Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 153/ 2024

26-04 -1446 H
29-10 -2024

TO: ALL LOCAL PHARMACEUTICAL COMPANIES, PHARMACEUTICAL CONSULTANCY OFFICES, SCIENTIFIC OFFICES, & PRIVATE DRUG STORES.

After Compliments,

Sub: Implementation of GCC Variation Guideline Version 6.2.

In reference to the above subject, kindly be informed that the GCC Guidelines for Variation Requirements Version 6.2 is now effective immediately. In view of the increasing number of applications, it is important to reduce administrative rejections and avoid the loss of submission slots. Hence, it is essential that applicants adhere to the following guidelines when submitting variation applications:

1. The Application Form for Post-Approval Changes (Variation) of a registered pharmaceutical product must be submitted in full compliance with the attached Appendix.
2. It is the responsibility of the applicant to thoroughly check all variation files and CDs prior to submission.
3. If the applicant submits files with missing documents, incorrect sequences, incorrect CDs, incorrect attachment placements, or files not in the eCTD format, the submission will be returned. A new appointment will have to be scheduled, and no resubmission slots will be allocated.
4. If the variation files are incomplete or not ready for submission, the applicant should notify the registration section immediately via the appointment email so that the submission slot can be reassigned to another applicant.
5. If an applicant repeatedly submits incorrect or incomplete files, they will forfeit their regular submission slots, which will be reassigned to other applicants.

Thank you for your cooperation.

Dr. Mohammed Hamdan Al Rubaie
Director General

Copy to:

- Drug Control Department, DDC
- SH, Registration of Human Medicines

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

Appendix-I

Application Form for Post Approval Changes (variation) of a Registered Pharmaceutical Product

This form should be filled by the company.

1. **This application concerns:**

- ☐ New Drug
- ☐ Generic (Multisource)
- ☐ Biological:
  - ○ Biosimilar
  - ○ Blood Product
  - ○ Vaccine
- ☐ Others (specify):

Product Information:

Registration No.:	Application No.:
Trade Name:	
Active Ingredient(s):	
Dosage Form:	
Strength/Unit:	
Package Size(s):	
Route of Administration:	
Primary Packaging:	
Secondary Packaging:	
Approved Shelf Life:	
Approved Storage Condition:	
Marketing Authorization Holder:	
Name:	Address:
Batch Releaser:	
Name:	Address:
Manufacturer:	
Name:	Address:

2. **Variation(s) type:**

   a. Copy of the relevant page(s) from the Variation Guidelines for this/these change(s) are attached and the relevant boxes for conditions and documentation.
   b. This Application includes the following variations.

Sr. No.	Variation Description as per GCC guidelines for variation	Variation Type	Date of Implementation*

*Date of implementation of Type IA variation should be specified as this variation could be implemented prior to this submission.

3. **Variation Description:**

   Full description of proposed changes

Proposed*	Current*

*Specify the precise present and proposed wording or specification, including dossier section number(s) at the lowest possible level.

For SPC, labeling and package leaflet changes, underline or highlight the changed words presented in the table above or provide as a separate Annex.

Declaration:

I hereby confirm that the submitted application for the above Marketing Authorization to be varied in accordance with the proposals given above. I declare that:

- ☐ The submitted information is true and accurate
- ☐ There are no changes other than those identified in this application (except for other variations addressed in other applications submitted in parallel)
- ☐ No other applications will be submitted for the same variations addressed in this application unless they are finalized by DGPA&DC. Otherwise, withdrawal request form will be requested
- ☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled

Company Director/CEO:

Signature:

Date: