Order no. 1295/2015

on manufacturing authorisation of manufacturers, importers of medicinal products for human use, investigational medicinal products included, of independent control sites and grant of Good Manufacturing Practice Certificates

ISSUED BY: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, PART I, NO. 837 OF 10 NOVEMBER 2015

On seeing Approval Report no. N.B. 10.483/2015 of the Directorate for Policies on Medicinal Product and Medical Devices of the Ministry of Health and notification no. 59.619E of the National Agency for Medicines and Medical Devices, registered with the Minister of Health under no. 74.407 of 4 December 2014,

Taking into account provisions of Articles Article 755 - 761 and Article 857(13) of Law 95/2006 on healthcare reform, republished,

Having regard to provisions of Article 12(9) of Government Decision No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

Based on Article 7 (4) of Government Decision No. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the Minister of Health hereby issues the following Order:

SECTION I

Introduction

ARTICLE 1

In the context of this order, terms and notions in use shall mean the following:

a) the *European Medicines Agency* – European institution founded in 1995, based on Council Regulation (EEC) 2.309/93, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, whose main task is scientific evaluation of applications for European Union (EU) marketing authorisations for human and veterinary medicines in the centralised procedure, resulting in grant of a marketing authorisation for new medicinal products by European Commission Decision;

b) the *National Agency for Medicines and Medical Devices* – the Romanian competent authority in the field of medicinal products for human use, further referred to as medicinal products;

c) *Manufacturing authorisation* – document issued by the NAMMD based on Article 755 of Law 95/2006 on healthcare reform, republished - title XVIII, "The medicinal product";

d) *Marketing authorisation* – document issued by the competent authority in the medicinal product field, based on evaluation and approval of documentation for authorisation submitted by the applicants to that specific authority, document allowing circulation of that medicinal product on the pharmaceutical market of the specific country;

e) *National marketing authorisation for medicinal products* – marketing authorisation for a medicinal product granted by the National Agency for Medicines and Medical Devices;

f) *Marketing authorisation valid in Romania* – national marketing authorisation on the national market or by European Commission Decision;

g) *Intra-community trade* – operations of introduction into Romania of medicinal products coming from member states of the European Economic Area; where these operations are concerned, the internal right of disposition is applied;

h) *European Commission Decision* – document granted by the European Commission concerning medicinal products authorised through centralised procedure in line with Regulation No. 726/2004 of the European Parliament and of the Council, of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, which allows the movement of the respective medicinal product throughout all member states of the European Economic Area;

i) *Excipient* – any constituent of a medicinal product which is not an active substance or a packaging material;

j) *Import of medicinal products*: operation of introducing in Romania medicinal products coming from third countries;

k) M*edicinal product importer* – person who carries out, in accordance with legal dispositions, importing operations of medicinal products, including investigational products;

l) A*ctive substance* – Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body;

m) *Medicinal products coming from the European Economic Area* – medicinal products manufactured within the European Economic Area or which, although not manufactured within this area, have acquired the right of free circulation within the European Economic Area; medicinal products not coming from the European Economic Area are third country medicinal products;

n) C*entralised procedure* – marketing authorisation procedure stipulated by Regulation (CE) No. 726/2004;

o) *National procedure* – marketing authorisation procedure, issued by the National Agency for Medicines and Medical Devices, based on national legislation in force;

p) M*utual recognition procedure* – European marketing authorisation procedure, carried on in accordance with stipulations of section 5 “Mutual recognition procedure and decentralised procedure” of Section III “Marketing

Authorisation" of Title XVIII – "Placement on the market" of Law 95/2006 on healthcare reform, republished;

q) *Decentralised procedure* – European marketing authorisation procedure, carried on in accordance with stipulations of section 5 of Section III of Title XVIII of Law 95/2006, as amended;

r) *European Economic Area* – member states of the European Union including Norway, Iceland and Liechtenstein;

s) *Control site* outside the manufacturing site (henceforth, referred to as independent control site) – separate legal entity, conducting control (physico-chemical, microbiological, biological etc.), undertaking contract-based analytical testing for grant of test bulletins, stability studies, development of control methodologies;

t) *Third countries* – countries other than member states of the European Economic Area.

SECTION II

Manufacturing authorisation

ARTICLE 2

(1) In compliance with Article 755 of Law No. 95/2006, republished, for manufacture of medicinal products inside Romania, investigational medicinal products included, applicants must own a manufacturing authorisation.

(2) According to the same legal provisions, for import of medicinal products into Romania, investigational medicinal products included, applicants must own an import authorisation.

ARTICLE 3

(1) The manufacturing authorisation is granted and issued by the National Agency for Medicines and Medical Devices, in compliance with provisions of Article 755 of Law No. 95/2006, republished.

(2) This manufacturing authorisation is also necessary for medicinal products exclusively intended for export, in case of manufacturers of sterile active substances or excipients, of manufacturers of active biological raw materials and of independent control sites performing testing activities on medicinal products for human use.

ARTICLE 4

(1) Manufacturing authorisations for manufacturing/import/control sites are granted on application by manufacturers/importers/independent control sites.

(2) Manufacturing authorisations are granted based on favourable inspection report prepared by NAMMD inspectors.

(3) For grant of manufacturing authorisation, applicants submit an application to the NAMMD requesting schedule of an inspection, in accordance with the form stipulated in Annex I and the form filled in as shown in Annexes III or IV, accompanied by the following documents:

a) administrative documents:

a1) statutes of the company;

a2) closure/resolution for company authorisation and registration;

a3) a certified copy of the registration certificate granted and issued by the Registry of Commerce, annexes included;

a4) fact-finding certificate issued 30 days prior to application submission;

a5) certified copy of proof of location ownership;

a6) for importers not holding their own storage facilities, service contract with an authorised medicinal product wholesaler;

b) technical documents;

b1) master file established for each manufacturing site, in line with Part III of the Guideline on Good Manufacturing Practice for medicinal products for human use; importers shall prepare a master file for each import place, taking into account import specificities; similarly, independent control sites shall prepare the master file in line with testing specificities;

b2) commitment concerning submission of accurate status of each import (according to Annex VI), immediately upon accomplishment thereof, drafted in the format provided in Annex VII – both on paper and in electronic format (requested of importers only).

ARTICLE 5

Ten days as of registration of the application, the National Agency for Medicines and Medical Devices notifies the applicant on status of documents submitted for conduct of the inspections:

a) For documentation compliant with provisions of Article 4 (3), the applicant is informed on acceptance of the respective application for inspection as well as on inspection fee, as approved through Order of the

Minister of Health; except otherwise justified, the inspection is conducted 10 days as of fee payment confirmation, on an agreed date;

b) For incomplete documentation, the applicant is notified as to further information to be submitted to the National Agency for Medicines and Medical Devices; in such cases, compliance with timeframes provided in Article 758 and 759 of Law No. 95/2006, republished, are suspended until submission of complete documentation.

