

Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland



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1 SCOPE

The purpose of this document is to provide guidance on the registration process for active substance manufacturers, importers and distributors in Ireland. It covers the criteria for registration as set out in Falsified Medicines Directive (FMD), Directive 2011/62/EU. It provides guidance on the administrative and technical aspects of the registration scheme and the processes for making an application to the Compliance Department of the Health Products Regulatory Authority (HPRA) for registration. The requirements of the FMD do not apply to active substances used for manufacture of investigational medicinal products for human use, medical devices or to veterinary medicines.

2 INTRODUCTION

Directive 2011/62/EU, which amends Directive 2001/83/EC, the key legal instrument governing medicinal products for human use, includes a number of implications for manufacturers, importers and distributors of active substances used in finished product manufacture. Article 52a (paragraph 1) of the FMD states that *'importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent authority of the Member State in which they are established.'* This document is intended to provide guidance to manufacturers, importers and distributors of active substances located in Ireland on the initial registration process.

The HPRA has set up a registration scheme, based on the EU format, for registration of manufacturers, importers and distributors of active substances. Any site located in Ireland which is engaged in any of these activities should register those activities with the HPRA. For the purpose of this registration scheme, the following definitions apply:

An **active substance** is any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make medical diagnosis.

Manufacture refers to both total and partial manufacture of an active substance. The principles set out in ICH Q7 are useful in determining where manufacture of the active substance can be considered to commence, through the definition it includes of an active substance (active pharmaceutical ingredient) starting material.

An **API starting material** is a raw material, intermediate, or an active pharmaceutical ingredient (API) that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. In all cases manufacturing would be considered to occur from the point at which the active substance starting material, as defined above, is incorporated into the process. In all cases the registered details (e.g. drug

master file or active substance master file) should be taken into account. Note that the terms 'active pharmaceutical ingredient' and 'active substance' can be considered interchangeable. Further information on the types of manufacturing operations which must be registered is provided in Appendix 1 of this document.

Importation refers to importation of active substances from countries located outside the European Economic Area. Further information on the importation of active substances is available on the European Commission's website in the form of questions and answers. The procurement (purchase), for the purpose of importation into the EEA, of active substances from sites in third countries or acting as site of physical importation of active substances from third countries are activities which require registration as an importer with the HPRA.

Distribution is considered to include any or all activities consisting of the procuring (purchase from sites in the EEA), holding, supplying or exporting of an active substance.

Manufacturers of medicinal products for human use (MIA holders)

Sites which hold an MIA are required to register any manufacturing activities relating to active substances. MIA holders are also required to register in relation to importation of active substances where the site procures and/or acts as the site of physical importation of an active substance from a third country.

An MIA holder which purchases and stores active substances sourced within the EEA for the purpose of manufacture of medicinal products at its site is not required to register as a distributor of active substances. However, an MIA holder which supplies active substances to another registered/authorised site in the EEA or exports the active substance outside the EEA is required to register as a distributor of active substances in relation to these activities.

Wholesalers of medicinal products for human use

A site which holds a Wholesale Dealers Authorisation (WDA) in relation to the distribution of medicinal products for human use is required to register any activities carried out in relation to the manufacture, importation or distribution of active substances.

3 HOW TO APPLY FOR A REGISTRATION

In order to register it is necessary to complete the registration application form for manufacturers, importers and distributors of active substances. This form is available on the 'Publications and Forms' section of www.hpra.ie. Guidance on completion of the application form is provided in Appendix I of this document. There are worked examples to demonstrate completion of the application form in Appendix II of this document.

Fees

A fee of €250 is payable for registration in relation to **each** of the following activities:

- 1 Manufacture of active substances
- 2 Importation of active substances
- 3 Distribution of active substances

Note, that there are some circumstances where an applicant needs to register for two activities but may only need to pay one registration fee. These relate to consequential registrations, outlined below:

- 1 Manufacture of active substances and distribution of only those active substances manufactured at the site to other sites. Register as manufacturer and distributor but only pay one registration fee (€250).
- 2 Importation of active substances and distribution of only those active substances to other sites. Register as an importer and distributor but only pay one registration fee (€250).

Applications should be sent to:
Licensing Section
Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Terrace
Dublin 2
D02 XP77

E-mail: compliance@hpra.ie

Note that an inspection may be performed as part of the registration process.

APPENDIX I GUIDE TO COMPLETING THE APPLICATION FORM



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

This document provides some additional guidance in shaded text boxes on completion of the application form. A working copy of the application form is available separately on the HPRA website for submission of applications.

APPLICANT DETAILS

Name or corporate name of registrant:

Company registration office number:

Permanent or legal address of registrant:

Appropriate documentation should be provided (e.g. supporting documentation from the Companies Registration Office in Ireland) as evidence of the name and legally registered address of the applicant. This address may differ from the address where activities take place but must be an address within the Republic of Ireland.

Address of site where registered activities take place in Ireland:

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed :

Contact telephone number:

Contact fax number:

E-mail address of applicant:

TYPE OF REGISTRATION REQUESTED

(Identify all activities for which registration is being sought.)

Note:

- *If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.*

- Registration for a manufacturer of an active substance
- Registration for an importer of an active substance
- Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

A separate 'Scope of registration' should be completed for each address where activities take place.

1 MANUFACTURING OPERATIONS

Active substance(s):

The names of the active substance should be entered above and the applicable manufacturing operations which are carried out in relation to that active substance should be identified below in sections A to E. If manufacturing operations are carried out on more than one active substance then the active substance section above and each of the relevant tabulated sections, A to E, should be reproduced as necessary and completed to identify the operations carried out on each active substance. The completed application should provide a sequential list of manufacturing operations carried out on each active substance at a given address.

If the site manufactures an active substance intermediate and does not manufacture the finished active substance, then the name of the active substance intermediate(s) should be entered above and the relevant manufacturing operations identified as described previously.

A	Manufacture of active substance by chemical synthesis
<p>Item 1 in this section may include any steps from manufacture of the defined starting materials until the step prior to manufacture of the crude active substance.</p>	
	<ul style="list-style-type: none"> <input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: <free text> (e.g. crystallisation) <input type="checkbox"/> 4. Other <free text>
B	Extraction of active substance from natural sources
<p>Item 5 in this section relates to chemical modification of the extracted active substance. Activities such as drying or milling are captured under the section on general finishing steps (F).</p>	
	<ul style="list-style-type: none"> <input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>
C	Manufacture of active substance using biological processes
<p>Where the manufacture of an active substance using a biological process is part of a continuum of processing steps in the manufacture of the finished medicinal product then this activity is considered to be partial manufacture of the finished medicinal products and requires a manufacturer's/importer's authorisation (MIA).</p>	
	<ul style="list-style-type: none"> <input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>

D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
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This section is completed in relation to registration of those steps in the manufacturing process which render an active substance sterile. Where a sterile active substance is used in the manufacture of medicinal product without any further sterilisation steps carried out at the finished product manufacturing site then this activity is considered to be partial manufacture of the medicinal product and such sites must hold a manufacturer's /importer's authorisation (MIA).

- | | |
|--|---|
| | <input type="checkbox"/> 1. Aseptically prepared
<input type="checkbox"/> 2. Terminally sterilised |
|--|---|

E	General finishing steps
----------	--------------------------------

- | | |
|--|---|
| | <input type="checkbox"/> 1. Physical processing steps <specify> (e.g. drying, milling / micronisation, sieving)
<input type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
<input type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.)
<input type="checkbox"/> 4. Other <free text> (for operations not described above) |
|--|---|

F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
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If quality control testing is the only activity performed in relation to active substances at a site then such sites are not required to submit a registration application in relation to this activity.

- | | |
|--|---|
| | <input type="checkbox"/> 1. Physical/chemical testing
<input type="checkbox"/> 2. Microbiological testing (excluding sterility testing)
<input type="checkbox"/> 3. Microbiological testing (including sterility testing)
<input type="checkbox"/> 4. Biological testing |
|--|---|

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	<p>Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i></p>		
<p>Insert additional rows as necessary in the table below. Only one active substance, third country manufacturer or distributor should appear in each row. 'Distributors' in this section refers to a source of the active substance in a third country other than the manufacturer of the active substance. Entries are not required in this section for importation operations relating to active substance intermediates.</p> <p>If the imported active is distributed to another site after importation then it is necessary to register this activity in the distribution section of this form.</p> <p>Under the clarifying remarks section below, identify the relevant operations which apply to importation operations. It is not necessary to specifically identify which importation operations (see below) apply individually to each active substance named in this section.</p>			
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the importation activities.</i></p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation)</p> <p><input type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA)</p> <p><input type="checkbox"/> 3. Other <free text></p>		

B	Distribution
<p>Enter the names of any active substances to which distribution activities apply. Entries are not required in this section for distribution activities relating to active substance intermediates.</p> <p>Identify the relevant operations which apply to distribution operations under the clarifying remarks section. It is not necessary to specifically identify which distribution operations (see below) apply individually to each active substance named in this section.</p>	
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i>
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the distribution activities.</i></p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA)</p> <p><input type="checkbox"/> 2. Holding (i.e. storage)</p> <p><input type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA Holders), located in the EEA)</p> <p><input type="checkbox"/> 4. Export (to sites outside the EEA)</p> <p><input type="checkbox"/> 5. Other <free text></p>

DECLARATION

I declare that the above particulars are, to the best of my knowledge and belief, correct.

Signature: _____ Date:

Print name: _____ Title/position:

CHECKLIST OF DOCUMENTS

The following information must be submitted with the application (except where not applicable).

Please tick the checkboxes below to confirm the documents have been included with the application.

- Letter of application
- Completed application form
- Certificate of incorporation
- Site master file if available (active substance manufacturers only)
- Signed declaration

APPENDIX II WORKED EXAMPLES FOR SITES CARRYING OUT ACTIVE SUBSTANCE MANUFACTURING, IMPORTATION AND DISTRIBUTION ACTIVITIES

This appendix includes some worked examples for sites carrying out active substance manufacturing, importation and distribution activities. The specific activities carried out are described for the site in each worked example and the appropriate entries to be included on the application form are also identified.

WORKED EXAMPLE 1

This is a worked example for a site carrying out the following activities at the registered address.

- Full manufacture of paracetamol active substance which is subsequently distributed to other sites
- Manufacture of diclofenac sodium from another salt form of the same active substance which is subsequently distributed to another site
- Manufacture of ibuprofen crude which is subsequently distributed to another site for further active substance processing steps
- Physical / chemical testing

The fee payable for registration of these activities is €250 (covering manufacture of actives and distribution of only those actives manufactured at the registered site.)



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

APPLICANT DETAILS

Name or corporate name of registrant: **Irish API Ltd.**

Company registration office number: **12341789**

Permanent or legal address of registrant: **Irish Pharmaco Ltd., 2 Earlsfort Terrace, Dublin 2**

Address of site where registered activities take place in Ireland:

**Irish API Ltd,
Unit 7 Balrothery Park
Balrothery
Co. Dublin**

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed: **As above**

Contact telephone number: **01 789789236**

Contact fax number: **01 789789 234**

E-mail address of applicant: **mary.smith@irishapi.ie**

TYPE OF REGISTRATION REQUESTED

(Identify all activities for which registration is being sought.)

Note:

- *If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.*

- Registration for a manufacturer of an active substance
- Registration for an importer of an active substance
- Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

**Irish API Ltd,
Unit 7 Balrothery Park
Balrothery
Co. Dublin**

1 MANUFACTURING OPERATIONS

Active substance(s): **Paracetamol**

A	Manufacture of active substance by chemical synthesis
	<input checked="" type="checkbox"/> 1. Manufacture of active substance intermediates <input checked="" type="checkbox"/> 2. Manufacture of crude active substance <input checked="" type="checkbox"/> 3. Salt formation/purification steps: crystallisation <input type="checkbox"/> 4. Other <free text>

B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>

C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>

D	Manufacture of sterile active substance (note Parts A, B and C, to be completed as applicable)
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised

E	General finishing steps
	<input checked="" type="checkbox"/> 1. Physical processing steps: drying and milling <input checked="" type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input checked="" type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)

1 MANUFACTURING OPERATIONS

Active substance(s): **Diclofenac sodium**

A	Manufacture of active substance by chemical synthesis
	<input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input checked="" type="checkbox"/> 3. Salt formation/purification steps: salt formation and crystallisation <input type="checkbox"/> 4. Other <free text>

B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>

C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>
D	Manufacture of sterile active substance (note Parts A, B and C, to be completed as applicable)
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised
E	General finishing steps
	<input checked="" type="checkbox"/> 1. Physical processing steps: drying and milling <input checked="" type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input checked="" type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)
F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input checked="" type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing) <input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

1 MANUFACTURING OPERATIONS

Active substance(s): **Ibuprofen crude**

A	Manufacture of active substance by chemical synthesis
	<input checked="" type="checkbox"/> 1. Manufacture of active substance intermediates <input checked="" type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: salt formation and crystallisation <input type="checkbox"/> 4. Other <free text>

B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>
C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>
D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised
E	General finishing steps
	<input checked="" type="checkbox"/> 1. Physical processing steps: drying and milling <input checked="" type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input checked="" type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)
F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input checked="" type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing) <input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i>		
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the importation activities.</i></p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation)</p> <p><input type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA)</p> <p><input type="checkbox"/> 3. Other <free text></p>		

B	Distribution		
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i> Paracetamol, Diclofenac Sodium		
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA)</p> <p><input checked="" type="checkbox"/> 2. Holding (i.e. storage)</p> <p><input checked="" type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA)</p> <p><input type="checkbox"/> 4. Export (to sites outside the EEA)</p> <p><input type="checkbox"/> 5. Other <free text></p>		

WORKED EXAMPLE 2

This example relates to a site carrying out the following activities at the registered address:

- Purchase and physical importation of aspirin from a distributor in India. The aspirin is subsequently distributed to sites in the EEA and outside the EEA.
- Distribution of ibuprofen sourced from another manufacturer in the EEA

The fee payable for registration of these activities is €500.



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

APPLICANT DETAILS

Name or corporate name of registrant: **Irish Pharmaco Ltd.**

Company registration office number: **12341234**

Permanent or legal address of registrant: **Irish Pharmaco Ltd., 2 Earlsfort Terrace, Dublin 2**

Address of site where registered activities take place:

**Irish Pharmaco Ltd,
Unit 5 Balrothery Park
Balrothery
Co. Dublin**

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed: **As above**

Contact telephone number: **01 789789789**

Contact fax number: **01 789789799**

E-mail address of applicant: **john.ryan@irishpharmaco.ie**

TYPE OF REGISTRATION REQUESTED

Note:

- If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.
- If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.
- Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.

- Registration for a manufacturer of an active substance
- Registration for an importer of an active substance
- Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

**Irish Pharmaco Ltd,
Unit 5 Balrothery Park
Balrothery
Co. Dublin**

1 MANUFACTURING OPERATIONS

Active substance(s):

A	Manufacture of active substance by chemical synthesis
	<input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: crystallisation <input type="checkbox"/> 4. Other <free text>

B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>
C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>
D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised
E	General finishing steps
	<input type="checkbox"/> 1. Physical processing steps: drying and milling <input type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)
F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing) <input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i>		
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	Aspirin	API Manufacturers pvt, Plot 7a, City Industrial Estate Mumbai India	API Distributors pvt. Plot10 City Industrial Estate Mumbai India
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the importation activities.</i></p> <p><input checked="" type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation)</p> <p><input checked="" type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA)</p> <p><input type="checkbox"/> 3. Other <free text></p>		

B	Distribution		
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i> Aspirin Ibuprofen		
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the distribution activities.</i></p> <p><input checked="" type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA)</p> <p><input checked="" type="checkbox"/> 2. Holding (i.e. storage)</p> <p><input checked="" type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA)</p> <p><input checked="" type="checkbox"/> 4. Export (to sites outside the EEA)</p> <p><input type="checkbox"/> 5. Other <free text></p>		

WORKED EXAMPLE 3

This example relates to an MIA Holder carrying out the following activities at the registered address:

- Procurement and physical importation of aspirin active substance from India for use in manufacture of tablets at the MIA holder's site
- Procurement and physical importation of ibuprofen which is distributed to another site in the EEA

The fee payable for registration of these activities is €500.



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

APPLICANT DETAILS

Name or corporate name of registrant: **Irish Medicines Ltd.**

Company registration office number: **12345381**

Permanent or legal address of registrant: **Irish Pharmaco Ltd., 2 Earlsfort Terrace, Dublin 2**

Address of site where registered activities take place:

**Irish Medicines Ltd,
Unit 2 Balrothery Park
Balrothery
Co. Dublin**

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed: **As above**

Contact telephone number: **01 789782345**

Contact fax number: **01 789782346**

E-mail address of applicant: **john.smith@irishmedicines.ie**

TYPE OF REGISTRATION REQUESTED

(Identify all activities for which registration is being sought.)

Note:

- *If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.*

- Registration for a manufacturer of an active substance
 Registration for an importer of an active substance
 Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

**Irish Medicines Ltd,
 Unit 2 Balrothery Park
 Balrothery
 Co. Dublin**

1 MANUFACTURING OPERATIONS

Active substance(s):

A	Manufacture of active substance by chemical synthesis
	<input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: crystallisation

	<input type="checkbox"/> 4. Other <free text>
B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>
C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>
D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised
E	General finishing steps
	<input type="checkbox"/> 1. Physical processing steps: drying and milling <input type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)
F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing)

<input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i>		
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	Aspirin	API Manufacturers pvt, Plot 7a, City Industrial Estate Mumbai India	API Distributors pvt. Plot10 City Industrial Estate Mumbai India
	Clarifying remarks related to the scope of these registered operations: <i>Tick all relevant operations which apply to the importation activities.</i> <input checked="" type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation) <input checked="" type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA) <input type="checkbox"/> 3. Other <free text>		

B	Distribution		
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i> Ibuprofen		
	Clarifying remarks related to the scope of these registered operations: <i>Tick all relevant operations which apply to the distribution activities.</i> <input type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA) <input checked="" type="checkbox"/> 2. Holding (i.e. storage) <input checked="" type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA) <input type="checkbox"/> 4. Export (to sites outside the EEA) <input type="checkbox"/> 5. Other <free text>		

WORKED EXAMPLE 4

This example relates to a site carrying out the following activities at the registered address:

- Receipt of active substance (diclofenac sodium) from sites located in the EEA on behalf of finished product manufacturer
- Site of physical importation for aspirin received from a site located in a third country
- Storage of the above actives on behalf of a finished product manufacturer
- Supply of these actives on behalf of the finished product manufacturer

The fee payable for registration of these activities is €500.



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

APPLICANT DETAILS

Name or corporate name of registrant: **Irish Storage Ltd.**

Company registration office number: **4653684**

Permanent or legal address of registrant: **Irish Storage Ltd., Unit 9 Balrothery Park,
Balrothery Co. Dublin.**

Address of site where registered activities take place:

**Irish Storage Ltd,
Unit 9 Balrothery Park
Balrothery
Co. Dublin**

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed: **As above**

Contact telephone number: **01 78974327**

Contact fax number: 01 78974328
E-mail address of applicant: anne.murphy@irishstorage.ie
TYPE OF REGISTRATION REQUESTED
<i>(Identify all activities for which registration is being sought.)</i>
Note:
<ul style="list-style-type: none"> - <i>If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.</i> - <i>If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.</i> - <i>Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.</i>
<input type="checkbox"/> Registration for a manufacturer of an active substance <input checked="" type="checkbox"/> Registration for an importer of an active substance <input checked="" type="checkbox"/> Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

**Irish Storage Ltd,
Unit 9 Balrothery Park
Balrothery
Co. Dublin**

1 MANUFACTURING OPERATIONS

Active substance(s):

A	Manufacture of active substance by chemical synthesis
	<input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: crystallisation <input type="checkbox"/> 4. Other <free text>
B	Extraction of active substance from natural sources

	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>
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C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>

D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised

E	General finishing steps
	<input type="checkbox"/> 1. Physical processing steps: drying and milling <input type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)

F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing) <input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i>		
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	Aspirin	API Manufacturers pvt, Plot 7a, City Industrial Estate Mumbai India	API Distributors pvt. Plot10 City Industrial Estate Mumbai India
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the importation activities.</i></p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation)</p> <p><input checked="" type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA)</p> <p><input type="checkbox"/> 3. Other <free text></p>		

B	Distribution		
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i> Diclofenac Sodium, Aspirin		
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the distribution activities.</i></p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA)</p> <p><input checked="" type="checkbox"/> 2. Holding (i.e. storage)</p> <p><input type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA)</p> <p><input type="checkbox"/> 4. Export (to sites outside the EEA)</p> <p><input type="checkbox"/> 5. Other <free text></p>		

WORKED EXAMPLE 5

There are two sites involved in these examples and both sites need to register separately in relation to the activities applicable at each site. (See Worked Example 5A and Worked Example 5B below.)

- Finished product manufacturer (Irish Medicines Ltd. – manufacturer of human medicines) purchases aspirin from an active substance manufacturer located in a third country.
- The imported aspirin is sent from the third country active substance manufacturer directly to a contract storage site (Irish Storage Ltd.) where the active is stored on behalf of the finished product manufacturer i.e. contract storage site is the site of physical importation for the aspirin.
- The aspirin is supplied to the finished product manufacturer as needed.

WORKED EXAMPLE 5A – REGISTRATION REQUIREMENTS FOR THE FINISHED PRODUCT MANUFACTURER (IRISH MEDICINES LTD.)

The fee payable for registration of these activities is €500.



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

APPLICANT DETAILS

Name or corporate name of registrant: **Irish Medicines Ltd.**

Company registration office number: **12345381**

Permanent or legal address of registrant: **Irish Pharmaco Ltd., 2 Earlsfort Terrace, Dublin 2**

Address of site where registered activities take place:

**Irish Medicines Ltd,
Unit 2 Balrothery Park
Balrothery
Co. Dublin**

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed: **As above**

Contact telephone number: **01 789782345**

Contact fax number: **01 789782346**

E-mail address of applicant: **john.smith@irishmedicines.ie**

TYPE OF REGISTRATION REQUESTED

(Identify all activities for which registration is being sought.)

Note:

- *If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.*

- Registration for a manufacturer of an active substance
 Registration for an importer of an active substance
 Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

**Irish Medicines Ltd,
Unit 2 Balrothery Park
Balrothery
Co. Dublin**

1 MANUFACTURING OPERATIONS

Active substance(s):

A	Manufacture of active substance by chemical synthesis
	<input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: crystallisation <input type="checkbox"/> 4. Other <free text>

B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>

C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>

D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised

E	General finishing steps
	<input type="checkbox"/> 1. Physical processing steps: drying and milling <input type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)

F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing) <input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i>		
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	Aspirin	API Manufacturers pvt, Plot 7a, City Industrial Estate Mumbai India	API Distributors pvt. Plot10 City Industrial Estate Mumbai India
	Clarifying remarks related to the scope of these registered operations: <i>Tick all relevant operations which apply to the importation activities.</i> <input checked="" type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation) <input type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA) <input type="checkbox"/> 3. Other <free text>		

B	Distribution
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i>
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the distribution activities.</i></p> <p><input type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA)</p> <p><input type="checkbox"/> 2. Holding (i.e. storage)</p> <p><input type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA)</p> <p><input type="checkbox"/> 4. Export (to sites outside the EEA)</p> <p><input type="checkbox"/> 5. Other <free text></p>

WORKED EXAMPLE 5B – REGISTRATION REQUIREMENTS FOR THE CONTRACT STORAGE SITE (IRISH STORAGE LTD.)

The fee payable for registration of these activities is €250.



