



**AWTORITA'
DWAR IL-MEDIĊINI**

**APPLICATION FOR A MANUFACTURER'S AND/OR
IMPORTER'S LICENCE FOR INVESTIGATIONAL MEDICINAL
PRODUCTS**

MEDICINES AUTHORITY

APPLICATION FOR MANUFACTURER'S AND/OR IMPORTER'S LICENCE FOR INVESTIGATIONAL MEDICINAL PRODUCTS (IMPs)

**PLEASE COMPLETE ALL RELEVANT SECTIONS IN THIS FORM TYPED OR
IN BLOCK CAPITALS LEGIBLY USING BLACK INK.**

(Complete in conjunction with guidance notes)

**If you hold an existing Manufacturer's Licence, Wholesale Dealer's Licence or
Importer's Licence please enter your current Licence Number in the box below.**

LICENCE NUMBER

If you hold an existing Manufacturer's Licence, Wholesale Dealer's Licence or
Importer's Licence, please identify in the grid below which type(s) of Licence(s) you
hold. (To ensure clarity, please write yes or no for each type)

	Yes	No
ML: Manufacturer's Licence		
WL: Wholesale Dealer's Licence		
IL: Importer's Licence		

**Please note – beyond this page the application form is structured into
seven sections. Section 1 only has to be completed once per
authorisation application. However, one copy of Sections 2-7 will
need to be completed for each site to be included on the same
authorisation. Please make additional copies of Sections 2-7 as
necessary to ensure you provide the Medicines Authority with one set
of Sections 2-7 per site.**

When complete please return the form to

Medicines Authority
BMW Buildings
198, Rue D'Argens,
Gzira, GZR 03,
Malta

SECTION 1

Legally registered address of licence holder:

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If you are applying on behalf of the Proposed Licence Holder please tick here (e.g. if you are a consultant/representative).

APPLICANT

Company name:	
Trading as:	
Applicant name:	
Address:	
Postcode:	
Telephone No:	
Mobile No:	
Fax:	
Email:	

CONTACT PERSON FOR COMMUNICATIONS (if different from above)

Contact name:	
Company Name:	
Address:	
Postcode:	
Telephone No:	
Mobile No:	
Fax:	
Email:	

Please attach all documents proving that the applicant and person for communications (if they are different) have legal status (articles of association, trade register inscription extract and other documentation).

SECTION 2

SITE INFORMATION

Please copy and complete. You will need to complete a copy of sections 2-7 for each site that you wish to include on the Licence

SITE NAME:	
TRADING AS:	
ADDRESS:	
POSTCODE:	

(Please attach evidence that the premises are legally occupied)

SITE CONTACT NAME:	
TELEPHONE NO :	
MOBILE NO:	
FAX:	
EMAIL:	

Please indicate site usage, for clarity please write Yes or No for use.

	Yes	No
MANUFACTURE:		
ASSEMBLY/PACKAGING:		
STORAGE & HANDLING:		
DISTRIBUTION:		
ANALYTICAL TESTING:		
IMPORT:		
EXPORT:		
BATCH RELEASE:		
LIVING ANIMALS KEPT:		
MATERIALS OF ANIMAL ORIGINS KEPT:		

SECTION 3

SITE NAME: _____

LOCALITY: _____

PART A –MANUFACTURING OPERATIONS

Please write Yes or No for each of the following operations proposed to be conducted

		Yes	No
A.1.1	Purchasing/Sourcing		
A.1.1.1	Purchasing Bulk Products		
A.1.1.2	Purchasing Intermediate Products		
A.1.1.3	Purchasing Finished Products		

If no, please advise who will be responsible for purchasing/sourcing? (e.g. Company Name / Sponsor) _____

If you write Yes in any of the boxes below (A.1.2.1-A.1.2.2) please complete section 3.1

		Yes	No
A.1.2	Production		
A.1.2.1	Sterile Products		
A.1.2.1.1	Aseptically Prepared		
A.1.2.1.2	Terminally Sterilised		
A.1.2.2	Non-sterile Products		

If you write Yes in any of the boxes below (A.1.3-A.1.3.2) please complete section 3.2

		Yes	No
A.1.3	Packaging		
A.1.3.1	Primary Packaging		
A.1.3.2	Secondary Packaging		
A.1.4	Blinding		
A.1.5	Quality Control		
A.1.6	Batch certification and Release		
A.1.7	Storage Related to these Operations (Production/Packaging)		
A.1.8	Testing Related to these Operations (Production/Packaging)		

SECTION 3.1

SITE NAME:

LOCALITY:

(Only complete if you answered Yes to questions A.1.2.1.1-A.1.2.2)

Please tick MA (Manufacture and Assembly) or MO (Manufacture Only) for each of the following operations proposed to be conducted. If you do not propose to conduct any please tick No.

