



**Notes for completing an application form for a
Manufacturer's and/or Importer's Authorisation
for Investigational Medicinal Products (IMPs)**

Notes for completing an application form for a Manufacturer's and/or Importer's Authorisation for Investigational Medicinal Products (IMPs)

Contact for information about this Guidance Note and for application forms for The Manufacturer's and/or Importer's Licence for Investigational Medicinal Products (IMPs)

Inspection and Enforcement Division
Malta Medicines Authority
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For further information regarding FAQs regarding Clinical Trial Directive, please visit the Medicines Authority website: <http://www.medicinesauthority.gov.mt>

General completion of the form information

These notes have been developed in order to assist you with filling in the application form. The form should be completed taking into account the manufacturing and/or importing operations undertaken when conducting clinical trials for IMP's

The form is divided into seven sections, comprising -

Section 1 Applicant

Section 2 Site Information

Section 3 (Part A) Manufacturing Operations (including assembly operations)

3.1 Production - Sterile/Non-Sterile products

3.2 Primary/Secondary Packaging

Section 4 (Part B) Import Operations (from outside the EU), Quality Control, Batch Release, Storage related to these operations

(Part C) Other operations, Sterilisation, Letting and or accepting contracts, Manufacture and Assembly for Export

4.1 Sterilisation, Contracts, Manufacture and Assembly for Export

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Section 5 Types of products

Section 6 Additional information request

Section 7 Personnel

All sections of the form should be completed **legibly in block capitals using black ink or typed**

Completed forms should be returned to-

Inspection and Enforcement Division
Medicines Authority
BMW Buildings
198, Rue D'Argens,
Gzira, GZR 03,
Malta

Forms returned without signatures will not be accepted. All personnel sections must be signed.

If a company applies for more than one licence, more than one application should be filled in, ex company X applies for both an importer's and a manufacturer's licence.

If company holds an existing licence (Manufacturer's/Wholesale Dealers) the number should be indicated in the licence number box. See example below.

LICENCE NUMBER	YYYY
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A Licence Number is a unique number, which the Medicines Authority allocates to companies who already have a licence. If a company has more than one licence with a different number, for example one for a WL (Wholesale Dealers Licence) **WL 00**; then another number for a IL (Import Licence) **IL 01**, the company only needs to state the number to which they wish to attach the ML (IMP). The company must decide which licence number they would like the (IMP) licence to be attached.

Completion of table:

If you hold an existing Manufacturer's Licence or Wholesale Dealer'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)

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For example this section could be filled in as follows

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

If Company does not hold an existing number this section should be left blank, and you should move onto section 1.

Section 1

Company name

Enter the company name e.g. ABC Limited. (This will represent the company to which the authorisation will be issued).

Trading As

If trading as a different name (i.e. any other business name) to current company name this should be indicated here.

Applicant Name

Enter the full name of the proposed authorisation holder e.g. Mr Abc. This is the person legally responsible for ensuring the regulation of the ML (IMP) is being implemented.

Telephone, Mobile, Fax, Email

The above information is for business purposes and will aid the Medicines Authority in administration / communications and should assist in the speedy processing of the application.

Contact details for communications

Enter the name of the person to contact, company name, address, and post code. This should be the person responsible for the submission of the application, who is knowledgeable about the application, if their details are different from the proposed authorisation holder details, e.g. Consultant/Agent/Head office.

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SECTION 2

Site Information

Please make additional copies of sections 2-7 and complete one copy for each individual site to be named on the licence.

Trading As

If the company trades as a different name (i.e. any other business name) to the current company name, enter this here.

Site Contact Name

Enter the name of the person to contact at the site (e.g. for inspection purposes)

Site Contact Details, Telephone, Mobile, Fax, Email

In this section of the form where it requests information re Telephone, Mobile, Fax, Email, this is optional strictly for business purposes. It will assist MMA solely for administration/communicating, also it will greatly assist in the speedy processing of the application.

