



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

MANUFACTURER OF MEDICINAL PRODUCTS FOR HUMAN USE**IMPORTER****WHOLESALE DEALER**

Company name: _____	Name and address of Manufacturer or Wholesaler (if different to licence holder): _____
Licence holder address: _____ _____ _____	_____ _____ _____
Licence number: _____	_____
Contact: _____	
Telephone number: _____	
Fax number: _____	

A. MANUFACTURER'S LICENCE	B. IMPORTER'S LICENCE
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 medicinal products imported
A4 Deletion of currently approved operations	B4 Change in classes of medicinal 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
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 medicinal products wholesaled
	C4 Change in classes of medicinal 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.

Main Signatory _____

Status (Job title)

Print name _____

Date