	MA	MO	No
A.1.2.1.1 Sterile Products – Aseptically Prepared			
Aseptically prepared large volume (100ml or more) sterile liquid dosage forms (including large volume parenteral and irrigation solutions)			
Aseptically prepared small volume (<100ml) sterile liquid dosage forms (including small volume parenterals and eye drops)			
Aseptically prepared semi-solid dosage forms including creams and ointments			
Solid fill sterile dosage forms (including powders for reconstitution)			
Freeze-dried (lyophilised) solid sterile dosage forms			
Sutures and licensable wound management devices (solid sterile dosage forms)			
Implants			
Other sterile products (as specified) continue on a separate sheet if necessary			
A.1.2.1.2 Sterile Products –Terminally Sterilised			
Terminally sterilised large volume (100ml or more) sterile liquid dosage forms for human use, (incl. large volume parenteral and irrigation solutions)			
Terminally sterilised small volume (<100ml) sterile liquid dosage forms (including small volume parenterals and eye drops)			
Terminally sterilised semi-solid dosage forms including creams and ointments			
Other Terminally sterilised (solids) continue on a separate sheet if necessary			

SECTION 3.1 CONTINUED

SITE NAME:	LOCALITY:
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(Only complete if you answered Yes to questions A.1.2.2)

Please tick MA (Manufacture and Assembly) or MO (Manufacture Only) for each of the following operations proposed to be conducted. If you do not propose to conduct any please tick No.

	MA	MO	No
A.1.2.2 Non-sterile Products			
Unit and multi-dose non-sterile liquids for internal use			
Unit and multi-dose non-sterile liquids for external use			
Unit and multi-dose non-sterile liquid aerosols (pressurised)			
Semi-solid and other liquid non-sterile dosage forms (as specified) continue on a separate sheet if necessary			
Solid non-sterile unit-dose forms – tablets			
Solid non-sterile unit-dose forms – capsules, hard gelatine			
Solid non-sterile unit dose forms – capsules, soft gelatine			
Solid non-sterile unit-dose forms suppositories/ pessaries			
Solid non-sterile multi-dose forms (including powders and granules)			
Other solid non-sterile dosage forms (as specified) – continue on a separate sheet if necessary			
Medical gases			
Licensable dressings			
Licensable medical devices (e.g. intra-uterine device)			
Other medicinal products, not included elsewhere (as specified) continue on a separate sheet if necessary			

SECTION 3.2

SITE NAME:

LOCALITY:

(Only complete if you answered Yes to questions A.1.3.1)

Please write Yes or No for each of the following operations proposed to be conducted

A.1.3.1 Primary Packaging	Yes	No
Filling of primary containers		
Liquid dosage forms		
Semi-solid dosage forms (including creams and ointments)		
Solid dosage forms (including tablets and powders)		
Form/Fill/Seal		
Medical gases		
Other dosage forms (as specified) – continue on separate sheet if necessary		
A.1.3.2 Secondary Packaging		
Labelling of primary containers		
Strip and/or blister packing		

SECTION 4

SITE NAME:

LOCALITY:

PART B – IMPORT OPERATIONS

Please write Yes or No for each of the following operations proposed to be conducted. (Import based on finished product)

		Yes	No
B.1.1	Import (from outside EU)		
B.1.2	Quality Control		
B.1.3	Batch Release		
B.1.4	Storage Related to these Operations		
B.1.5	Related controls for these operations		

If you have written yes to B.1.1 Import (from outside EU) please provide detailed information in section 6

PART C – OTHER OPERATIONS

If you write Yes in any of the boxes below (C.1.1 – C.1.3) please complete section 4.1

		Yes	No
C.1.1	Sterilisation		
C.1.2	Letting and or accepting contracts		
C.1.3	Manufacture and Assembly for Export		

SECTION 4.1

SITE NAME:

LOCALITY:

(Only complete if you answered Yes to the above questions C.1.1-C.1.3.)

	Yes	No
C.1.1 Sterilisation		
Sterilisation by steam or steam/air		
Sterilisation by dry heat		
Sterilisation by irradiation/electron beam		
Sterilisation by biocidal gas/chemical		
Sterilisation by ethylene oxide		
Sterilisation by filtration		
C.1.2 Letting and or accepting contracts		
Applicant intends to be contract acceptor (i.e. Manufactures partially/wholly for others)		
Applicant intends to be contract giver (i.e. uses external manufacturers for some products)		
Applicant intends to be contract acceptor (i.e. carries out testing partially/wholly for others)		
Applicant intends to be contract giver (i.e. uses external test houses for some/all testing)		
C.1.3 Manufacture and Assembly for Export		
Applicant intends to manufacture for export		
Applicant intends to assemble for export		

SECTION 5

SITE NAME:

LOCALITY:

PART D – CLASSES OF PRODUCTS

Please write Yes or No for each of the following products proposed to be handled.

		Yes	No	Yes	No	Yes	No
		Manufacture		Assembly		Import	
D.1.1	Products Containing Biological Active Substances						
D.1.1.1	Blood and Blood Derivatives						
D.1.1.2	Immune Sera						
D.1.1.3	Vaccines						
D.1.1.4	Allergens						
D.1.1.5	Cell Therapy						
D.1.1.6	Gene Therapy						
D.1.1.7	Recombinant DNA (rDNA)						
D.1.1.8	Human or Animal Derived Substances						
D.1.1.9	Others (as specified) – continue on separate sheet if necessary						
D.1.2	Products Containing Chemical Active Substances						
D.1.2.1	Penicillins						
D.1.2.2	Cephalosporins						
D.1.2.3	Other sensitising agents (as specified) – continue on separate sheet if necessary						
D.1.2.4	Hormones						
D.1.2.5	Cytostatics / cytotoxics						
D.1.2.6	Others (as specified) – continue on separate sheet if necessary						
D.1.3	Herbal Products						
D.1.4	Homeopathic Products						
D.1.5	Radiopharmaceutical Products						

SECTION 6**SITE NAME:****LOCALITY:****FURTHER INFORMATION WHICH SHOULD BE ATTACHED****IMPORT OPERATIONS (Continued from section 4 – Part B)**

On a separate sheet of paper please provide an outline of the arrangements for maintaining production or importation records, analytical and other testing procedures applied during manufacturing, assembly or importation, for keeping reference samples of materials used in the manufacture of any IMP.

Where the application relates to importation of IMP's from third countries please provide the address of each premises where the investigational products are to be manufactured.

On a separate sheet, please provide evidence to demonstrate GMP (Good Manufacturing Practice) is being implemented.

FACILITIES ON SITE

On a separate sheet of paper, please provide a brief description (approximately 500 words) of the premises available. Also include a precise description of each of the different areas in which the manufacturing or import operations are carried out (production, packaging, blinding, quality control, storage, distribution).

EQUIPMENT ON SITE

On a separate sheet of paper, please describe all the major items of equipment for manufacture, assembly or importation - approximately 500 words, (other than transport available for the storage and distribution) of each type of medicinal product. The location of each item of equipment should also be included.

Please provide a statement of any manufacturing operations other than those to which the manufacturing authorisation is to relate, that are carried out by the proposed authorisation holder on or near each of the premises, and of the substances or articles which are the subject of any such operation.

OTHER ACTIVITIES

Please include a description of all activities which are not related to medicinal products carried out on the site.

CONTROL FACILITIES

Please include a description of the control facilities.

PLEASE ATTACH ANY OTHER INFORMATION THAT MAY SUPPORT YOUR APPLICATION.

SECTION 7

SITE NAME:

LOCALITY:

Please indicate in the box below how many of the following types of personnel you have working at this site.

Personnel	Number
Qualified Person (QP)	
Production Manager/Supervisor (PM)	
Person responsible for Quality Control (QC)	
Person responsible for animals (AN)	
Person responsible for living tissue culture (LTC)	

For each and every personnel type listed in the above box, please complete one of the appropriate following pages.

Please include a statement or organisational chart specifying areas of responsibility, relating to persons responsible for production and quality control.

SITE NAME:	LOCALITY:
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All applications by a QP must include a relevant CV and each QP nomination must be signed by both the nominee and the applicant.

QUALIFIED PERSON

Please give the following details of the person(s) who is to carry out the functions of the qualified person (QP). Please complete a separate page for each person.

