e-form

Variation Application to a Manufacturer's Importer's or Wholesale Dealer's Licence

THIS APPLICATION RELATES TO: (PLEASE TICK ACCORDINGLY)

- ☐ MANUFACTURER OF MEDICINAL PRODUCTS/INVESTIGATIONAL MEDICINAL PRODUCTS FOR HUMAN USE.
- ☐ IMPORTER OF MEDICINAL PRODUCTS/INVESTIGATIONAL MEDICINAL PRODUCTS FOR HUMAN USE.
- ☐ WHOLESALE DEALER OF MEDICINAL PRODUCTS/ INVESTIGATIONAL MEDICINAL PRODUCTS FOR HUMAN USE.

Licence holder name:	
Licence Holder address	
Site Name / Number:	
Street:	
Locality:	
Postcode:	
Number of Licence being varied:	
Contact name:	
Mobile number:	
Telephone number:	

E-mail address:

Name of Manufacturer, Importer or Wholesaler
(if different to that of licence holder):

Address of Manufacturer, Importer or Wholesaler (if different to that of licence holder):

Site Name / Number:

Street:

Locality:

Postcode:

A MANUFACTURER'S LICENCE (PLEASE TICK ACCORDINGLY)

- A1 Change in the name and/or address of the licence holder.
- A2 Change in name of manufacturer or actual site of manufacture.
- A3 Addition to currently approved operations.
- A4 Deletion of currently approved operations.
- A5 Application for approval of a contract manufacturing and/or assembly site which is currently licensed by the Malta Medicines Authority to carry out the activities proposed in the variation.
- A6 Application for approval of a contract manufacturing and/or assembly site which is not currently licensed by the Malta Medicines Authority to carry out the activities proposed in the variation.
- A7 Addition of a testing Contract Laboratory.

A8 Removal of a testing Contract Laboratory.

A9 Addition of Qualified Person.

A10 Removal of Qualified Person.

A11 Addition of Person Responsible for Production.

A12 Removal of Person Responsible for Production.

A13 Addition of Person Responsible for Quality Control.

A14 Removal of Person Responsible for Quality Control.

B IMPORTER'S LICENCE (PLEASE TICK ACCORDINGLY)

B1 Change in the name and/or address of the licence holder.

B2 Change in name of importer or actual site of importer.

B3 Change in categories of products imported.

B4 Change in classes of products imported.

B5 Change in list of products imported.

B6 Addition of a testing Contract Laboratory.

B7 Removal of a testing Contract Laboratory.

B8 Addition of Qualified Person.

B9 Removal of Qualified Person.

C WHOLESALE DEALER'S LICENCE (PLEASE TICK ACCORDINGLY)

☐ C1 Change in the name and/or address of the wholesale dealer licence holder.

☐ C2 Change in name of wholesale dealer or actual site of wholesale dealer.

☐ C3 Change in categories of products wholesaled.

☐ C4 Change in classes of products wholesaled.

☐ C5 Change of Responsible Person.

(Specify the precise present and proposed wording underlining or highlighting the changed words.)

Present:	Proposed:

Background (Please give brief background explanation for the proposed changes to your licence).

I hereby make application for the above Manufacturer's, Importer's and/or Wholesale Dealer's Licence to be varied in accordance with the proposals given above and certify that the changes will not adversely affect the quality, efficacy or safety of any medicinal product on the premises. I declare that amended documents have been supplied and that the supporting information is correct. I declare that all changes have been identified and that there are no other changes in the amended documentation.

***Licence Holder Signature:**	Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications A Declaration form should be submitted for each signatory.
Name & Surname:	
Status (Job title):	
Date:	

*** In case of a company the legal & judicial representative of the company. Please submit copy of a recent Memorandum of Articles issued by MFSA in support of this.**

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