HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

MANUFACTURERS AUTHORISATION

1.	Authorisation number	**IMP11207/00001**
2.	Name of authorisation holder	**Hovione Limited**
3.	Address(es) of manufacturing site(s) (All authorised sites should be listed if not covered by separate licences)	Loughbeg API, Ringaskiddy, Co. Cork, P43 DY23, Ireland
4.	Legally registered address of authorisation holder	(Companies Registration Office Number: 463979) Loughbeg API, Ringaskiddy, Co. Cork, P43 DY23, Ireland
5.	Scope of authorisation and dosage forms	ANNEX 2
6.	Legal basis of authorisation	Art. 13 of Directive 2001/20/EC
7.	Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Paulina Nulty
8.	Signature	
9.	Date	21 October 2020
10.	Annexes attached	ANNEX 1 - Scope of Authorisation ANNEX 2 -Scope of Authorisation(Investigational Medicinal Products) ANNEX 3 -Address(es) of Contract Manufacturing Site(s) ANNEX 4 -Address(es) of Contract Laboratories ANNEX 5 -Name(s) of Qualified Person(s) ANNEX 6 -Names of persons responsible for quality control / production ANNEX 7 -Date of Inspection on which authorisation granted ANNEX 8 -Products authorised for import

Requirements to be met by an authorisation holder manufacturing medicinal products
(Ref. Schedule 2 of the Medicinal Products (Control of Manufacture) Regulations 2007 -2013)

1. In this Schedule, the term 'marketing authorisation' includes a certificate of registration and a certificate of traditional-use registration.

2. The authorisation holder shall—
   (*a*) provide and maintain such staff, premises, equipment and facilities as are necessary for the carrying out, in accordance with the terms of his or her authorisation and relevant marketing authorisation, of such stages of manufacture as are undertaken by him or her;
   (*b*) not use for such purposes premises other than those specified in his or her authorisation or which may be approved in writing from time to time by the Authority; and
   (*c*) in the distribution of medicinal products, comply with the principles and guidelines on good distribution practice for medicinal products published by the Commission under Article 84 of the 2001 Directive;

3. The authorisation holder shall—
   (*a*) provide and maintain such staff, premises, installations and equipment for the handling, storage and distribution of medicinal products that he or she handles, stores or distributes under his or her authorisation as are necessary to maintain the quality of the medicinal products to which the authorisation relates; and
   (*b*) not use for such purposes premises other than those specified in his or her authorisation or which may be approved in writing from time to time by the Authority.

4. The authorisation holder shall conduct all manufacturing operations in such a way as to ensure that the medicinal products conform with the standards of strength, quality and purity applicable to them whether under the relevant marketing authorisation, or under any pharmacopoeial standard or other specification to which they may be manufactured.

5. The authorisation holder shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person at his or her disposal pursuant to Regulation 13(1) to carry out the duties referred to in Regulation 13(3).

6. The authorisation holder shall give prior notice to the Authority of any changes he or she may wish to make to any of the particulars supplied in his or her application made pursuant to Regulation 6 and Schedule 1.

7. The authorisation holder shall immediately inform the Authority if the qualified person referred to in Regulation 13 is replaced unexpectedly.

8. The authorisation holder shall place the quality control system referred to in Article 11.1 of the GMP Directive under the authority of the person notified to the Authority in accordance with paragraph 7(3) of Schedule 1.

9. The authorisation holder may use a contract laboratory pursuant to Article 11.2 of the GMP Directive if such laboratory and the person operating it has been approved by the Authority.

10. The authorisation holder shall inform the Authority—
    (*a*) before making any material change in the premises, installations or equipment used under his authorisation, or in the operations for which they are used; and
    (*b*) of any change that he or she proposes to make in the personnel named in his authorisation as respectively—

(i) responsible for supervising production operations; or
(ii) responsible for quality control of the medicinal products being manufactured, divided up, packaged, labelled or presented, including the person named as the qualified person for, the purposes of Regulation 13.

