e-form

Application for a Manufacturer's / Importer's Licence for Medicinal Products and / or Investigational Medicinal Products for use in Humans

SECTION A: GENERAL INFORMATION

1 DETAILS OF PROPOSED LICENSE HOLDER

1.1 If Individual:

Name:	
Surname:	
ID or passport number:	

1.2 If Company:

Name:	
Company registration number:	

Legal and judicial representative of company:

Name:	
Surname:	
ID or passport number:	

2 LEGAL ADDRESS OF PROPOSED LICENCE HOLDER

Building Name/No.:

Street:

Locality:

Postcode:

If individual – address on national ID card.
If company – address registered with national competent authority.

3 DETAILS OF PROPOSED LICENCE HOLDER CONTACT

3.1 Name:

Surname:

3.2 Address of Licence Holder Contact if different from Section 2:

Building Name/No.:

Street:

Locality:

Postcode:

3.3 Telephone number:

Mobile number:

E-mail address:

SECTION B: SITE INFORMATION

4 SITE DETAILS:

4.1 Name of proposed manufacturer/importer:

4.2 Site Address of proposed manufacturer/importer:

Building Name/No.:	
Street:	
Locality:	
Postcode:	

4.3 Site contact (if different from 3):

Name:	
Surname:	
Telephone number:	
Mobile number:	
E-mail address:	

4.4 Site Usage [tick as appropriate]:

Indicate any other activities on this site which are not associated with medicinal products or investigational medicinal products:

Manufacture/importation/distribution/holding of medical devices.

Manufacture/importation/distribution/holding of food supplements.

Manufacture/importation/distribution/holding of veterinary medicinal products.

Manufacture/importation/distribution/holding of cosmetic products.

For sites with proposed importation activity, indicate if the site will be used:

Only for distribution (onward despatch of ready packed orders).

For other purposes not indicated above. (Please specify;
e.g. order receipt; invoicing; order picking; handling of returned goods etc.).

5 ACTIVITIES AT SITE Tick the activities to be held at the site:

A. Manufacturing of Medicinal Products

1 .1 Sterile products

1.1.1 Aseptically prepared (list of dosage forms):

1.1.1.1 Large volume liquids.

1.1.1.2 Lyophilisates.

1.1.1.3 Semi-solids.

1.1.2 Terminally sterilised (list of dosage forms):

- [ ] 1.1.2.1 Large volume liquids.
- [ ] 1.1.2.2 Semi-solids.
- [ ] 1.1.2.3 Small volume liquids.
- [ ] 1.1.2.4 Solids and implants.
- [ ] 1.1.2.5 Other aseptically prepared products:

Please specify

- [ ] 1.1.3 Batch certification only.

1.2 Non-sterile products:

1.2.1 Non-sterile products (list of dosage forms):

- [ ] 1.2.1.1 Capsules, hard shell.
- [ ] 1.2.1.2 Capsules, soft shell.
- [ ] 1.2.1.3 Chewing gums.
- [ ] 1.2.1.5 Liquids for external use.
- [ ] 1.2.1.6 Liquids for internal use.
- [ ] 1.2.1.7 Medicinal gases.
- [ ] 1.2.1.8 Other solid dosage forms:

Please specify

1.2.1.9 Pressurised preparations.

1.2.1.9 Pressurised preparations.

1.2.1.10 Radionuclide generators.

1.2.1.11 Semi-solids.

1.2.1.12 Suppositories.

1.2.1.13 Tablets.

1.2.1.14 Transdermal patches.

1.2.1.15 Intraruminal devices.

1.2.1.16 Veterinary premixes.

1.2.1.17 Other non-sterile medicinal product:

Please specify

1.3 Biological medicinal products

1.3.1 Biological medicinal products:

- [ ] **1.3.1.1 Immunological products.**
- [ ] **1.3.1.2 Cell therapy products.**
- [ ] **1.3.1.3 Gene therapy products.**
- [ ] **1.3.1.4 Biotechnology products.**
- [ ] **1.3.1.5 Human or animal extracted products.**
- [ ] **1.3.1.6 Other biological medicinal products excluding blood products:**

Please specify

1.3.2 Batch certification only (list of product types):

- [ ] **1.3.2.1 Immunological products.**
- [ ] **1.3.2.2 Cell therapy products.**
- [ ] **1.3.2.3 Gene therapy products.**
- [ ] **1.3.2.4 Biotechnology products.**
- [ ] **1.3.2.5 Human or animal extracted products.**
- [ ] **1.3.2.6 Other biological medicinal products excluding blood products:**

Please specify

1.4 Other products or manufacturing activity

1.4.1 Manufacture of:

- [ ] **1.4.1.1 Herbal products.**
- [ ] **1.4.1.2 Homeopathic products.**
- [ ] **1.4.1.3 Biological active starting materials.**
- [ ] **1.4.1.4 Other:**

Please specify

1.4.2 Sterilisation of active substances/excipients/finished product:

- [ ] **1.4.2.1 Filtration.**
- [ ] **1.4.2.2 Dry heat.**
- [ ] **1.4.2.3 Moist heat.**
- [ ] **1.4.2.4 Chemical.**
- [ ] **1.4.2.5 Gamma irradiation.**
- [ ] **1.4.2.6 Electron beam.**
- [ ] **1.4.3 Others:**

Please specify

1.5 Packaging only

1.5.1 Primary packing:

- [ ] **1.5.1.1 Capsules, hard shell.**
- [ ] **1.5.1.2 Capsules, soft shell.**
- [ ] **1.5.1.3 Chewing gums.**
- [ ] **1.5.1.4 Impregnated matrices.**
- [ ] **1.5.1.5 Liquids for external use.**
- [ ] **1.5.1.6 Liquids for internal use.**
- [ ] **1.5.1.7 Medicinal gases.**
- [ ] **1.5.1.8 Other solid dosage forms:**

Please specify

- [ ] **1.5.1.9 Pressurised preparations.**
- [ ] **1.5.1.10 Radionuclide generators.**
- [ ] **1.5.1.11 Semi-solids.**
- [ ] **1.5.1.12 Suppositories.**
- [ ] **1.5.1.13 Tablets.**

1.5.1.14 Transdermal patches.

1.5.1.15 Intraluminal devices.

1.5.1.17 Other non-sterile medicinal products:

Please specify

1.5.2 Secondary packing.

1.6 Quality control testing

1.6.1 Microbiological: sterility.

1.6.2 Microbiological: non-sterility.

1.6.3 Chemical/Physical.

1.6.4 Biological.

Any clarifying remarks related to the scope of these manufacturing operations:

B. Importation of Medicinal Products

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility.

2.1.2 Microbiological: non-sterility.

2.1.3 Chemical/ Physical.

2.1.4 Biological.

2.2 Batch certification of imported medicinal products

2.2.1 Sterile products:

2.2.1.1 Aseptically prepared.

2.2.1.2 Terminally sterilised.

2.2.2 Non-sterile products.

2.2.3 Biological medicinal products:

2.2.3.1 Immunological products.

2.2.3.2 Cell therapy products.

2.2.3.3 Gene therapy products.

2.2.3.4 Biotechnology products.

2.2.3.5 Human or animal extracted products.

2.2.3.6 Other biological medicinal products excluding blood products (please specify):

2.2.4 Other importation activities (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.).

2.2.4.1 Radiopharmaceuticals/ Radionuclide generators.

2.2.4.2 Medicinal gases.

2.2.4.3 Herbal products.

2.2.4.4 Homeopathic products.

2.2.4.5 Biological active starting materials.

2.2.4.6 Other (please specify):

Any clarifying remarks related to the scope of these importing operations:

C. Manufacturing of Investigational Medicinal Products

1 .1 Sterile investigational medicinal products

1.1.1 Aseptically prepared (list of dosage forms):

1.1.1.1 Large volume liquids.

1.1.1.2 Lyophilisates.

1.1.1.3 Semi-solids.

1.1.1.4 Small volume liquids.

1.1.1.5 Solids and implants.

1.1.1.6 Other aseptically prepared products (please specify):

1.1.2 Terminally sterilised (list of dosage forms):

1.1.2.1 Large volume liquids.

1.1.2.2 Semi-solids.

1.1.2.3 Small volume liquids.

1.1.2.4 Solids and implants.

1.1.2.5 Other terminally sterilised prepared products (please specify):

1.1.3 Batch certification only:

1.2 Non-sterile investigational medicinal products

1.2.1 Non-sterile products (list of dosage forms):

1.2.1.1 Capsules, hard shell.

1.2.1.2 Capsules, soft shell.

1.2.1.3 Chewing gums.

1.2.1.4 Impregnated matrices.

1.2.1.5 Liquids for external use.

1.2.1.6 Liquids for internal use.

1.2.1.7 Medicinal gases.

1.2.1.8 Other solid dosage forms (please specify):

1.2.1.9 Pressurised preparations.

1.2.1.10 Radionuclide generators.

1.2.1.11 Semi-solids.

1.2.1.12 Suppositories.

1.2.1.13 Tablets.

1.2.1.14 Transdermal patches.

1.2.1.15 Other non-sterile medicinal product (please specify):

1.2.2 Batch certification only.

1.3 Biological investigational medicinal products

1.3.1 Biological medicinal products (list of product types):

1.3.1.2 Immunological products.

1.3.1.3 Cell therapy products.

1.3.1.4 Gene therapy products.

1.3.1.5 Biotechnology products.

1.3.1.6 Human or animal extracted products.

1.3.1.7 Other biological medicinal products excluding blood products (please specify):

1.3.2 Batch certification only (list of product types):

1.3.2.2 Immunological products.

1.3.2.3 Cell therapy products.

1.3.2.4 Gene therapy products.

1.3.2.5 Biotechnology products.

1.3.2.6 Human or animal extracted products.

1.3.2.7 Other biological medicinal products excluding blood products(please specify):

1.4 Other investigational medicinal products or manufacturing activity:

1.4.1 Manufacture of:

1.4.1.1 Herbal products.

1.4.1.2 Homeopathic products.

1.4.1.3 Biological active starting materials.

1.4.1.4 Other (please specify):

1.4.2 Sterilisation of active substances/excipients/finished product:

1.4.2.1 Filtration.

1.4.2.2 Dry heat.

1.4.2.3 Moist heat.

1.4.2.4 Chemical.

1.4.2.5 Gamma irradiation.

1.4.2.6 Electron beam.

1.4.3 Others (please specify):

1.5 Packaging only

1.5.1 Primary packing:

1.5.1.1 Capsules, hard shell.

1.5.1.2 Capsules, soft shell.

1.5.1.3 Chewing gums.

1.5.1.4 Impregnated matrices.

1.5.1.5 Liquids for external use.

1.5.1.6 Liquids for internal use.

1.5.1.7 Medicinal gases.

1.5.1.8 Other solid dosage forms (please specify):

1.5.1.9 Pressurised preparations.

1.5.1.10 Radionuclide generators.

1.5.1.11 Semi-solids.

1.5.1.12 Suppositories.

1.5.1.13 Tablets.

1.5.1.14 Transdermal patches.

1.5.1.15 Other non-sterile medicinal products (please specify):

1.5.2 Secondary packing.

1.6 Quality control testing

1.6.1 Microbiological: sterility.

1.6.2 Microbiological: non-sterility.

1.6.3 Chemical/ Physical.

1.6.4 Biological.

Any clarifying remarks related to the scope of these manufacturing operations:

D. Importation of Investigational Medicinal Products

2.1 Quality control testing of imported investigational medicinal products

2.1.1 Microbiological: sterility.

2.1.2 Microbiological: non-sterility.

2.1.3 Chemical/ Physical.

2.1.4 Biological.

2.2 Batch certification of imported investigational medicinal products:

2.2.1 Sterile products:

2.2.1.1 Aseptically prepared.

2.2.1.2 Terminally sterilised.

2.2.2 Non-sterile products.

2.2.3 Biological products:

2.2.3.2 Immunological products.

2.2.3.3 Cell therapy products.

2.2.3.4 Gene therapy products.

2.2.3.5 Biotechnology products.

2.2.3.6 Human or animal extracted products.

2.2.3.7 Other biological medicinal products excluding blood.

2.2.4 Other importation activities (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.).

2.2.4.1 Radiopharmaceuticals/ Radionuclide generators.

2.2.4.2 Medicinal gases.

2.2.4.3 Herbal products.

2.2.4.4 Homeopathic products.

2.2.4.5 Biological active starting materials.

2.2.4.6 Other.

Any clarifying remarks related to the scope of these importing operations

6 OTHER ACTIVE INGREDIENTS produced or handled and appearing in the finished product

[A] Potentially hazardous

Penicillins:

☐ Manufacture ☐ Assembly

Cephalosporins:

☐ Manufacture ☐ Assembly

Hormones:

☐ Manufacture ☐ Assembly

Cytostatics/ cytotoxics:

☐ Manufacture ☐ Assembly

Others (please specify):

[B] Miscellaneous:

Radioactive materials:

☐ Manufacture ☐ Assembly

Homoeopathics:

☐ Manufacture ☐ Assembly

7 INVESTIGATIONAL MEDICINAL PRODUCTS ONLY

If you propose to manufacture investigational medicinal products, indicate which of the following activities you intend to conduct (tick as appropriate):

☐ **Bulk products will be purchased or otherwise sourced.**

☐ **Intermediate products will be purchased or otherwise sourced.**

☐ **Finished products will be purchased or otherwise sourced.**

☐ **Blinding of investigational medicinal product.**

If none of the above have been ticked, please state who will be responsible for purchasing/sourcing (eg. Company Name/ Sponsor):

8 FOR PARTIAL MANUFACTURING ONLY (tick as appropriate)

8.1 OVER-PRINTING AND OVER-LABELLING

- [ ] Overprinting of primary packaging.
- [ ] Overprinting of secondary packaging.
- [ ] Over-labelling of primary packaging.
- [ ] Over-labelling of secondary packaging.

