPV & LSR
Local Agents

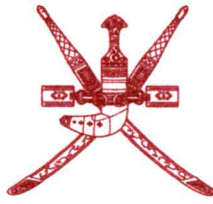
After Compliments,

Please find attached our Circular **No:118/2023** dated 07/06/2023 regarding Submission of Educational Materials (EMs) & Communication Plan.

Copy to:

- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Section Head PV for Herbal Medicine & Health Products.
- Section Head PV for Human Medicine
- Section Head of Central Drug Information





Circular No. **118 / 2023**

Date: 7th June 2023

Submission of Educational Materials & Communication Plan

Reference to our Circular No: 40/219 (Supplement to Chapter 11-Educational Materials) dated 21/05/2019, kindly note the following:

1. Complete the "Submission Form for Educational Materials & Communication Plan" attached when submitting the proposed educational materials to the Department of Pharmacovigilance & Drug Information (DPV&DI) and refer to the mentioned circulars for further details and requirements.
2. Submit the completed form along with the material(s) in the Ministry of Health website (*Submission Type*: Educational Material).
3. During the assessment, the DPV&DI may send comments to the MAH. The Reference number should be quoted in all subsequent submission.
4. Updated EMs should be submitted following:
 - An update of the RMP
 - A major variation of the marketing authorization (with an impact on key element of the EMs).
5. EMs should not include any material that might be considered commercial promotional, or which constitutes advertising.
6. A copy of the final agreed version of the EMs & the communication plan must be submitted to the DPV&DI for final approval before dissemination.

Effective Date: 7th June 2023


Ph. Hussain Al Ramimmy
Director of DPV&DI



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: 100 - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

 dgpa_dc Email: dg-padc@moh.gov.om



Submission Form for Educational Materials EMs

1. Submission details:

Product concerned	Active substance: Trade name (s): Dosage form: MOH Registration Number:
Marketing Authorization Holder (MAH)	
MAH contact point	Name: Email: Tel:

2. Educational Material (ME):

Objective (s) and rational for EM	
Type of material	<input type="checkbox"/> Guide <input type="checkbox"/> Checklist <input type="checkbox"/> Alert Card <input type="checkbox"/> Charts <input type="checkbox"/> Other: specify.....
Target Population	<input type="checkbox"/> HCPs <input type="checkbox"/> Patients <input type="checkbox"/> Caregiver <input type="checkbox"/> Other: specify.....
Material	<input type="checkbox"/> New material (s) <input type="checkbox"/> Updates to previously approved materials
Language of the material	<input type="checkbox"/> English <input type="checkbox"/> Arabic
The Draft EMs	<input type="checkbox"/> Included <input type="checkbox"/> Not Included

3. Proposed Communication Plan:

Proposed Communication Plan	<input type="checkbox"/> Dissemination List: <i>Recipient name, Specialty and Contact information</i>
	<input type="checkbox"/> Dissemination Mechanism: <input type="checkbox"/> Paper <input type="checkbox"/> Email <input type="checkbox"/> Social <input type="checkbox"/> Media <input type="checkbox"/> Website <input type="checkbox"/> Other; specify.....
	Time for dissemination: Estimated date of launch/ implementation: / /
Proposed evaluation of effectiveness plan (where applicable)	Relevant version of the SmPC/ Package leaflet
The intended layout	<input type="checkbox"/> Word <input type="checkbox"/> PDF <input type="checkbox"/> Picture <input type="checkbox"/> Chart <input type="checkbox"/> Diagrams <input type="checkbox"/> Videos <input type="checkbox"/> Other: Specify.....

4. Reference Documents (to be attached)

<input type="checkbox"/> Relevant version of the SmPC/ Package leaflet
<input type="checkbox"/> Annexes of the RMP describing the EMs
<input type="checkbox"/> Literature articles referenced in the EMs (if applicable)
<input type="checkbox"/> Other supporting data.....