ARTICLE 6

The inspection is conducted in line with an inspection plan established by an inspector/inspectors nominated by the NAMMD; the respective plan is notified to the applicant site at least 3 days prior to the date of inspection.

ARTICLE 7

(1) The inspection for manufacturing authorisation assesses compliance with Good Manufacturing Practice principles related to medicinal products for human use, investigational medicinal products included, as well as compliance with the Guideline for Good Manufacturing Practice for medicinal products.

(2) Manufacturing authorisation is required both for total and partial manufacture and for various operations concerning medicinal products division, packaging or change of presentation form (repackaging, relabelling), investigational medicinal products included.

ARTICLE 8

(1) No later than 20 days as of the inspection date, the list of deficiencies/inspection report is provided to the applicant, as appropriate; for the list of deficiencies, within 15 days, the applicant is required to submit the proposed corrective and preventive action plan; in case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan.

(2) In case of unfavourable inspection reports (concluding on GMP non-compliance), in the shortest time possible, the NAMMD issues a GMP Non-compliance Statement in the European format approved by the European Commission; in such cases, after resolution of deficiencies found, the inspectee may apply for a new inspection;

(3) In case of favourable inspection reports (concluding on GMP compliance), the National Agency for Medicines and Medical Devices grants the manufacturing authorisation within 90 days as of the registration date of the full documentation submitted by the applicant;

(4) Follow-up of resolution of potential deficiencies found is performed after issue of the manufacturing authorisation, in accordance with provisions of article 757 (2) of Law No. 95/2006, republished, based on documentation submitted by the applicant or by means of a new inspection.

ARTICLE 9

The manufacturing authorisation is issued in the format approved by the European Commission, in two original copies, one of which is handed to the applicant unit, while the other remains with the National Agency for Medicines and Medical Devices – the Pharmaceutical Inspection Department.

ARTICLE 10

(1) Frequency of follow-up inspections at medicinal products manufacturers/importers/independent control sites is established as appropriate, in line with NAMMD Scientific Council Decision on approval of the Model for Risk Based Planning for Inspections of Pharmaceutical Manufacturers; at the same time, frequency of the next inspection is noted in the inspection report. Further, 90 days prior to the scheduled date, the MAH shall request the National Agency for Medicines and Medical Devices for conduct of the inspection.

(2) The inspection is performed within 10 days after inspection fee payment confirmation, on a date established jointly with the inspected site; the inspection is conducted in agreement with provisions of Articles 6-8.

(3) When the inspection is not applied for within the legally established timeframe or is deferred for inspectee-related reasons, the NAMMD decides on inspectee GMP compliance status and takes appropriate measures.

ARTICLE 11

For inspections under Article 10 (1), 90 days prior to the date of the next inspection specified in the previous inspection report, the MAH shall submit an application for inspection scheduling (as per Annex II), accompanied by the Site Master File (according to Part III of the GMP Guideline), the updated

version of administrative documents mentioned in Article 4 (3) (in case of changes) and the status of corrective and preventive measures implemented after the previous inspection.

ARTICLE 12

Changes subsequent to grant of the manufacturing authorisation are notified to the National Agency for Medicines and Medical Devices in advance, in accordance with Article 761 c) of Law No. 95/2006, republished, at the same time with an application for new authorisation or change of one/several annexes of the authorisation; depending on the nature of the change, the manufacturing authorisation is granted based on an updated dossier submitted (for administrative changes) or a new favourable inspection report (for technical changes).

ARTICLE 13

In line with legal provisions in force on the legal status of psychoactive and psychotropic plants and drugs, for manufacture and import of medicinal products containing psychoactive and psychotropic substances, after grant of manufacturing authorisation, applicants must apply to the Ministry of Health for grant of authorisations required for manufacture and import of this type of medicinal products.

ARTICLE 14

Loss of the manufacturing authorisation results in cancellation thereof; grant of a duplicate manufacturing authorisation is done based on the following documents:

a) application as per the form mentioned in Annex V;
b) proof of publication of the loss in a widely circulated daily;
c) statutory declaration that no changes have been made to information allowing for initial grant of manufacturing/import authorisation.

ARTICLE 15

(1) When non-compliance with Good Manufacturing Practice Rules is found on any inspection, measures are taken in relation with the Manufacturing Authorisation in line with Decision of the NAMMD Scientific Council on the Procedure for dealing with serious GMP non-compliance or

suspension/revocation of certificates of Compliance with the European Pharmacopoeia, requiring co-ordinated measures, posted on the NAMMD website.

(2) Should one or several conditions for conditional authorisation be found, except for the situation stipulated under (1), that had not been met, the National Agency for Medicines and Medical Devices shall suspend the manufacturing authorisation granted, in part or in whole, until remedy of deficiencies found or revoke the manufacturing authorisation in case deficiencies found are beyond remedy.

(3) Should the company cease its activity, the manufacturing authorisation shall be returned to the National Agency for Medicines and Medical Devices for cancellation.

SECTION III

Good Manufacturing Practice certificate

ARTICLE 16

Pursuant to Article 857(135) of Law 95/2006 for healthcare reform, republished, in case of inspections concerning authorisation of medicinal product manufacturers/importers/independent control sites of follow-up inspections, the National Agency for Medicines and Medical Devices grants the Good Manufacturing Certificate within 90 days as of the inspection date, on condition the inspection report confirms compliance with Good Manufacturing Practice Rules.

ARTICLE 17

(1) As regards applications for marketing authorisation or variation to marketing authorisation terms concerning a medicinal product in Romania, the NAMMD decides on necessity of inspection to assess compliance with Good Manufacturing Practice Rules at the site of manufacturers of medicinal products or active substances, in a third country, in accordance with Article 729 a) and Article 857 (12) of Law 95/2006, republished; in this case, the NAMMD requires the third country manufacturer of the medicinal product/active substance or the manufacturer’s representative in Romania to submit for inspection documents mentioned in Article 18 (1). The application shall not dispute possible arrangements concluded between the EU and the respective third country as regards Good Manufacturing Practice inspections.

(2) The inspection stipulated under (1) is performed in accordance with the procedure of the Compilation of European Procedures regarding the guideline for a Procedure for Verification of the GMP Status of Manufacturers in Third Countries, transposed into Romanian through NAMMD Scientific Council Decision and posted on the NAMMD website.

(3) In line with the procedure in the Guidance on the occasions when it is appropriate for competent authorities to conduct inspections at the premises of manufacturers, importers and distributors of active substances and manufacturers or importers of excipients used as starting materials, transposed into Romanian through NAMMD Scientific Council Decision and posted on the NAMMD website, inspections at the site of a manufacturer of active substance/excipient in Romania or a third country can be performed following NAMMD decision in accordance with stipulations under (1), at EMA/EDQM/manufacturer request. If the inspection is requested by a manufacturer of an active substance/excipient in a third country or by their representative in Romania, documents mentioned in Article 18 (1) shall be submitted for inspection.

(4) For import of medicinal products from third countries to Romania, on issuance of the GMP compliance certificate for a third country medicinal product manufacturer, the NAMMD becomes the monitoring authority for that manufacturing site and must inspect it periodically.

(5) When non-compliance with legal provisions and with principles and guidelines of Good Manufacturing Practice mentioned in Article 761 f) of Law 95/2006, republished, is suspected, the NAMMD may conduct inspections at the sites of manufacturers/importers of active substances in third countries, who are involved in procedures for marketing authorisation /variations handled by the NAMMD.

(6) When non-compliance with legal provisions and with principles and guidelines of Good Manufacturing Practice mentioned in Article 761 f) of Law 95/2006, republished, is suspected, the NAMMD may conduct inspections at the sites of manufacturers/importers of excipients involved in procedures for marketing authorisation /variations handled by the NAMMD.

ARTICLE 18

(1) In order to obtain a Good Manufacturing Practice certificate, the manufacturer of medicinal products in Romania/a third country, the importer of medicinal products, manufacturer of active substances/excipients in

Romania/a third country or the independent control site in Romania submits to the NAMMD an application for inspection planning in accordance with the draft in Annex II, accompanied by the master file of the site/import/independent control site (in case of third country manufacturers, the documentation is submitted in English).

(2) When non-compliance is suspected with legal provisions and with principles and guidelines of Good Manufacturing Practice mentioned in Article 761 f) of Law 95/2006, republished, the NAMMD may require the manufacturer of medicinal products in Romania/third country, the importer, the manufacturer of active substances in Romania/third country, the manufacturer of excipients or the independent control site to submit the documents mentioned in paragraph (1), for inspection.

ARTICLE 19

Within 20 days as of receipt of the application, the National Agency for Medicines and Medical Devices provides the applicant a response in relation with the documents submitted for inspection:

a) In case of comprehensive documentation submitted, the applicant is notified on acceptance of their application for inspection and inspection fee, as approved through Order of the Minister of Health; except otherwise justified, the inspection takes place within 30 days as of the confirmation of fee payment, on an agreed date;

b) In case of incomprehensive documentation submitted, the applicant is notified on the additional data to be submitted to the National Agency for Medicines and Medical Devices.

ARTICLE 20

The inspection is carried out in line with an inspection plan established by an inspector/inspectors nominated by the National Agency for Medicines and Medical Devices; the plan is notified to the applicant at least 3 days prior to inspection date.

ARTICLE 21

(1) The inspection for grant of Good Manufacturing Practice certificate pursues compliance with the principles and guidelines for medicinal products Good Manufacturing Practice, investigational medicinal products included, approved through Order of the Minister of Health and compliance with the Guideline for medicinal product Good Manufacturing Practice.

(2) The inspection for grant of active substance/excipients Good Manufacturing Practice certificate pursues compliance with Part II of the Good Manufacturing Practice Guideline and the Guideline for formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use, respectively.

ARTICLE 22

(1) Within 30 days as of the inspection date, the list of deficiencies/ inspection report is notified to the applicant, as the case may be; for lists of deficiencies, within 15 days, the applicant shall submit the proposed corrective and preventive action the plan; should the corrective and preventive action proposed be unsuitable or submitted in non-compliance with the legal timeframe, before preparation of the inspection report, the inspectee may be forwarded a single notification for supplementation/revision of the plan.

(2) In case of an unfavourable inspection report (because of non-compliance with Good Manufacturing Practice), the NAMMD issues a Declaration of Non-compliance with the Good Manufacturing Practice, in accordance with the draft approved by the European Commission; in such cases, the NAMMD applies the provisions of the community procedure related to resolution of cases of severe non-compliance with the Good Manufacturing Practice (GMP), which requires coordinated measures for public health safeguard, as approved through NAMMD Scientific Council Decision, posted on the NAMMD website; following resolution of findings discovered by inspectors, the inspected unit may apply for a new inspection;

(3) In case of a favourable inspection report, the Good Manufacturing Practice certificate is issued by the National Agency for Medicines and Medical Devices in maximum 90 days from the date of inspection.

ARTICLE 23

The Good Manufacturing Practice certificate is issued in the format approved by the European Commission; it is issued in bilingual form, in two original copies, one of which is handed to the applicant unit, while the other remains with the NAMMD.

ARTICLE 24

(1) Within 90 days prior to the expiry date stipulated in the Good Manufacturing Practice certificate, the active substance manufacturer/third country manufacturer or their Representative to Romania submits an application for inspection (according to Annex II), accompanied by Site

Master File (according to Annex III of the Guideline on Good Manufacturing Practice); if the manufacturer of medicinal products/active substances in a third country holds a Good Manufacturing Practice certificate issued by an EEA authority, he/she will submit it to the NAMMD to prove GMP compliance.

(2) Good Manufacturing Practice certificate renewal is done in accordance with stipulations of articles 18 - 23.

ARTICLE 25

Loss of the Good Manufacturing Practice leads to its cancellation and a copy may be issued based on the following documents:

a) application submitted in the format mentioned in Annex V;

b) proof of published notification of the loss in a widely circulated daily;

c) a statutory declaration mentioning that no changes have been implemented to data initially allowing grant of manufacturing/import authorisation.

ARTICLE 26

(1) Should non-compliance be found with the terms underlying grant of the certification, in other circumstances than mentioned under (1), as required, the NAMMD shall proceed to partial suspension of the Good Manufacturing Practice Certificate (when only certain activities are not GMP compliant), full suspension, until remedy of deficiencies found, or revocation in case deficiencies found are beyond remedy.

(2) If the unit ceases its activity, Good Manufacturing Practice certificates are submitted to the NAMMD for cancellation.

ARTICLE 27

Authorisations for independent control sites issued until entry into force of this Order shall remain valid and may be changed prior to expiry of their validity, upon request of the legal authorisation holder.

ARTICLE 28

Annexes I - VII*) are integral part of this Order.

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*) Annexes I - VII shall be published in the Official Gazette of Romania, Part I, no. 837 bis, available for purchase at the Centre for Public Relations of the "Monitorul Oficial" Independent Company (Regia Autonoma), located in Bucharest, 1Panduri.

ARTICLE 29

On the date of this Order coming into force, Order of the Ministry of Public Health No. 873/2006 on approval of Regulations for manufacturing authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products, and of starting materials used in the manufacturing of medicinal products for human use, including investigational medicinal products, published in the Official Gazette of Romania, Part I, No. 643 of 26 July 2006, as amended, and Order of the Minister of Health no. 312/2009 on approval of Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products and grant of the good manufacturing practice certificate to manufacturers of medicinal products for human use and/or active substances, published in the Official Gazette of Romania, Part I, no. 198 and 198 bis of 30 March 2009, as amended, shall be repealed.

ARTICLE 30

This Order is to be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Dorel Săndesc,
Secretary of the State
Bucharest, 16 October 2015.
No. 1295.

ANNEX

Annexes no. I-VII to Order of the Minister of Health no. 1.295/2015 on manufacturing authorisation of manufacturers, importers of medicinal products for human use, investigational medicinal products included, of independent control sites and grant of Good Manufacturing Practice certificates of 16.10.2015

ANNEX I

To

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

The Pharmaceutical Inspection Department

I, the undersigned, ... (Name and Surname), representative of …....., hereby apply for schedule of an inspection at the site for manufacturing authorisation/grant of a Good Manufacturing Practice certificate for manufacturing /import/testing activities (fill in as required).

Please find attached to the present application documentation required under Order of Minister of Health on approval of Regulations regarding manufacturing / import authorisation of medicinal products for human use, investigational medicinal products included and Good Manufacturing Practice certification for manufacturers of medicines/active substances.

Signature, stamp

. . . . . .

ANNEX II

To

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

The Pharmaceutical Inspection Department

I, the undersigned, ..., representative of …....., (Name and Surname), hereby apply for schedule of an inspection at the site for grant of a Good Manufacturing Practice Certificate in relation to manufacturing/import/testing in Romania*, for manufacturing of the following medicine/medicines* ……., currently undergoing authorisation/renewal of authorisation by the National Agency for Medicines and Medical Devices/ for the following active substances**…… .

* delete as required.

** to be filled in by third country manufacturers or their representatives in Romania.

** to be filled in by active substances third country manufacturers.

Please find attached to the present application documentation required under Article 4 (4) of Order of Minister of Health on approval of Regulations for authorisation of manufacturing/import of medicinal products for human use, investigational medicinal products included and independent control sites and grant of Good Manufacturing Practice Certificate.

Signature, stamp

. . . . . ……

ANNEX III

Application Form

Manufacturing Authorisation

(Please complete all relevant sections in this form typed or in block capitals legibly, using black ink)

1. Application Form: administrative data

1.1. Applicant's details

Authorisation number (if previously authorised):	
Name of the company:	
Name of the applicant:	
Address:	

Postal code:		Telephone No.:	
Mobile phone No.:		Fax No.:	
E-mail address:			

The application is submitted on behalf of the proposed authorisation holder (e.g. if a consultant or representative). If YES, please fill in section 1.2

☐ *yes* ☐ *no*

Contact name:			
Name of the company:			
Address:			
Postal code:		Tel. No.:	
Mobile phone		Fax No.:	
E-mail address:			

1.3 Information on invoicing address (if other than that of the authorisation holder)

Contact name:			
Company:			
Address:			
Postal code:		Telephone No.:	
Mobile phone No.:		Fax No.:	
E-mail address:			

Section 2: Information regarding the manufacturing site

2.1 Information on manufacturing site

Sections 2 and 3 have to be filled in for <u>each</u> total, partial manufacturing or import site to be included in the authorisation

Name of the manufacturing site:			
Address:			
Postal code:			
Contact name			
Telephone No.:		Fax No.:	
Mobile phone No.:			
E-mail address:			

2.2 Types of medicinal products manufactured/imported

Medicinal products for human use ☐ *yes* ☐ *no*

Medicinal products for veterinary use ☐ *yes* ☐ *no*

2.3 Types of activities conducted at the manufacturing site

☐ Manufacturing ☐ Dividing and packaging ☐ Storage and handling

☐ Distribution ☐ Analytic testing ☐ Contract laboratory

☐ Batch release ☐ Vivarium ☐ Preservation of animal origin material

☐ Biological products ☐ Non-biological products ☐ Import

☐ Export ☐ Other, please specify:

Name of manufacturing site ☐ Postal Code ☐

2.4 Types of operations

Part 1 MANUFACTURING (AND TESTING) OPERATIONS

1.1	**Sterile products**	**Manufacture (please tick)**
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 <free text>	
1.1.2	*Terminally sterilised (list of dosage forms)*	
	1.1.2.1. Large volume liquids	
	1.1.1.6 Semi-solids	
	1.1.1.7 Small volume liquids	
	1.1.1.8 Solids and implants	
	1.1.1.6. Other aseptically prepared products <free text>	
1.1.3	**Batch certification only**	

1.2	**Non-sterile products**	**Manufacture (please tick)**
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	
	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 <free text >	
1.2.2	**Batch certification**	

1.3	**Biological medicinal products**	**Manufacture (please tick)**
1.3.1	**Biological medicinal products**	
	1.3.1.1 Blood products	
	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. Tissue-engineered products	
	1.3.1.7 Human or animal extracted products	
	1.3.1.8 Other biological medicinal products <free text >	
1.3.2	**Batch certification**	
	1.3.2.1 Blood products	
	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 Tissue-engineered products	
	1.3.2.8 Other biological medicinal products <free text >	

1.4	**Other products or manufacturing activity**	**Manufacture (please tick)**
1.4.1	**Manufacture of:**	
	1.4.1.1 Herbal products	
	1.4.1.2 Homoeopathic products	
	1.4.1.3 Biological active starting materials	
	1.4.1.4 Other <free text >	
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**	**Packaging (please tick)**
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	
	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**	**Activities related to manufacture (please tick)**
	1.6.1 Microbiological: sterility	
	1.6.2 Microbiological: non-sterility	
	1.6.3 Chemical/Physical	
	1.6.4 Biological	

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

2.1	**Quality control testing of imported medicinal products**	**Import (please tick)**
	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. Blood 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. Tissue-engineered products	
	2.2.3.8 Other biological medicinal products <free text >	
2.2.4	***Other importation activities*** **(any other relevant importation activity that is not covered above**	
	2.2.4.1. Physical site of import	

	2.2.4.2. Import of intermediate products undergoing subsequent processing	
	2.2.4.3. Biological active starting materials	
	2.2.4.4 Other <free text >	

2.5 Imported products

Please answer to the question below for import activities performed

Are there authorised medicines from outside European Economic Area (EEA) imported at this site?

☐ *yes* ☐ *no*

If Yes, please indicate below all authorised products, imported from outside AEE, including products authorised in EU.

MA number	Product name	Country of origin

2.6 Other information

The following information is required by the Inspectorate to be included in the authorisation

Manufacture of bulk product or partial manufacture ☐ *yes* ☐ *no*

Parallel imported products assembly ☐ *yes* ☐ *no*

Total and partial manufacturing for export ☐ *yes* ☐ *no*

Partial manufacturing for export ☐ *yes* ☐ *no*

Are present at the manufacturing site materials or products of animal origin? ☐ *yes* ☐ *no*

CONTRACT GIVING AND/OR ACCEPTING

Applicants to be contract acceptors (e.g. providing partial/total manufacturing to other parties) ☐ *yes* ☐ *no*

Applicants to be contract givers (e.g. use external manufacturers for certain products) ☐ *yes* ☐ *no*

Applicants to be contract acceptors (e.g. providing partial/total testing to other parties) ☐ *yes* ☐ *no*

Applicants to be contract givers (e.g. use external testing units for certain/all tests) ☐ *yes* ☐ *no*

ADDITIONAL INFORMATION RELATING TO TESTING IN THIS MANUFACTURING SITE

Stability testing?

☐ *yes* ☐ *no*

Is the manufacturing site involved in finished products testing? ☐ *yes* ☐ *no*

Is the manufacturing site involved in microbiological Testing of finished products and/or raw materials? ☐ *yes* ☐ *no*

If NO to the above, please explain the activities:

Other information

Do you possess stocks of products requiring freezing or low temperature storage? ☐ *yes* ☐ *no*

Do you import intermediate products for further processing? ☐ *yes* ☐ *no*

Are the premises ready to be inspected? ☐ *yes* ☐ *no*

Are you familiar with Good Manufacturing Practice Principles and Good Manufacturing Practice Guideline and are relevant procedures and records available? ☐ *yes* ☐ *no*

If applicable, your contracts are available for inspection? ☐ *yes* ☐ *no*

2.4 Additional information required

Have you submitted a Site Master File of your site containing your initial application? ☐ *yes* ☐ *no*

Notice: All Unit Standard Dossiers have to be submitted on paper or CD format.

If not, will the Site Master File be available during inspection? ☐ *yes* ☐ *no*

MANUFACTURING SITES FACILITIES

Details must be included in the Site Master File

MANUFACTURING AND CONTROL EQUIPMENT

Details must be included in the Site Master File

Section 3. Assigned persons

Please indicate below staff categories working at the manufacturing site

Staff	**Number**
Qualified person (QP)	
Manufacture responsible person	
Quality control responsible person (QC)	

Please ensure you have included copies of the required documentation.

3.1 Qualified person

1. Please fill in a separate page for each QP
2. QP assignation should be signed by the person assigned and the applicant
3. QP applications should include a relevant CV and a copy of the PQ Certificate issued by the NAMMD

Family name:			
Name:			
Office address:			
Postal code:		Telephone No.:	
Fax No.:		Mobile No.:	
E-mail address:			

Please indicate your status

Permanent employee ☐ Consultant ☐ Temporary employee ☐

If a consultant, please give details on your availability. How often do you visit the site?

Qualifications (relevant for authorisation purposes)

Experience (brief outline of jobs and responsibilities relevant for authorisation purposes)

Professional Bodies:

I hereby confirm that all above details are accurate and true according to my knowledge and opinions. I agree with my assignment as Qualified Person

Signature (of the assigned person):
_____Date:_____
Name in full: _____
Signature (of the applicant):
_____Date:_____
Name in full:
_____

3.2 Manufacture responsible person

Please fill in an individual sheet for each Manufacture responsible person. What is your position as signatory? Please specify below.

Manufacture manager ☐ Section manager (manufacturing flow) ☐

Family name:			
Name:			
Office address:			
Postal code:		Telephone No.:	
Fax No.:		Mobile No.:	
E-mail address:			

Qualifications (relevant for authorisation purposes)

Experience (brief outline of jobs and responsibilities relevant for authorisation purposes)

Name and position of seniors:

Responsibility scope

I hereby confirm that all above details are accurate and true according to my knowledge and opinions. I agree with my assignment as Manufacture responsible person

Signature (of the assigned person of the applicant):
_____Date:_____
Name in full: _____
Signature (of the applicant):
_____Date:_____
Name in full: _____

3.3 Quality control responsible person

Please fill in the following details of the person(s) in charge with quality control. When the responsibility is shared among several persons, please fill in an individual sheet for each person and give details on each person's responsibility scope.

Family name:			
Name:			
Office address:			
Postal code:		Telephone No.:	
Fax No.:		Mobile No.:	
E-mail address:			

Qualifications (relevant for authorisation purposes)

Experience (brief outline of jobs and responsibilities relevant for authorisation purposes)

Name and position of seniors:

Responsibility scope

I hereby confirm that all above details are accurate and true according to my knowledge and opinions. I agree with my assignment as quality control responsible person.

Signature (of the assigned person):
_____Date:_____
Name in full: _____
Signature (of the applicant):
_____Date:_____
Name in full: _____

Section 4: Contract Laboratories

Please complete a copy of section 4 for <u>each</u> contract laboratory you wish to name on this authorisation

Laboratory Name:	
Address:	
Postal code:	
Site Contact Name:	
Telephone:	Fax:
Mobile:	
Email address:	

Please indicate the type of testing carried out by ticking the relevant box(es) below.

Quality Control Testing

Microbiological: sterility		Yes		No
Microbiological: non-sterility		Yes		No

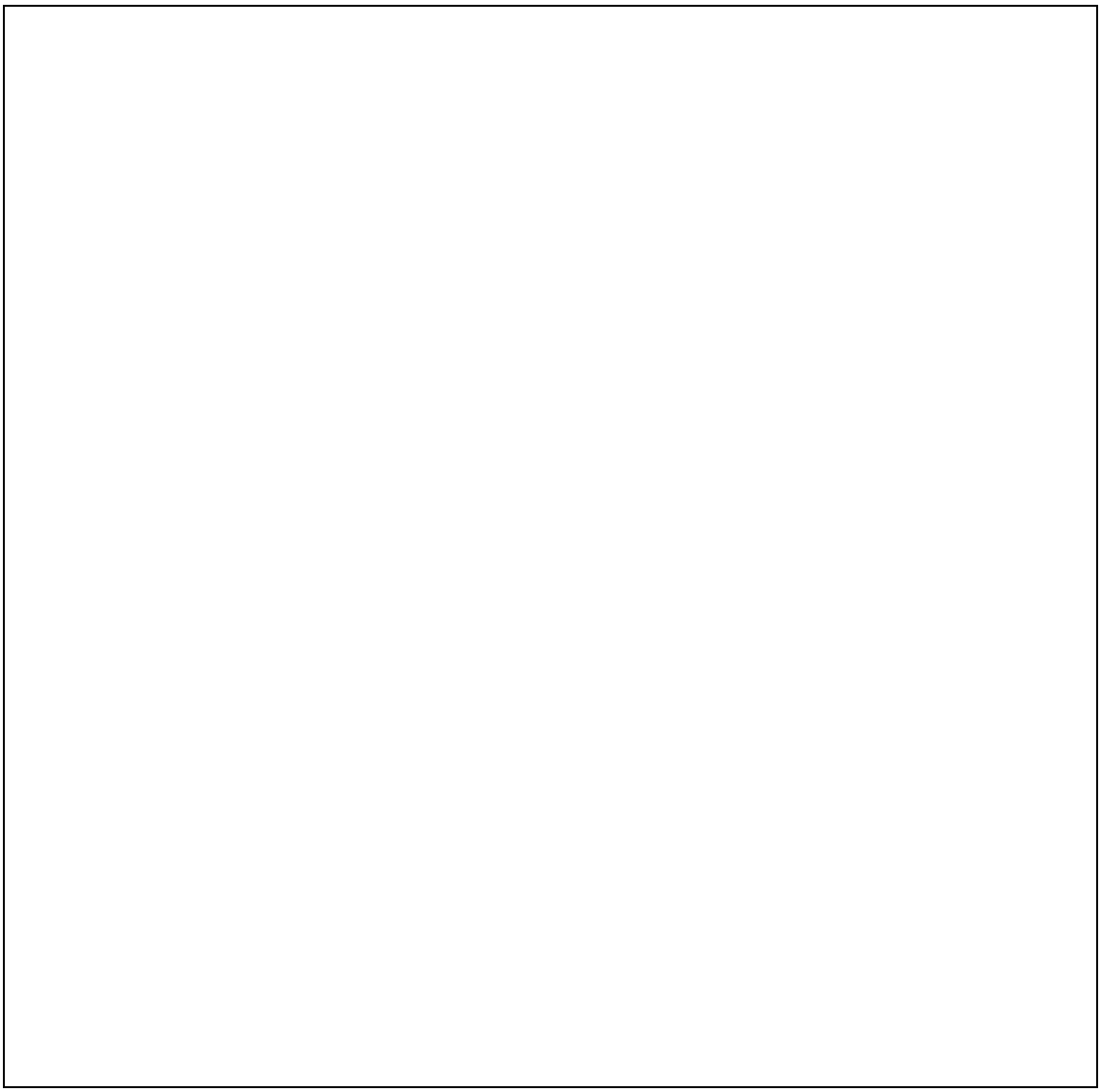
Chemical/Physical		Yes		No
Biological		Yes		No
Stability testing?		Yes		No
Is this site involved in doing finished product testing?		Yes		No
Is this site involved in microbiological testing of finished products and/or raw materials?		Yes		No
If answer No to above, explain activities:				

Please complete a copy of section 5 for <u>each</u> storage and handling site that you wish to include on the licence.

Site Name:	
Address:	
Postal code:	
Site Contact Name:	
Telephone:	Fax:
Mobile:	
Email address:	

Section 6: Comments

Please provide any other information that may support your application. You can also detail any changes to addresses, person names etc.



Section 7: Declaration

I/We hereby apply for grant of a Manufacturing/Import Authorisation (MIA) to the proposed holder named in this application form in respect of the activities to which the application refers.

7.1 The activities are to be only in accordance with the information set out in the application or furnished in connection with it.

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

Signed (Applicant): _____ **Date:** _____

Print Name: _____

Capacity in which signed:

ANNEX IV

Application Form
Manufacturing authorisation
for investigational medicinal products for human use

(Please complete all relevant sections in this form typed or in block capitals legibly, using black ink)

Section 1: Administrative Data

1.1 Applicant's Details

Authorisation Number (if known):	
Company Name:	
Applicant's Name:	
Address:	

Postal code:		Telephone no.:	
Mobile no.:		Fax no.:	
Email address:			

Are you applying on behalf of the Proposed Authorisation Holder?
(e.g. if you are a consultant/representative)

☐ yes ☐ no

if YES please fill out section 1.2

1.2 Contact Details for Communication (if different from the applicant address)

Contact Name	
Company Name:	
Address:	

Postal code:		Telephone:	
Mobile:		Fax:	
Email address:			

1.3 Invoicing Address Details (if different from Authorisation Holder Address)

Contact Name:	
Company:	
Address:	

Postal code:		Telephone:	
Mobile:		Fax:	
Email address:			

Section 2: Site Information

2.1 Site Details

You will need to complete one copy of Sections 2 & 3 for <u>each</u> manufacturing site that you wish to include on the Authorisation.

Site Name:	
Address:	
Postal code:	
Contact Name:	
Telephone:	Fax:
Mobile:	
Email address:	

2.2 Use of manufactured/imported/tested products at Site

Are the products for administration to human beings? ☐ Yes ☐ No

2.3 Site Types

Manufacture ☐ Assembly and Packaging ☐

Batch Certification	☐	QC Testing	☐
Biological	☐	Non-biological	☐
Export	☐	Import	☐
Storage and Handling	☐	Other, please specify	☐

Site name:		**Postal code:**	

2.4 Site Functions

Part 1 – MANUFACTURING OPERATIONS (testing included)

1.1	**Sterile Products**	**Manufacture (Please Tick)**
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)	

Site name:		**Postal code:**	

1.1.2	**Terminally Sterilised (processing operations for other dosage forms)**	**Manufacture (Please Tick)**
	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**	

1.2	Non-sterile products	Manufacture (Please Tick)
1.2.1	**Non-sterile products (processing operations for other 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	

Site name:		**Postal code:**	

	Non-sterile products	**Manufacture (Please Tick)**
	1.2.1.9 Pressurised preparations	
	1.2.1.10 Radionuclide generators	
	1.2.1.11Semi-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 products (please specify)	
1.2.2	**Batch certification**	

Site ID: (Variations only)		**Site Name:**	

1.3	**Biological Investigational Medicinal Products**	**Manufacture (Please Tick)**
1.3.1	**Biological Investigational Medicinal Products**	
	1.3.1.1 Blood products	
	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 Tissue-engineered products	
	1.3.1.7 Other biological medicinal products (please specify)	

1.4.1	**Manufacture of:**	
	1.4.1.1 Herbal products	
	1.4.1.2 Homoeopathic products	
	1.4.1.3 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)	

Site name:		**Postal code:**	

1.5	Packaging	Packaging (Please Tick)
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	
	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**	

Site name:		**Postal code:**	

1.6	**Quality control testing**	**Manufacture related (Please Tick)**
	1.6.1 Microbiological: sterility	
	1.6.2 Microbiological: non-sterility	
	1.6.3 Chemical/Physical	
	1.6.4 Biological	

Part 2 – IMPORT OF INVESTIGATIONAL MEDICINAL PRODUCTS

2.1	**Quality control testing of imported Investigational Medicinal Products**	**Import (Please tick)**
	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 Investigational Medicinal Products**	
2.2.3	**Biological Investigational Medicinal Products**	
	2.2.3.1 Blood 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 Tissue-engineered products	

	2.2.3.7 Other biological medicinal products (please specify)	

Site name: | | **Postal code:** | |

2.2.4	**Other importation activities (any other relevant importation activity that is not covered above)**	**Import (Please Tick)**
	2.2.4.1 Site of import	
	2.2.4.2 Import of intermediate products subject to further processing	
	2.2.4.3 Biological active substances	
	2.2.4.4 Other (please specify)	

Site name:		**Postal code:**	

2.6 Other Information

The following information is required for inspectorate action but will not appear on your authorisation.

OTHER SPECIFIC PROCESSES/ACTIVITIES

Bulk or partial manufacturing		**Yes**		**No**
Manufacture and assembly for export		**Yes**		**No**
Assembly for export		**Yes**		**No**
Are materials or manufactured/imported/tested products of Animal Human Origin (AHO) present at this site?		**Yes**		**No**

LETTING AND/OR ACCEPTING CONTRACTS

Applicants intends to be contract acceptor (i.e. manufactures partially/wholly for others)		**Yes**		**No**
Applicant intends to be contract giver (i.e. uses external manufacturers for total or partial manufacture)		**Yes**		**No**
Applicant intends to be contract acceptor (i.e. carries out testing		**Yes**		**No**

partially/wholly for others)				
Applicants intends to be contract giver (i.e. uses external test houses for some/all testing)		**Yes**		**No**

SUPPLEMENTARY QC TESTING INFORMATION AT THIS SITE

Stability testing?		**Yes**		**No**
Is this site involved in doing finished product testing?		**Yes**		**No**
Is this site involved in microbiological testing of finished products and/or raw materials?		**Yes**		**No**
If answer No to above, explain activities:				

Site name:		**Postal code:**	

OTHER INFORMATION

Do you handle medicines which require refrigeration or low temperature storage?	**Yes**	**No**
Do you import intermediate products for further processing?	**Yes**	**No**
Is this site ready for inspection?	**Yes**	**No**
Are you conversant with the Rules and Guidance for Pharmaceutical Manufacturers and Distributors and do you have available the relevant procedures and records?	**Yes**	**No**
Are signed technical agreements available for inspection where applicable?	**Yes**	**No**

2.7 Further information which should be attached

Have you submitted a Site Master File with your initial application? ☐ **Yes** ☐ **No**

NOTE: All Site Master Files should be submitted either as a hard copy or as a CD ROM.

If No, will a Site Master File be available on site during an inspection? ☐ **Yes** ☐ **No**

ON SITE FACILITIES

Details should be included in your Site Master File

EQUIPMENT ON SITE

Details should be included in your Site Master File.

Site name:		**Postal code:**	

Section 3: Named Persons

Please indicate 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)	

Please ensure you have included copies of the required documentation.

Site name:		**Postal code:**	

3.1. Qualified Person

1. **Please complete a separate page for each QP.**

2. **Each QP nomination must be signed by both the nominee and the applicant.**

3. **All applications by a QP must include a relevant CV and a copy of the nominee's certificate attesting the QP status, issued by the NAMMD**

Title:			
First name(s):			
Surname:			
Business Address:			
Postal code:		Telephone:	
Fax:		Mobile:	
Email			

address:

Please indicate your status

Permanent employee ☐ Consultant ☐ Temporary employee ☐

If a consultant, please give details of your availability. How frequently will you visit?

Site name: **Postal code:**

Qualifications (relevant to this authorisation)

Experience (brief details of employment and responsibilities relevant to this authorisation)

Professional Association(s):

Site name:		**Postal code:**	

I hereby confirm that the above particulars are accurate and true to the best of my knowledge and belief. I agree to be nominated as a Qualified Person.

Signed (Nominee): _____ **Date:** _____

Print Name: _____

Signed (Applicant): _____ **Date:** _____

Print Name: _____

Site name:		**Postal code:**	

3.2. Person Responsible for Manufacture

Please complete a separate sheet for each person responsible for production.

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

Manufacture Manager ☐ Manufacture Supervisor ☐

Title:		
First name(s):		
Surname:		
Business Address:		
Postal code:		Telephone no.:
Fax no.:		Mobile no.:
Email address:		

Qualifications (relevant to this authorisation)

Experience (brief details of employment and responsibilities relevant to this authorisation)

Site name: **Postal code:**

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

Area of responsibility

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

Signed (Nominee): _____ **Date:** _____

Print Name: _____

Signed (Applicant): _____ **Date:** _____

Print Name: _____

Site name:		**Postal code:**	

3.3. Quality Control Responsible Person

Please give the following details of the person(s) with overall responsibility for Quality Control. Where this responsibility is shared between more than one person, please complete a separate page for <u>each</u> person, and give details of each person's areas of responsibility.

Title:	_____	_____
First name(s):		
Surname:		
Business Address:		

Postal code:		Telephone no.:	
Fax no.:		Mobile no.:	
Email address:			

Qualifications (relevant to this authorisation)

Experience (brief details of employment and responsibilities relevant to this authorisation)

Site ID: (Variations only)		**Site Name:**	

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

Area of responsibility

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

Signed (Nominee): _____ **Date:** _____

Print Name: _____

Signed (Applicant): _____ **Date:** _____

Print Name: _____

Section 4: Contract Laboratories

Please complete a copy of section 4 for <u>each</u> contract laboratory you wish to name on this authorisation

_____

Site Name:	
Address:	

Postal code:	
Site Contact Name:	
Telephone no.:	Fax no.:
Mobile no.:	
Email address:	

Please indicate the type of testing carried out by ticking the relevant box(es) below.

Quality Control Testing				
Microbiological: sterility		Yes		No
Microbiological: non-sterility		Yes		No
Chemical/Physical		Yes		No
Biological		Yes		No
Stability testing?		Yes		No
Is this site involved in doing finished product testing?		Yes		No
Is this site involved in microbiological testing of finished products and/or raw materials?		Yes		No
If No to the above, please explain activities:				

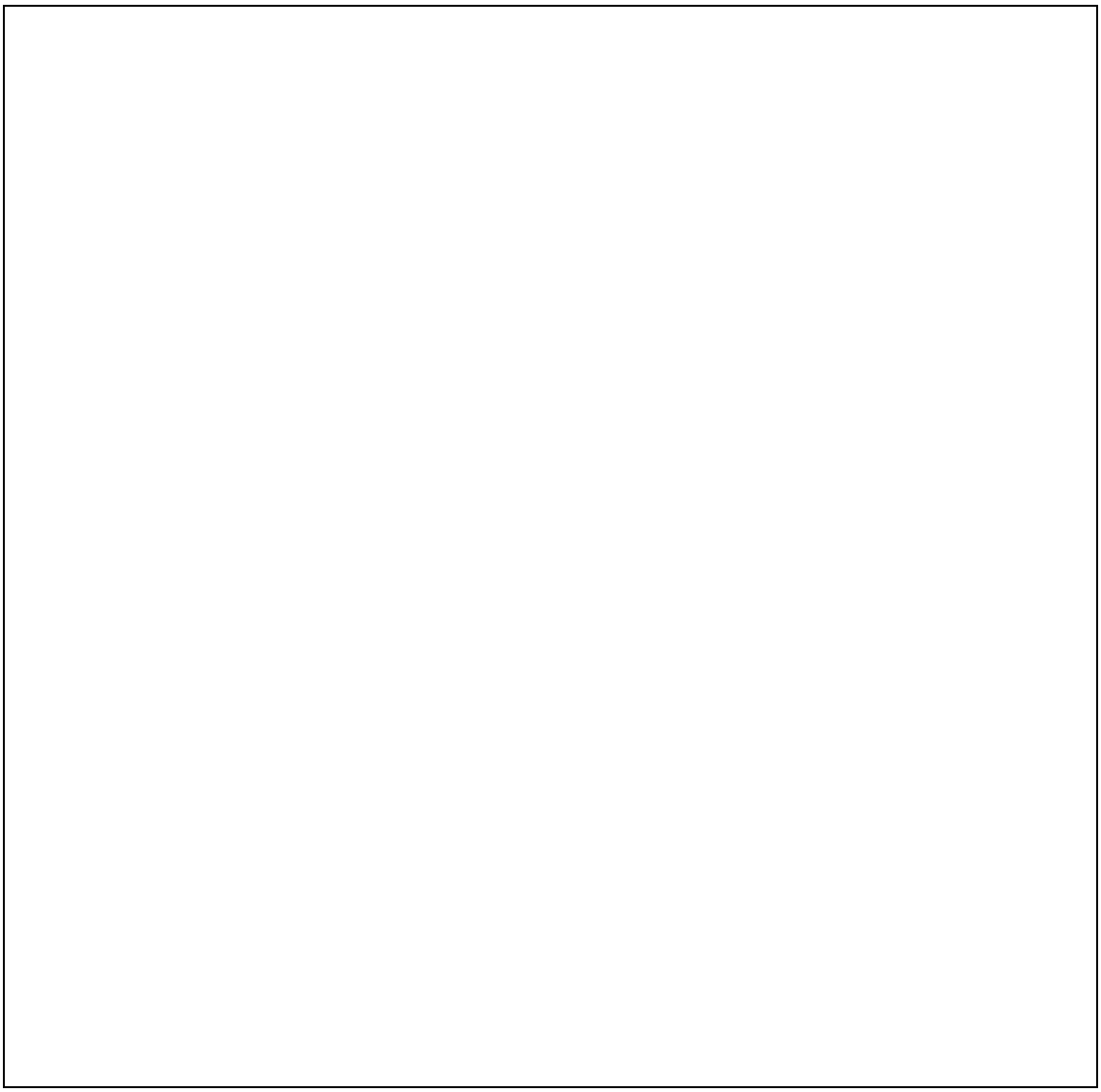
Section 5: Storage & Handling Sites

Please complete a copy of section 5 for <u>each</u> storage and handling site that you wish to include on the authorisation.

Name of the storage and handling site:	
Address:	
Postal code:	
Site Contact Name:	
Telephone no.:	Fax no.:
Mobile no.:	
Email address:	

Section 6: Comments

Please provide any other information that may support your application. You can also detail any changes to addresses, person names etc.



Section 7: Declaration

I/We hereby apply for grant of Manufacturing Authorisation to the proposed Holder named in this application form in respect of the activities to which the application refers.

7.1 The activities are to be only in accordance with the information set out in the application or furnished in connection with it.

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

Signed (Applicant): _____ **Date:** _____

Print Name: _____

Capacity in which signed:

ANNEX V

To

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES
The Pharmaceutical Inspection Department

The . . . . . .established in . . . . . address . . . . . ……Telephone/fax number. . . . . registered with the Registry of Commerce under . . . . . fiscal code . . . . . represented by (name and surname) . . . . . ……, in line with the Order of the Minister of Health on manufacturing authorisation of manufacturers, importers of medicinal products for human use, investigational medicinal products included, and of independent control sites and grant of a Good Maufacturing Pratice Certificate, hereby apply for release of a copy of the Manufacturing Authorisation/Good Manufacturing Practice Certificate no.. . . . . .

Please find attached the proof of notification on loss of the Manufacturing Authorisation/Good Manufacturing Practice certificate as publicly notified in …….. .....

(name of the newspaper)

Signature, stamp

…….

ANNEX VI

UNDERTAKING

The ……..…, established in ……, address ……......, represented by …….....…, position …… ……..., hereby undertake to submit information required under Annex V to this Order on manufacturing authorisation of manufacturers, importers of medicinal products for human use, investigational medicinal products included, and of independent control sites and grant of a Good Manufacturing Practice Certificate for each import.

Signature, stamp

.....

ANNEX VII

NOTIFICATION OF IMPORT

NOTICE: Information required in this Annex is to be submitted to the National Agency for Medicines and Medical Devices – The Pharmaceutical Inspection Department, by importers only. The data should be submitted in tabulated form, immediately upon each import.

The table obligatorily consists of 14 columns, filled in as follows:

1. No.
2. Product
3. International Non-proprietary Name (INN)
4. Pharmaceutical form
5. Strength
6. Packaging
7. Release (on-prescription/OTC)
8. Marketing Authorisation Holder
9. Manufacturer
10. Country of origin
11. Batch(es)
12. Date of import
13. Imported quantity (quantity of each batch and total quantity)
14. Notes