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. 43 / 2019

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To:

The Marketing Authorisation Holders / QPPV/ Pharmaceutical Companies

After Compliments,

Sub: Guideline for Direct Healthcare Professional Communications (DHPCs)

This has reference to the Guideline on Good Pharmacovigilance Practices in Oman for MAH and Pharmaceutical companies, Version 1, 2017, (by Circular 5/2017, dated 22/01/2017) and Circular No. 75/2018, dated 27/11/2018, Report to Department of Pharmacovigilance and Drug Information, via MOH e-Portal.

A guideline and a template for the Direct Healthcare Professional Communications (DHPCs) is made available on MOH website for the MAHs and Pharmaceutical companies, to get approval for dissemination of the DHPCs.

You are hereby advised to follow the procedure as laid down by the guideline and adhere to the template as designed for the smooth distribution of the DHPCs.

Yours faithfully,

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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Director, Department of Pharmacovigilance and Drug Information

Cc: DG – for kind inf.

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Sultanate of Oman
Ministry of Health
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Department of Pharmacovigilance & Drug Information

Guideline for:

Direct Healthcare Professional Communications (DHPCs)

1. Introduction

According to 'Guideline on good Pharmacovigilance Practices for Arab Countries' a Direct Healthcare Professional Communication (DHPC) is defined as a communication intervention by which important safety information is delivered directly to individual healthcare professionals by a marketing authorisation holder (MAH), to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product.

Direct Healthcare Professional Communication are not replies to enquiries from healthcare professionals, nor are they meant as educational material for routine risk minimisation activities.

Dissemination of DHPC is usually done by one or a group of marketing authorisation holders for the respective medicinal product(s) or active substance(s), either at the request of Department of Pharmacovigilance & Drug Information (DPV&DI), or on the marketing authorisation holder's own initiative. The marketing authorisation holder should seek the agreement of the DPV&DI regarding the content of a DHPC (and communication plan) prior to dissemination.

2. Processing of DHPCs

2.1. The marketing authorisation holder should submit the following to DPV&DI in the MOH e-portal (Submission type "DHPC"):

1. **Draft DHPC.**
2. **The Communication Plan**

- **The dissemination list:**
  Should include

Sr.No	intended recipients name	specialty	Address

- **Time Table for disseminating the DHPC:**
  The proposed timetable should be appropriate according to the urgency of the safety concern (usually maximum of 15 calendar days is considered appropriate).
- **Dissemination Mechanism:**
  How the DHPC is planned to be disseminated.

2.2. The marketing authorisation holder should allow a minimum of five working days for comments by DPV&DI. However, whenever possible more time should be allowed. The timing may be adapted according to the urgency of the situation.

2.3 Once the content of a DHPC and communication plan from the MAH are agreed by DPV&DI, the MAH can start dissemination of the agreed DHPC (i.e. the MAH shall NOT start disseminating the DHPC prior to obtaining the approval from DPV&DI.