Site Usage

Enter Yes or No to indicate what the site is used for, see example below
Please indicate site usage, for clarity please write Yes or No.

	Yes	No
Manufacture	Yes	
Assembly / packaging	Yes	
Storage & handling		No
Distribution	Yes	
Analytical testing		No

SECTION 3

From section 3 Part A onwards each page will have Site Name and Locality see below for such an example:

SITE NAME: ABC LTD	LOCALITY: YYY YYY
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This is at the **top of each page and must be completed for each page,**

Part A Manufacturing Operations

Enter yes or no for any of the manufacturing operations that are proposed to be conducted, for example the form could be filled in like below, this method of entering Yes or No should be applied throughout the form.

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

Production

Enter yes or no for any production operations proposed to be conducted in relation to (A.1.2 - A.1.2.2). If yes is written in any of these boxes, section 3.1 should be completed. See below for example. This method of applying yes or no should also be applied to sections A.1.3 - A.1.8

		<i>Yes</i>	<i>No</i>
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		

E.g. because A.1.2.1.1 was ticked in section 3, Part A Production, section 3.1 also needs to be completed. This provides detailed information regarding 'Aseptically prepared' production.

(Only to be completed if you answered Yes to questions A.1.2 - A.1.3.2)

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.

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Section 3.1

	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)		√	

SECTION 4

Part B Import Operations

Enter yes or no for any of the import operations proposed to be conducted. (Import based on finished product) See example below.

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

If you have ticked Yes to B.1.1 Import (from outside EU) you will need to provide detailed information in section 6.

Part C – Other Operations

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

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For example as yes has been written in the above section C.1.1, section 4.1 should be complete. The same procedure should be applied when completing the remainder of the form, e.g. sections regarding contracts, manufacture and assembly for export.

(Only complete Section 4.1 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	Yes	
Sterilisation by dry heat	Yes	
Sterilisation by irradiation/electron beam		No

Section 5

Part D Classes of Products

Enter yes or no for any of the products proposed to be handled. See example below (When entering Yes or No this should be indicated under the headings of Manufacture, i.e. if you manufacture the product, or Import, i.e. if you import the product)

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	Yes		No		No	
D.1.1.2	Immune Sera	Yes		Yes		No	
D.1.1.3	Vaccines	No		No		No	

Section 6

All of the information requested in section 6 should be included in the Site Master File (SMF). This should contain specific and factual information about the production and/or control of the pharmaceutical manufacturing operations to be carried out. The SMF should be prepared, so it is available prior to inspections or when requested by inspectorate.

In section 6 you are required to provide detailed information regarding Import Operations, (Continued from section 4 – Part B). Information required includes outlining any production or importation records, analytical and other testing procedures applied during manufacturing, assembly or importation.

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Facilities/ Equipment on site.

A description highlighting the facilities and equipment available at each of the premises for storing and distributing the investigational medicinal products, also major items of equipment other than transport available for the storage and distribution of medicinal products should be included.

Additional information to support application

An additional box has been provided, this can be filled in if there is any other information that you would like to include to support your application.

Section 7

Personnel Information

For this section you will need to stipulate how many personnel member(s) are present at each site, an appropriate set of pages should be copied for each personnel member at each site.

The number reflected in the number box should be equivalent to the number of sets of pages filled in by each personnel member for each site. E.g. see below, (therefore 3 (QP) documents) should have been copied and filled in, 1 (PM) 1 (QC) 1 (AN) and 1 for (LTC) should be completed and returned with application form.)

Personnel Number

Personnel	Number
Qualified Person (QP)	3
Person responsible for Production (PM)	1
Person responsible for Quality Control (QC)	1
Person responsible for Animals (AN)	1
Person responsible for Living Tissue Culture (LTC)	1

Please ensure the following documents are sent

Completed application form

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Experience/qualifications, e.g, Copy of CV (only for QP) and copies of certificates