e-form

# Notification of Changes to Labelling and Package Leaflets in accordance with article 61(3)

Office use only:
Application received on:

APPLICATION FORM

PLEASE USE THE GUIDELINES FOR FURTHER INFORMATION.

## 1 PRODUCT DETAILS

1.1 (a) Product Name:

1.1 (b) Active substance/s:

1.1 (c) Pharmaceutical Form:

1.1 (d) Strength/s:

1.1 (e) Marketing Authorisation Number/s:

## 2 Authorisation Holder / Contact Person/s

### 2.1 Marketing Authorisation Holder

| | |
|---|---|
| **Name:** | |
| **Address:** | |
| **Telephone:** | |
| **E-mail:** | |

### 2.2 Person / Company Authorised for Communication / Signing of documents on behalf of the Authorisation Holder

| | |
|---|---|
| **Name:** | |
| **Address:** | |
| **Telephone:** | |
| **Fax:** | |
| **E-mail:** | |

**3 Declaration**

**This notification is submitted under Article 61(3) of Council Directive 2001/83/EC. I hereby confirm that the conditions associated with the change have been met and that no other changes have been introduced.**

**3.1 I declare that (Please tick if applicable):**

- ☐ **The amended actual size colour mock-ups have been submitted.**
- ☐ **There are no other changes than those specified in this application.**
- ☐ **The amended package leaflet has been submitted.**
- ☐ **The change/s do not affect the Summary of Product Characteristics.**
- ☐ **The change/s will not have an impact on the quality, efficacy and safe use of the product.**
- ☐ **The required supporting information has been submitted.**

**3.2 Date when proposed change will be implemented**

dd/mm/yyyy

| | |
|---|---|
| **3.3 Name of the Applicant (Block Letters):** | |
| **Signature/s:** | Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications<br>A Declaration form should be submitted for each signatory. |
| **Position:** | |
| **Place and Date:** | |

**4 Details of change/s:**

**Changes notified fall into the following categories:**

**(Give a brief explanation for the proposed changes to labelling and /or package leaflet.
Provide one full mock-up of the currently approved labelling and package leaflet, one full mock up of the proposed labelling and package leaflet (hard and electronic copies) clearly indicating the proposed changes)**