2.4 MAH should submit, online, progress report to DPV&DI if requested (submission type "Other").

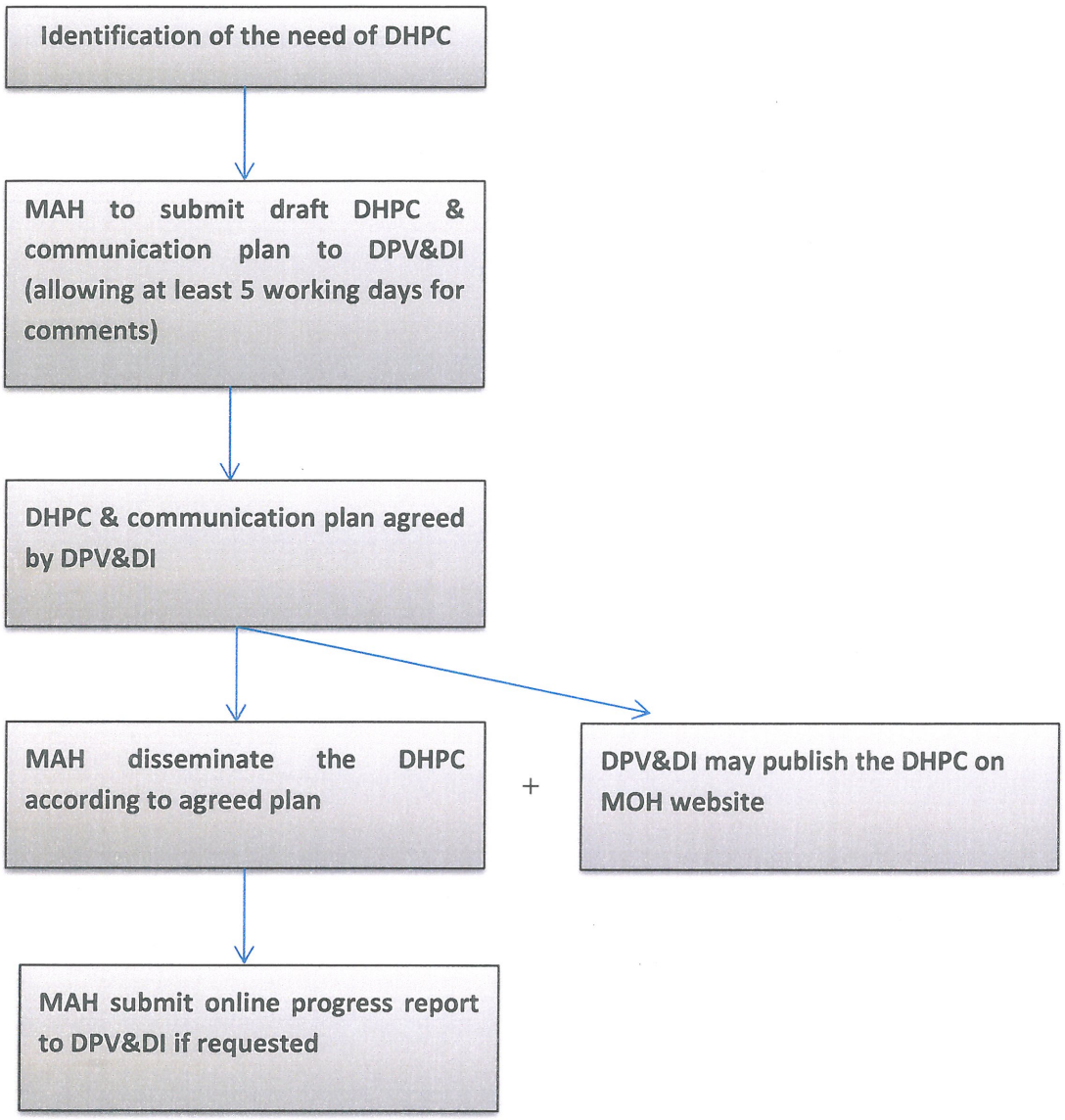
3. Translation of DHPCs

The usual language for preparing the DHPCs will be English.

4. Publication of DHPCs

Department of Pharmacovigilance & Drug Information may publish the final DHPC on MOH website. It may also issue an additional safety announcement, and disseminate the DHPC to relevant healthcare professionals' organisations as appropriate.

Flow chart for the processing of DHPCs in DPV&DI



DHPC Templates

<Date>

<Active substance, name of medicinal product and main message *(e.g. introduction of a warning or a contraindication>*

Dear Healthcare professional,

<Name of marketing authorisation holder> in agreement with Department of Pharmacovigilance & Drug Information, Directorate General of Pharmaceutical Affairs & Drug Control, MOH,Oman> would like to inform you the following:

Summary

Guidance: This section should be in bold/larger font size than the other sections of the DHPC and preferably in bullet points.

- < Brief description of the safety concern, in the context of the therapeutic indication, recommendations for risk minimisation (e.g. *contraindications, warnings, precautions of use*) and, if applicable, switch to alternative treatment>
- Recall information, if applicable, including level (pharmacy or patient) and date of recall>

Background on the safety concern

Guidance: This section may include the following information:

- < Brief description of the therapeutic indication of the medicinal product>
- < Important details about the safety concern (adverse reaction, seriousness, statement on the suspected causal relationship, and, if known, the pharmacodynamic mechanism, temporal relationship, positive re-challenge or de-challenge, risk factors)>
- < An estimation of the frequency of the adverse reaction or reporting rates with estimated patient exposure>
- < A statement indicating any association between the adverse reaction and off-label use, if applicable>
- < If applicable, details on the recommendations for risk minimisation>
- < A statement if the product information is to be or has been revised, including a description of the changes made or proposed>
- < Place of the risk in the context of the benefit>
- < The reason for disseminating the DHPC at this point in time>
- < Any evidence supporting the recommendation (e.g. include citation(s) of key study/ies)>
- < A statement on any previous DHPCs related to the current safety concern that have recently been disseminated>
- < Any for follow-up action(s) by the marketing authorisation holder/competent authority, if applicable>

Call for Reporting

- < A reminder of the need and how to report adverse reactions as well as product quality complaints and medication errors associated with the medicinal product

Department of Pharmacovigilance & Drug Information Directorate General of Pharmaceutical Affairs & Drug control Ministry of Health, Sultanate of Oman **Phone No:** 22357687/ 22357686 **Fax:** 22358489 **Email**: dg-padc@moh.gov.om **Website**: www.moh.gov.om	دائرة التيقظ والمعلومات الدوائية المديرية العامة للصيدلة والرقابة الدوائية وزارة الصحة، سلطنة عمان هاتف: ٢٢٣٥٧٦٨٧/ ٢٢٣٥٧٦٨٦ فاكس: ٢٢٣٥٤٨٨٩ البريد الالكتروني: dg-padc@moh.gov.om الموقع الالكتروني: www.moh.gov.om

- < For biological medicinal products, also include a reminder to report the product name and batch details>
- < Mention if product is subject to additional monitoring and the reason why>

Company contact point

- < Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes (If applicable)

- < Link/ reference to other available relevant information, such as information on the website of a competent authority>
- < Additional scientific information, if applicable>
- < List of literature references, if applicable>

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 (Annex II-Templates: Direct Healthcare Professional Communication (DHPC) (Rev 1), EMA/36988/2013 Rev 1.