MALTA MEDICINES AUTHORITY

IN001-12 APPENDIX 5 VERSION 1

VARIATION APPLICATION TO A MANUFACTURER'S, IMPORTER'S OR WHOLESALE DEALER'S LICENCE

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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 : _____
Licnece Holder address:
Site Name / Number:_____
Street:_____
Locality:_____
Postcode; _____

Number of Licence being varied: _____
Contact name:_____
Telephone number: _____
Mobile 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)***	***B. IMPORTER'S LICENCE*** ***(PLEASE TICK ACCORDINGLY)***
A1 Change in the name and/or address of the licence holder	**B1** Change in the name and/or address of the licence holder
A2 Change in name of manufacturer or actual site of manufacture.	**B2** Change in name of importer or actual site of importer
A3 Addition to currently approved operations	**B3** Change in categories of products imported
A4 Deletion of currently approved operations	**B4** Change in classes of products imported
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**.**	**B5** Change in list of products imported
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**.**	**B6** Addition of a testing Contract Laboratory
A7 Addition of a testing Contract Laboratory	**B7** Removal of a testing Contract Laboratory
A8 Removal of a testing Contract Laboratory	**B8** Addition of Qualified Person
A9 Addition of Qualified Person	**B9** Removal of Qualified Person
A10 Removal of Qualified Person	
A11 Addition of Person Responsible for Production	***C. WHOLESALE DEALER'S LICENCE*** ***(PLEASE TICK ACCORDINGLY)***
A12 Removal of Person Responsible for Production	**C1** Change in the name and/or address of the wholesale dealer licence holder
A13 Addition of Person Responsible for Quality Control	**C2** Change in name of wholesale dealer or actual site of wholesale dealer
A14 Removal of Person Responsible for Quality Control	**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.)

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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** _____

Print Name & Surname_____

* 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.

Status (Job title)

_____

Date

_____

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