Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 142/2024

21-03-1446 H
24-09-2024

To
All Local Pharmaceutical Manufacturers

After compliments,

Subject: Request for Submission of Qualified Person for Pharmacovigilance (QPPV) and Associated Documents

With reference to the above mentioned subject and in line with the Guide for Good Pharmacovigilance Practices (GPVP) in Oman for MAH/Pharmaceutical Companies issued in 2017, we kindly request you to provide the following information and documents to ensure compliance with the regulatory requirements:

1. Qualified Person for Pharmacovigilance (QPPV) & QPPV Back-up

A brief description of the responsibilities assigned to the QPPV & QPPV Back-up within your organization, including their role in ensuring compliance with pharmacovigilance obligations.

Details	QPPV	QPPV Back-up
Full Name		
Qualification		
Pharmacist License Number		
Type of Training Obtained		
Contact Number		
Email Address		
Office Address		

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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2. Pharmacovigilance System Master File (PSMF)

Submit the PSMF in accordance as per Module 1.6 of the relevant guidelines and the summary of PSMF to DPV&DI through MOH e-portal.

3. Risk Management Plan (RMP)

Submit the Risk Management Plan (RMP) as per Module 1.6 of the relevant guidelines.

All submissions should adhere to the National GPVP guidelines issued in 2017. We kindly request that you submit the requested information and documents by the end of October, 2024.

Failure to provide the requested details may result in regulatory actions as per the applicable laws and regulations.

Should you have any questions or require further clarification, please feel free to contact our office at 22357687/22357690.

Thank you for your cooperation and prompt attention to this matter.

Yours sincerely,

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

CC:

- DPV&DI
- DCD
- PSI

DSC مركز سلامة الدواء Drug Safety Center

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