8.2 ASSEMBLY ACTIVITIES:

- [ ] Replacement of secondary packaging.
- [ ] Replacement of secondary packaging with change in blister quantity in each box.
- [ ] Removal of leaflet.
- [ ] Insertion of leaflet.
- [ ] Removal/ Insertion of other items (please specify):

8.3 DOSAGE FORMS ASSEMBLED

- [ ] Liquid dosage forms.
- [ ] Semi-solid dosage forms (including creams and ointments).
- [ ] Solid dosage forms (including tablets and powders).
- [ ] Medical gases.
- [ ] Other dosage forms. Please specify:

9 CONTRACT MANUFACTURE AND/OR ASSEMBLY [tick if applicable]

☐ Licence holder/applicant is contract giver
(i.e. uses external manufacturers for some products).

List contract manufacturers/assemblers (as on contractor's license):

Name of proposed subcontractor:

Site address of proposed manufacturer/importer:

Building Name/No.:

Street:

Locality:

Postcode:

Country:

Print this section and fill in additional copies if necessary.

Number of copies attached:

10 CONTRACT QUALITY CONTROL TESTING (including testing for stability studies) [tick if applicable]

☐ Licence holder/applicant is contract giver (i.e. uses external test houses for some/all testing).

List contract laboratories (as on contractor's license/ GMP certificate):

Name of proposed subcontractor and site address of proposed manufacturer/ importer:

Site address of proposed laboratory:

Building Name/No.:

Street:

Locality:

Postcode:

Country:

Testing activities at this site:

☐ Chemical/physical.

☐ Microbiological/ sterility/ environmental/ LAL.

☐ Pyrogens (rabbit method).

☐ Bioassay.

☐ Other (please specify:)

Print this section and fill in additional copies if necessary.

Number of copies attached:

11 OTHER SPECIFIC PROCESSES/ACTIVITIES (tick as applicable)

- [ ] Form/ fill/ seal processes.
- [ ] Strip and/ or blister packing.
- [ ] Assembly of parallel-imported products.
- [ ] Manufacture and/or assembly for export.

Sterilisation processes used (for products or components):

- [ ] Dry heat.
- [ ] Steam or steam/ air.
- [ ] Irradiation/ electron beam.
- [ ] Biocidal gas/ chemical.

12 QUALIFIED PERSON

Please give the following details of the person who is to carry out the functions of Qualified Person (QP).

Name:	
Surname:	
Pharmacy Council QP Registration Number:	
Contact details:	
Home telephone number:	
Office telephone number:	
Mobile number:	
E-mail address:	
Position held with the company other than QP if any:	

Type of employment with the company:

- ☐ Full time.
- ☐ Part time.
- ☐ Contract basis.

Experience: Please state what experience you have had of the activities to be performed under the licence and how this has been acquired.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

Signed (proposed QP):	
Date:	
Signed (proposed Licence holder):	
Date:	

Print this section and fill in additional copies if necessary.

Number of copies attached:	

13 PERSON/S RESPONSIBLE FOR PRODUCTION

Please give the following details of the person/s with overall responsibility for production.

Surname:	
Name:	
Qualifications:	
Experience:	
Name and function of the person(s) to whom he reports:	

14 PERSON/S RESPONSIBLE FOR QUALITY CONTROL

Please give the following details of the person/s with overall responsibility for quality control.

Surname:	
Name:	
Qualifications:	
Experience:	
Name and function of the person(s) to whom he reports:	

Print this sheet and fill in additional copies if necessary.

Number of copies attached:	

15 STORAGE AND HANDLING OF MATERIALS

15.1SITE NAME (if different from name of the licence applicant):

15.2SITE ADDRESS:

15.3SITE CONTACT

Surname:

Name:

Telephone Number:

Fax Number:

15.4SITE USAGE

Is this site used for distribution only (i.e. onward dispatch of ready packed orders): Yes No

Or is this site used for other purposes: Yes No

Please specify these other purposes (e.g. order receipt, invoicing, assembly/ picking of orders, handling of goods returned from customers).

Print the whole section and fill in additional copies if necessary.

Number of copies attached:

SECTION C: PROPOSED LICENSE HOLDER'S DECLARATION

I/We apply for the grant of a Manufacturer's/Importer's Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Manufacturer's Licences under regulations for the time being in force under.

2. The manufacturing operations are to be only in accordance with the information set out in the application or furnished in connection with it.

3. I/ We declare that we hold the relevant product licences or are named on the relevant product licences as manufacturers and/or assemblers relating to the medicinal products we wish to manufacture and/or assemble pursuant to this application.

4. To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

Signed:	
Surname:	
Name:	
Date:	

ANNEX 1: DOCUMENTS TO BE ATTACHED TO APPLICATION

A) Site Master File.

B) Curriculum vitae of Production Manager.

C) Curriculum vitae of Quality Control Manager.

D) Certificate of Registration issued by MFSA (for private & public companies only).

E) MEPA Permits for unlicensed sites listed on the application.