Application for Registration of Manufacturer, Importer or Distributor of Active Substances

<p>APPLICANT DETAILS</p> <p>Name or corporate name of registrant: Irish Storage Ltd.</p> <p>Company registration office number: 4653684</p> <p>Permanent or legal address of registrant: Irish Storage Ltd., Unit 9 Balrothery Park, Balrothery Co. Dublin.</p> <p>Address of site where registered activities take place: Irish Storage Ltd, Unit 9 Balrothery Park</p>

**Balrothery
Co. Dublin**

If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):

Name and address of applicant to whom correspondence should be addressed: **As above**

Contact telephone number: **01 78974327**

Contact fax number: **01 78974328**

E-mail address of applicant: **anne.murphy@irishstorage.ie**

TYPE OF REGISTRATION REQUESTED

(Identify all activities for which registration is being sought.)

Note:

- *If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.*
- *Please review the 'Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland' prior to completing this form, as it provides worked examples on how to complete it correctly.*

- Registration for a manufacturer of an active substance
- Registration for an importer of an active substance
- Registration for a distributor of an active substance

SCOPE OF REGISTRATION

Name and address of the site:

**Irish Storage Ltd,
Unit 9 Balrothery Park
Balrothery
Co. Dublin**

1 MANUFACTURING OPERATIONS

Active substance(s):

A	Manufacture of active substance by chemical synthesis
	<input type="checkbox"/> 1. Manufacture of active substance intermediates <input type="checkbox"/> 2. Manufacture of crude active substance <input type="checkbox"/> 3. Salt formation/purification steps: crystallisation <input type="checkbox"/> 4. Other <free text>
B	Extraction of active substance from natural sources
	<input type="checkbox"/> 1. Extraction of substance from plant source <input type="checkbox"/> 2. Extraction of substance from animal source <input type="checkbox"/> 3. Extraction of substance from human source <input type="checkbox"/> 4. Extraction of substance from mineral source <input type="checkbox"/> 5. Modification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 6. Purification of extracted substance <specify source 1,2,3,4> <input type="checkbox"/> 7. Other <free text>
C	Manufacture of active substance using biological processes
	<input type="checkbox"/> 1. Fermentation <input type="checkbox"/> 2. Cell culture <specify cell type> (e.g. mammalian/bacterial) <input type="checkbox"/> 3. Isolation/purification <input type="checkbox"/> 4. Modification <input type="checkbox"/> 5. Other <free text>
D	Manufacture of sterile active substance <i>(note Parts A, B and C, to be completed as applicable)</i>
	<input type="checkbox"/> 1. Aseptically prepared <input type="checkbox"/> 2. Terminally sterilised

E	General finishing steps
	<input type="checkbox"/> 1. Physical processing steps: drying and milling <input type="checkbox"/> 2. Primary packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) <input type="checkbox"/> 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.) <input type="checkbox"/> 4. Other <free text> (for operations not described above)

F	Quality control testing <i>Complete this section only if any parts of sections A, B, C, D, E are completed.</i>
	<input type="checkbox"/> 1. Physical/chemical testing <input type="checkbox"/> 2. Microbiological testing (excluding sterility testing) <input type="checkbox"/> 3. Microbiological testing (including sterility testing) <input type="checkbox"/> 4. Biological testing

2 IMPORTATION AND DISTRIBUTION OPERATIONS

A	Importation <i>(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)</i>		
	Active substance	Third-country manufacturer (name and address)	Distributor (name and address)
	Aspirin	API Manufacturers pvt, Plot 7a, City Industrial Estate Mumbai India	API Distributors pvt. Plot10 City Industrial Estate Mumbai India
	Clarifying remarks related to the scope of these registered operations: <i>Tick all relevant operations which apply to the importation activities.</i> <input type="checkbox"/> 1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation) <input checked="" type="checkbox"/> 2. Site of physical importation (site receiving active substance from outside the EEA) <input type="checkbox"/> 3. Other <free text>		

B	Distribution
	Active substance(s) <i>(list all active substances for which distribution operations apply)</i> Aspirin
	<p>Clarifying remarks related to the scope of these registered operations:</p> <p><i>Tick all relevant operations which apply to the distribution activities.</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> 1. Procurement (purchase of active substance from sites in the EEA) <input checked="" type="checkbox"/> 2. Holding (i.e. storage) <input type="checkbox"/> 3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA) <input type="checkbox"/> 4. Export (to sites outside the EEA) <input type="checkbox"/> 5. Other <free text>