

Circular No. **119 / 2023**

18-11-1444 H
07-06-2023

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

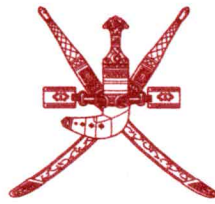
After Compliments,

Please find attached our Circular **No:119/2023** dated 07/06/2023 regarding Submission of Direct Healthcare Professional Communication (DHPCs) & 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. **119 / 2023**
Date: 7th June 2023

نتقدم بثقة
Moving Forward
with Confidence


رؤية عمان
2040
Oman Vision

Submission of Direct Healthcare Professional Communication (DHPC) & Communication Plan

Reference to our Circular No: 43/2019 (Guideline for Direct Healthcare Professional Communication) dated 26/05/2019. Kindly note the following:

1. Complete the "Submission Form for Direct Healthcare Professional Communication & Communication Plan" when submitting the proposed DHPC to the 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 MOH website (*Submission Type: DHPC*).
3. During the assessment, the DPV&DI may send comments to the MAH. The Reference number should be quoted in all subsequent submission.
4. DHPCs should not include any material that might be considered commercial promotional, or which constitutes advertising.
5. A copy of the final agreed version of the DHPC & 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





Submission Form for Direct Healthcare Professional Communication (DHPC) & Communication Plan

1. Submission details:

Product concerned	Active substance: Trade name (s): Dosage form: MOH Registration Number:
MAH	
MAH contact point	Name: Email: Tel:
Joint DHPC	<input type="checkbox"/> Yes <input type="checkbox"/> No
Regulatory context Communication is outcome of:	<input type="checkbox"/> A variation <input type="checkbox"/> PSUR <input type="checkbox"/> Signal <input type="checkbox"/> Other: specify.....

2. Draft DHPC & Communication Plan

Safety concerned	
Reason for communication	
Target audience	
Dissemination mechanism	<input type="checkbox"/> Paper <input type="checkbox"/> Email <input type="checkbox"/> Website <input type="checkbox"/> Social <input type="checkbox"/> Media <input type="checkbox"/> Other: specify.....
Dissemination Date	/ /
DHPC Publication in MOH Website	<input type="checkbox"/> Yes <input type="checkbox"/> No

3. Attached Documents

<input type="checkbox"/> Draft DHPC
<input type="checkbox"/> The Dissemination List
<input type="checkbox"/> Timetable for Dissemination DHPC