11. (1) The authorisation holder shall—
(a) keep readily available for inspection by an authorised officer, the batch documentation pursuant to Article 9.1 of the GMP Directive; and
(b) permit the authorised officer to take copies or make extracts from such documentation.
(2) Such records shall be retained for at least one year after the expiry date of the batches to which they relate or at least 5 years from the date of certification, by the qualified person, as referred to in Regulation 13(3)(f), whichever is the longer period.
(3) In the case of investigational medicinal products, such records shall be retained for at least five years after completion or formal discontinuation of the last clinical trial in which the batch was used.

12. The authorisation holder shall maintain a system for recording and reviewing complaints concerning reported defects associated with any medicinal product to which his authorisation relates and of the outcome to any investigation carried out in respect of each such complaint.

13. The authorisation holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal product to which the authorisation relates. Such documents shall be readily available for inspection by an authorised officer.

14. The authorisation holder shall keep an adequate sample of each batch and of each active constituent used in the manufacture of such medicinal product to which the authorisation relates, for the period which ends one year after the labelled expiry date of the product, and shall furnish on request by the Authority a sufficient sample of each such batch for the purpose of any test,examination or analysis which may be requested by the Authority.

15. The authorisation holder shall ensure that any tests for determining conformity with the standards and specifications applying to any product used in the manufacture of a medicinal product shall, except insofar as the specifications for that product otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage(s) in the manufacture as may be required or approved in writing by the Authority.

16. Except in the case of investigational medicinal products or exempt medicinal products, the authorisation holder shall—
(a) only use active substances manufactured in accordance with the principles and guidelines of good manufacturing practice for active substances, as adopted by the Commission pursuant to Article 47 of the 2001 Directive,
(b) only use active substances distributed in accordance with the principles and guidelines of good distribution practices for active substances, as adopted by the Commission pursuant to Article 47 of the 2001 Directive,
(c) conduct audits, personally or through an entity acting on his or her behalf under a contract, of manufacturing and distribution sites to ensure compliance with subparagraphs (a) and (b),
(d) verify that all manufacturers, importers and distributors from whom he or she obtains active substances are registered with the competent authority of the EEA State in which they are established, and (e) verify the authenticity and quality of the active substances he or she uses.

17. For the purposes of paragraph 16, the manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material, as defined in Part I, point 3.2.1.1(b) of Annex I of the 2001 Directive, and the various processes of dividing up, packaging or presentation prior to its incorporation into a medicinal product, including repackaging or re-labelling, such as are carried out by a distributor

of starting materials.

18. The authorisation holder shall ensure that any human blood or blood component imported into the State and used by him or her as a starting material or as a raw material in the manufacture of a medicinal product shall meet the equivalent standards of quality and safety to those laid down in Commission Directive 2004/33/EC14, implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

19. The authorisation holder, who is not the holder of a marketing authorisation in respect of a medicinal product to which the authorisation relates, shall comply with any provisions of such authorisation which relate to the sale or supply of that medicinal product and shall, by means of a label or otherwise, communicate the particulars of such provisions as they relate to method of sale or supply or restriction as to sale or supply to any person to whom the authorisation holder sells or supplies that medicinal product.

20. (1) Subject to subparagraph (2), the authorisation holder shall not supply a medicinal product that is the subject of a marketing authorisation except to persons—
(a) who are themselves the holders of a wholesaler's authorisation, or
(b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the wholesale distribution of those products, or
(c) who are authorised or entitled to lawfully supply the said medicinal product to the public, or
(d) who are lawfully entitled to administer the said medicinal product to patients in the course of a professional practice, or business as a hospital, and, the supply of the said product is in conformity with the provisions of its relevant marketing authorisation.
(2) The provisions of this paragraph shall not apply to investigational medicinal products supplied in accordance with Regulation 11 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended).

21. The authorisation holder shall, in the distribution of authorised medicinal products to which his or her authorisation relates, within the limits of his or her responsibility as a distributor of such medicinal products, ensure appropriate and continued supplies of such products to the persons referred to in paragraph 20(c) and (d), so that the needs of patients in the State in respect of such products are covered.

22. (1) The authorisation holder, in making a sale by wholesale to persons referred to in paragraph 20(c) and (d), shall enclose with the medicinal product a document that makes it possible for such persons to ascertain:
— the date on which the sale took place,
— the name and pharmaceutical form of the product supplied,
— the quantity of the product supplied, and
— the name and address of the supplier and consignor.
(2) Such records shall be retained for at least 5 years from the date on which it was supplied and during that period shall be available for inspection by officers of the Authority.

23. (1) Subject to subparagraph (2), the authorisation holder shall not sell by wholesale any medicinal product—
(a) other than a product to which the authorisation relates,
(b) unless there has been granted in respect of such product, a marketing authorisation which is for the time being in force, and
(c) unless the sale of such product is in conformity with the provisions of its marketing authorisation.
(2) Subparagraph (1)(b) and (c) shall not apply—
(a) until 30 April 2011, to the sale by wholesale of any traditional herbal medicinal product

that was already on the market in the State, on the date of the coming into force of these Regulations;

(b) to the sale by wholesale of an exempt medicinal product;

(c) to the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation by virtue of legislation adopted by that State under Article 5.2 of the 2001 Directive; and

(d) to investigational medicinal products supplied in accordance with Regulation 11 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended).

24. The authorisation holder shall supply such information as may be requested by the Authority for the purposes of these Regulations about the medicinal products currently being manufactured and about the operations being carried out in relation to such manufacture.

25. The authorisation holder shall for the purpose of enabling the Authority—
(a) to verify any statement contained in an application for a manufacturer's authorisation or marketing authorisation, or
(b) to ascertain whether there are any grounds for suspending, revoking or amending any such authorisation, permit, and provide all necessary facilities to enable, authorised officers to enter and inspect his or her premises at any time and to take such samples or to take copies of any documents in relation to any such application or authorisation as may be required.

26. The authorisation holder shall from time to time permit such inspection and make available such information as may be required to satisfy the Authority that the conditions of the authorisation are being complied with.

27. Where the authorisation holder has been informed by the Authority that any part of a batch of a medicinal product to which his authorisation relates has been found not to conform as regards strength, quality or purity with the specifications of the relevant product he or she shall, if so directed by the Authority, immediately withhold the remainder of that batch from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies already sold, supplied or exported from that batch.

28. Where the authorisation holder has been informed by the Authority that a medicinal product to which his or her authorisation relates has been found to give rise to concerns in regard to its safety or efficacy, he or she shall, if so directed by the Authority, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of such product already sold, supplied or exported.

29. Where the authorisation holder has been informed by the Authority that any batch of a medicinal product, or part thereof, to which his authorisation relates, has not been manufactured in accordance with the principles and guidelines of good manufacturing practice set out in the GMP Directive, he or she shall, if so requested by the Authority, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of such product already sold, supplied or exported.

30. Where the authorisation holder decides for whatever reason to recall a particular batch of a medicinal product manufactured by him or her, or part thereof, he or she shall forthwith inform the Authority of the decision to recall and of the reason for such recall.

31. Where the authorisation holder considers that there may be grounds for the recall, or for the imposition of an abnormal restriction on the supply of a particular medicinal product manufactured by him or her, or of a batch or part of batch thereof, he or she shall consult with the Authority in relation to the action which may be considered appropriate in the circumstances.

32. (1) The authorisation holder, in the case of an advanced therapy medicinal product, shall establish and maintain a system ensuring that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used.
(2) Where an authorisation holder manufactures an advanced therapy medicinal product that contains human cells or tissues, he or she shall ensure that the traceability systems established in accordance with paragraph 1 are complementary to, and compatible with, the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC as regards human cells and tissues other than blood cells, and Articles 14 and 24 of Directive 2002/98/EC22 as regards human blood cells.
(3) The authorisation holder shall keep the data referred to in subparagraph (1) for a minimum of 30 years after the expiry date of the product.
(4) In case of bankruptcy or liquidation of the authorisation holder who has manufactured an advanced therapy medicinal product, and in the event that the manufacturing authorisation is not transferred to another legal entity, the data referred to in paragraph (1) shall be transferred to the Authority.
(5) In the event that the manufacturing authorisation is suspended, revoked or withdrawn, the holder of the manufacturing authorisation shall remain subject to the obligations laid down in paragraphs (1), (2) and (3).
(6) Subparagraphs (3) to (5) shall not apply to an authorisation holder where the holder of a marketing authorisation for the relevant advanced therapy medicinal product is, by virtue of such marketing authorisation, responsible for the retention of such data.

33. In paragraphs 2(c), 19, 20 and 23(1)(b) and (c), every reference to a medicinal product shall be a reference to a medicinal product that is intended to be placed on the market in the State or in another EEA State.

34. Except in the case of investigational medicinal products and exempt medicinal products, the authorisation holder shall—
(a) ensure that excipients he or she uses are suitable for use in medicinal products by applying the appropriate good manufacturing practice ascertained following a formalised risk assessment in compliance with the requirements of the second paragraph of Article 46(f) of the 2001 Directive,
(b) document the measures taken under subparagraph (a), and 12 [163]
(c) verify the authenticity and quality of the excipients he or she uses.

35. The authorisation holder shall immediately inform the Authority, and the holder of the relevant Community marketing authorisation, marketing authorisation, certificate of registration or certificate of traditional-use registration, if he or she obtains information that medicinal products which come under the scope of his or her manufacturer's authorisation are, or are suspected of being, falsified, irrespective of whether those medicinal products were distributed within the legal supply chain or by illegal means, including legal and illegal sale by means of information society services.

This authorisation is subject to any other requirement as specified in the Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

Requirements to be met by an authorisation holder importing medicinal products from a third country

(Ref. Schedule 3 of the Medicinal Products (Control of Manufacture) Regulations 2007-2013)

1. In this Schedule, the term 'marketing authorisation' includes a certificate of registration and a certificate of traditional-use registration.

2. The authorisation holder shall—
(a) provide and maintain such staff, premises, equipment and facilities as are necessary for the

handling, control, storage and distribution of medicinal products which he or she handles, stores and distributes under his or her authorisation, as are necessary to maintain the quality of those medicinal products;

(b) not use for such purposes premises other than those specified in his or her authorisation or which may be approved in writing from time to time by the Authority;

(c) at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person at his or her disposal pursuant to Regulation 13(1) to carry out the duties referred to in Regulation 13(3);

(d) give prior notice to the Authority of any changes he or she may wish to make to any of the particulars supplied in his or her application made pursuant to Regulation 6 and Schedule 1;

(e) immediately inform the Authority if the qualified person referred to in Regulation 13 is replaced unexpectedly;

(f) inform the Authority—

(i) before making any material change in the premises, installations or equipment used under his authorisation, or in the operations for which they are used; and

(ii) of any change that he or she proposes to make in the personnel named in his authorisation as responsible for quality control of the medicinal products being imported by him or her, including the person named as the qualified person for the purposes of Regulation 13;

(g) in his or her distribution of medicinal products, comply with the principles and guidelines on good distribution practice for medicinal products published by the Commission under Article 84 of the 2001Directive.

3. (1) Subject to subparagraph (2), the authorisation holder shall not supply a medicinal product that is the subject of a marketing authorisation except to persons—

(a) who are themselves the holders of a wholesaler's authorisation, or

(b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the wholesale distribution of those products, or

(c) who are authorised or entitled to lawfully supply the said medicinal product to the public, or

(d) who are lawfully entitled to administer the said medicinal product to patients in the course of a professional practice or business as a hospital, and, the supply of the said product is in conformity with the provisions of its relevant marketing authorisation.

(2) The provisions of this paragraph shall not apply to investigational medicinal products supplied in accordance with Regulation 11 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended).

4. The authorisation holder shall, in the distribution of authorised medicinal products to which his or her authorisation relates, within the limits of his or her responsibility as a distributor of such medicinal products, ensure appropriate and continued supplies of such products to the persons referred to in paragraph 3(c) and (d), so that the needs of patients in the State in respect of such products are covered.

5. The authorisation holder shall place the quality control system referred to Article 11.1 of the GMP Directive under the authority of the person notified to the Authority in accordance with paragraph 7(3) of Schedule 1.

6. The authorisation holder may use a contract laboratory pursuant to Article 11.2 of the GMP Directive, if such laboratory and the person operating it has been approved by the Authority.

7. (1) The authorisation holder shall—

(a) keep readily available for inspection by an authorised officer, the batch documentation pursuant to Article 9.1 of the GMP Directive; and

(b) permit the authorised officer to take copies or make extracts from such documentation.

(2) Such records shall be retained for at least one year after the expiry date of the batches to which they relate or at least 5 years from the date of certification, by the qualified person, as referred to in Regulation 13(3)(f), whichever is the longer period.

(3) In the case of investigational medicinal products, such records shall be retained for at least five

years after completion or formal discontinuation of the last clinical trial in which the batch was used.

8. The authorisation holder shall maintain a system for recording and reviewing complaints concerning reported defects associated with any medicinal product to which his authorisation relates and of the outcome to any investigation carried out in respect of each such complaint.

9. The authorisation holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal product to which the authorisation relates. Such documents shall be readily available for inspection by an authorised officer.

10. The authorisation holder shall keep an adequate sample of each batch to which the authorisation relates, for the period which ends one year after the labelled expiry date of the product, and shall furnish on request by the Authority a sufficient sample of each such batch for the purpose of any test, examination or analysis which may be requested by the Authority.

11. The authorisation holder shall ensure that any tests for determining conformity with the standards and specifications applying to any product used in the manufacture of a medicinal product shall, except insofar as the specifications for that product otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage(s) in the manufacture as may be required or approved in writing by the Authority.

12. (1) Subject to subparagraph (2) and paragraph 25, the authorisation holder shall not sell by wholesale any medicinal product—
    (a) other than a product to which the authorisation relates,
    (b) unless there has been granted in respect of such product, a marketing authorisation which is for the time being in force, and
    (c) unless the sale of such product is in conformity with the provisions of its marketing authorisation.
    (2) Subparagraph (1)(b) and (c) shall not apply—
    (a) until 30 April 2011, to the sale by wholesale of any traditional herbal medicinal product that was already on the market in the State, on the date of the coming into force of these Regulations;
    (b) to the sale by wholesale of an exempt medicinal product;
    (c) to the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation by virtue of legislation adopted by that State under Article 5.2 of the 2001 Directive; and
    (d) to investigational medicinal products supplied in accordance with Regulation 11 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended).

13. (1) The authorisation holder, in making a sale by wholesale to persons referred to in paragraph 3(c) and (d), shall enclose with the medicinal product a document that makes it possible for such persons to ascertain:
    — the date on which the sale took place,
    — the name and pharmaceutical form of the product supplied,
    — the quantity of the product supplied, and
    — the name and address of the supplier and consignor.
    (2) Such records shall be retained for at least 5 years from the date on which it was supplied and during that period shall be available for inspection by officers of the Authority.

14. The authorisation holder, who is not the holder of a marketing authorisation in respect of a medicinal product to which the authorisation relates, shall comply with any provisions of such authorisation which relate to the sale or supply of that medicinal product and shall, by means of a label or otherwise, communicate the particulars of such provisions as they relate to method of sale or supply or restriction as to sale or supply to any person to whom the authorisation holder sells or

supplies that medicinal product.

15. The authorisation holder shall supply such information as may be requested by the Authority for the purposes of these Regulations about the medicinal products being imported and about the operations being carried out in relation to such products.

16. The authorisation holder shall for the purpose of enabling the Authority—
    (a) to verify any statement contained in an application for a manufacturer's authorisation or marketing authorisation, or
    (b) to ascertain whether there are any grounds for suspending, revoking or amending any such authorisation, permit, and provide all necessary facilities to enable, authorised officers to enter and inspect his or her premises at any time and to take such samples or to take copies of any documents in relation to any such application or authorisation, as may be required.

17. The authorisation holder shall from time to time permit such inspection and make available such information as may be required to satisfy the Authority that the conditions of the authorisation are being complied with.

18. Where the authorisation holder has been informed by the Authority that any part of a batch of a medicinal product to which his or her authorisation relates has been found not to conform as regards strength, quality or purity with the specifications of the relevant product, he or she shall, if so directed by the Authority, immediately withhold the remainder of that batch from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies already sold, supplied or exported from that batch.

19. Where the authorisation holder has been informed by the Authority that a medicinal product to which his or her authorisation relates has been found to give rise to concerns in regard to its safety or efficacy, he or she shall, if so directed by the Authority, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all suppliesof such product already sold, supplied or exported.

20. Where the authorisation holder has been informed by the Authority that any batch of a medicinal product, or part thereof, to which his or her authorisation relates, has not been manufactured in accordance with the principles and guidelines of good manufacturing practice set out in the GMP Directive, he or she shall, if so requested by the Authority, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of such product already sold, supplied or exported.

21. Where the authorisation holder decides for whatever reason to recall a particular batch of a medicinal product imported by him or her, or part thereof, he or she shall forthwith inform the Authority of the decision to recall and of the reason for such recall.

22. Where the authorisation holder considers that there may be grounds for the recall, or for the imposition of an abnormal restriction on the supply of a particular medicinal product imported by him or her, or of a batch or part of batch thereof, he or she shall consult with the Authority in relation to the action which may be considered appropriate in the circumstances.

23. The authorisation holder shall ensure that medicinal products (other than exempt medicinal products) imported by him or her, use as starting materials only active substances, which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials.

24. For the purposes of paragraph 23, the manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material, as defined in Part I, point 3.2.1.1(b) of Annex I of the 2001 Directive, and the various processes of dividing up, packaging or presentation prior to its incorporation into a medicinal

product, including repackaging or re-labelling, such as are carried out by a distributor of starting materials.

25. (1) Where and insofar as the authorisation relates to medicinal products to which paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007 apply, the authorisation holder shall only import such products from a third country—
(a) in response to an order, or in anticipation of an order, which satisfies the requirements of paragraph 2 of Schedule 1 to those Regulations; and
(b) where the conditions set out in subparagraphs (2) to (9) are complied with.

(2) The authorisation holder shall, in the case of each importation of an exempt medicinal product, make, and keep available for inspection by officers of the Authority, for a period of not less than five years, written records showing the following particulars—
(a) the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the particular medicinal product is to be sold or supplied in the State;
(b) the dosage form;
(c) the trading style or name of the manufacturer of the medicinal product;
(d) in respect of each active constituent of the medicinal product, any international non-proprietary name or the monograph name or, where that constituent does not have an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of that constituent;
(e) the quantity of medicinal product which has been imported;
(f) the batch number of the medicinal product which has been imported; and
(g) the name and address of the manufacturer of that medicinal product in the form in which it was imported and, if the person who supplied the medicinal product for importation is not the manufacturer, the name and address of such supplier.

(3) Where the authorisation holder sells or supplies an exempt medicinal product, he or she shall, in addition to those records mentioned in sub-paragraph(2), make and maintain written records relating to—
(a) the batch number of the batch of the product from which each sale or supply was made;
(b) details of any suspected adverse reaction to the product so sold or supplied of which he or she becomes aware; and
(c) details of any quality defect relating to the product so sold or supplied of which he or she becomes aware.

(4) The authorisation holder shall not issue any advertisement, other than one that states only the trade name, pack size, price and dose, relating to an exempt medicinal product or make any resentations in respect of such product.

(5) The authorisation holder shall inform the Authority forthwith of any matter, including suspected adverse reactions and quality defects, coming to his or her attention, in respect of an exempt medicinal product imported by him or her.

(6) The authorisation holder shall cease importing or supplying an exempt medicinal product if he or she has received a notice in writing from the Authority directing that, as from a date specified in that notice, a particular product or class of products shall no longer be imported or supplied.

(7) The authorisation holder shall, on being informed by the Authority, or by the manufacturer or person who supplied the medicinal product for importation, that the medicinal product can not be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality or efficacy for such administration, immediately withdraw any supplies of that product held by him or her and immediately recall all supplies already sold or distributed.

(8) With effect from the 1 January 2008, the authorisation holder shall, not later than seven days of his or her importation of an exempt medicinal product, notify the Authority of each such importation. Each such notification shall include the particulars set out in subparagraph (2).

(9) With effect from the 1 January 2009, the notifications referred to in subparagraph (8) shall, except in exceptional circumstances, be communicated electronically to the Authority and within a timeframe of two working days from the date of each such importation.

(10)In this paragraph—

'common name' means the international non-proprietary name, or, if one does not exist, the usual common name;

'international non-proprietary name' means the international non-proprietary name recommended by the World Health Organisation; and

'monograph name' means the name or approved synonym which appears at the head of a monoraph in the current edition of the European Pharmacopoeia or the British Pharmacopoeia, or a foreign or international compendium of standards and

'current' in this definition means current at the time the notice is sent to the Authority.

26. In paragraphs 2(g), 3, 12(1)(b) and (c) and 14, every reference to a medicinal product shall be a reference to a medicinal product that is intended to be placed on the market in the State or in another EEA State.

This authorisation is subject to any other requirement as specified in the Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

This annex is not applicable

Name and address of the site: Hovione Limited, Loughbeg API, Ringaskiddy, Co. Cork, P43 DY23, Ireland

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

1	**MANUFACTURING OPERATIONS**
	1.2 Non-sterile Products
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.17 Other non-sterile medicinal product: Spray dried bulk powder/granulate intermediate for further processing
	1.6 Quality control testing
	1.6.3 Chemical / Physical

ADDRESS(ES) OF CONTRACT MANUFACTURING SITES

ANNEX 3

This annex is not applicable

ADDRESS(ES) OF CONTRACT LABORATORIES

ANNEX 4

Name of Contract Laboratory:	**Microchem Laboratories (Ireland) Limited T/A Eurofin Lancaster Laboratories**
Address:	**Clogherane, Dungarvan, Co. Waterford, Ireland** Microbiological : Non Sterility Chemical / Physical
Name of Contract Laboratory:	**Butterworth Laboratories**
Address:	**54-56 Waldegrove Road, Teddington, Middlesex, TW11 8NY, United Kingdom** Chemical / Physical
Name of Contract Laboratory:	**Hovione FarmaCiencia, S.A**
Address:	**Sete Casas, Loures, 2674-506, Portugal** Microbiological : Non Sterility Chemical / Physical
Name of Contract Laboratory:	**Solvias AG**
Address:	**Romer Park 2, 4303, Kaiseraugst, Switzerland** Chemical / Physical
Name of Contract Laboratory:	**Hovione Pharmascience Ltd**
Address:	**Estrada Coronel Nicolav de Mesquita, Taipa, Macau, SAR, China** Chemical / Physical
Name of Contract Laboratory:	**Charles River**
Address:	**9 Allée Moulin Berger, 69130 Ecully, France** Microbiological : Non Sterility

NAMES OF QUALIFIED PERSONS

ANNEX 5

Name: Dr. Hugh McMahon

Qualifications: PhD Biotechnology

NAMES OF PERSONS RESPONSIBLE FOR QUALITY CONTROL

ANNEX 6

Name: Mr. John O'Neill

Qualifications: Ph.D in organic synthesis and bio-synthetic studies

NAMES OF PERSONS RESPONSIBLE FOR PRODUCTION

Name: Mr. Stewart Howlett

Qualifications: PhD Organic & Analytical Chemistry

DATE OF INSPECTION WHICH AUTHORISATION GRANTED ANNEX 7

This annex is not applicable

PRODUCTS AUTHORISED FOR IMPORT
ANNEX 8

This annex is not applicable