A **Name & Surname:** **Title:**

Pharmacy Council registration number: _____

b **Business Address:**

c **Telephone Number:**

d **Mobile Phone Number:**

e **Please indicate your Status:**

Permanent QP	
Contract QP	

SITE NAME:

LOCALITY:

f If Contract QP– give details of availability (frequency of visits) and function at the site:

g Qualifications:

Attach certificates of qualifications.

h Experience:

Attach certificates of experience.

i Professional Association:

Attach Pharmacy Council registration letter

SITE NAME:

LOCALITY:

j Are you nominated on any other Licence? If yes please state.

Please include a statement or organisational chart specifying areas of responsibility, relating to persons responsible for production and quality control.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true. I agree to be nominated as a Qualified Person on licence number (if such a licence number was previously granted).

Signed (Nominee): _____

Date: _____

Print Name: _____

Signed (Applicant): _____

Date: _____

Print Name: _____

SITE NAME:

LOCALITY:

PERSON RESPONSIBLE FOR PRODUCTION

(This section is only relevant if you intend to manufacture and/or assembly).

In what capacity are you signing this? Please indicate in the box below

Manager of Production:

Supervisor of production:

Please give the following details for the person(s) with overall responsibility for production. Where this responsibility is split between more than one person, please complete a separate page for each person, and give details of each person's area of responsibility.

a

Surname:

Initials:

Title:

b

Qualifications:

c

Experience:

d

Address for communications, if not permanently based at this site:

SITE NAME: _____ **LOCALITY:** _____

e Name and function of the person(s) to whom he/she reports:

f Area of responsibility:

I confirm that the above particulars are to the best of my knowledge and belief accurate and true. I agree to be nominated as the person responsible for Production.

Signed (Nominee): _____

Date: _____

Print Name: _____

Signed (Applicant): _____

Date: _____

Print Name: _____

SITE NAME:**LOCALITY:****PERSON RESPONSIBLE FOR QUALITY CONTROL**

Please give the following details of the person(s) with overall responsibility for quality control. Where this responsibility is split between more than one person, please complete a separate page for each person, and give details of each person's area of responsibility.

a **Surname:** **Initials:** **Title:**

b **Qualifications/Diplomas:**

c **Experience:**

d **Address for communications, if not permanently based at this site:**

e **Name and function of the person(s) to whom he/she reports:**

SITE NAME:

LOCALITY:

f (I) Please stipulate the extent of your authority (i.e. what is the procedure for rejecting unsatisfactory batches of IMP's)

(ii) please specify the name, function of the person to whom you are responsible

g Area of responsibility:

I confirm that the above particulars are to the best of my knowledge and belief accurate and true. I agree to be the person responsible for Quality Control.

Signed (Nominee): _____

Date: _____

Print Name: _____

Signed (Applicant): _____

Date: _____

Print Name: _____

SITE NAME:**LOCALITY:****PERSON (S) IN CHARGE OF ANIMALS**

Please give the following details of the person (s) in charge of animals.
Please complete a separate page for each person.

a **Surname:** **Initials:** **Title:**

b **Address for communications, if not permanently based at this site**

c **Name and function of the person to whom he/she reports**

**SITES ON WHICH LIVING ANIMALS ARE KEPT FROM WHICH
SUBSTANCE ARE OBTAINED FOR USE IN THE PRODUCTION OF
MEDICINAL PRODUCTS – Please give name and address below.**

SITE NAME:

LOCALITY:

d Qualifications:

e Experience:

I confirm that the above particulars are to the best of my knowledge and belief accurate and true. I agree to be the person responsible for animals.

Signed (Nominee): _____

Date: _____

Print Name: _____

Signed (Applicant): _____

Date: _____

Print Name: _____

SITE NAME:**LOCALITY:****PERSON (S) RESPONSIBLE FOR LIVING TISSUE CULTURES**

Please give the following details of the person (s) responsible for living tissue cultures. Please complete a separate page for each person.

a**Surname:****Initials:****Title:****b****Address for communications, if not permanently based at this site****c****Qualifications:****d****Experience:****e****Name and function of the person to whom he/she reports**

SITE NAME: _____	LOCALITY: _____
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I confirm that the above particulars are to the best of my knowledge and belief accurate and true. I agree to be the person responsible for living tissue cultures.

Signed (Nominee): _____

Date: _____

Print Name: _____

Signed (Applicant): _____

Date: _____

Print Name _____

SITE NAME:	LOCALITY:
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DECLARATION

I/we apply for the grant of a Manufacturer's Licence - Investigational Medicinal Products (MI/IMP) to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The activities are to be only in accordance with the information set out in the application or furnished in connection with it.
2. To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed: _____

Date _____

Name: _____
(BLOCK CAPITALS)

State capacity in which signed:

