

**Application for Variation to a Marketing Authorization**

طلب التغييرات على رخصة التسويق

|  |  |
| --- | --- |
| **Product type:** | □ Human Medicinal Product□ Health/Herbal Product□ Veterinary Product |
| **Sub-product No.** |  |
| **Request No.** |  |
| **Registration No.** |  |

**1. Product information:**

|  |  |
| --- | --- |
| Trade Name: |  |
| Active Ingredient(s): |  |
| Dosage Form: |  |
| Strength/Unit: |  |
| Package Size(s): |  |
| Route of Administration: |  |
| Primary Packaging: |  |
| Secondary Packaging: |  |
| Approved Shelf Life: |  |
| Approved Storage Conditions: |  |
| Marketing Authorization Holder: |  |
| Agent:  |  |

**2. Type of the variation:**

* Type II
* Type IB
* Type IA
* Type IAIN
* Annual Report

**3. This application concerns:**

* Administrative Changes
* Quality Changes
* Safety, Efficacy, or Pharmacovigilance Changes

**4. Does this change affect the last updated drug application form?**

* Yes
* No

**5. Type(s) of Variation(s):**

**5.1 Variations included in this application:**

|  |  |  |
| --- | --- | --- |
| **Number and title of variation, as per the GCC guidelines for the variation requirements** | **Procedure Type** | **Date of Implementation** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**5.2 Precise scope and background for change (Include a description and background of all the proposed changes with its proposed Classification):**

|  |  |
| --- | --- |
| **Current** | **Proposed** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**6. Declaration:**

* I hereby certify that the submitted information is true and accurate.
* The submitted variations in this application is only variations that will be studied by SFDA

Title:

Name:

Signature:

Date:

Company stamp: