An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION (MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation number	**W13022/00001**
2. Name of authorisation holder	**New Life Biopharma Limited**
3. Legally registered address of authorisation holder	**(Companies Registration Office Number: 703328) Office 12 Unit 9a, Plato Business Park, Damastown Road, Damastown Industrial Park, Dublin 15, Co. Dublin, D15 PA4C, Ireland**
4. Address of site	**Office 12 Unit 9a, Plato Business Park, Damastown Road, Damastown Industrial Park, Dublin 15, Co. Dublin, D15 PA4C, Ireland**
5. Scope of authorisation	**See Annex 1**
6. Legal basis of authorisation	**Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013**

7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation

Paulina Nulty

8. Signature Paulina Nulty

9. Date of authorisation **14 February 2024**

10. Annexes attached

Annex 1	Scope of wholesale distribution authorisation
Annex 2	Address(es) of contract wholesale distribution sites and their authorisation number
Annex 3	Name(s) of responsible person(s)

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: **New Life Biopharma Limited, Office 12 Unit 9a, Plato Business Park, Damastown Road, Damastown Industrial Park, Dublin 15, Co. Dublin, D15 PA4C, Ireland**

1. MEDICINAL PRODUCTS

1.1 With a Marketing Authorisation in EEA country(s)

1.2 Without a Marketing Authorisation in the EEA and intended for EEA market*

1.3 Without a Marketing Authorisation in the EEA and intended for exportation

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.3 Supply

2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.3 Cold chain products (requiring low temperature handling)

3.4 Other products: (please specify here or see remarks)

3.4.1 Prescription only medicinal products

3.4.2 Medicinal products for general sale

3.4.3 Over the counter medicinal products for sale through pharmacies only

3.4.4 Unauthorised medicinal products

3.4.5 Vaccines

3.4.12 Biological products

Annex 2

Address(es) of contract wholesale distribution sites and their authorisation number	HSD Healthcare Ltd Unit 28, Western Parkway Business Centre Lower Ballymount Road Dublin 12 D12 NC80 Ireland	**W11254/00001**

Annex 3

Name of Responsible Person:	Giles Durcan
Name(s) of Deputy Responsible Person(s):	N/A

Schedule 1

Requirements to be met by an authorisation holder as per Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013

1. In this Schedule, the term ‘marketing authorisation’ includes a certificate of registration and a certificate of traditional-use registration.
2. (1) Subject to subparagraph (2), the authorisation holder shall obtain his or her supplies of medicinal products only from persons—
(a) who are themselves the holders of a manufacturer’s authorisation or a wholesaler’s authorisation in respect of such products, or
(b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture or the wholesale distribution of such products.
(2) Where a medicinal product is directly received from a state other than an EEA State but not imported into the State—
(a) subparagraph (1) shall not apply, and
(b) the authorisation holder shall ensure that the medicinal product is obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the state concerned,
3.(1) Subject to subparagraph (2) and paragraph 17, 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; and
(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.
4. The authorisation holder shall only sell medicinal products by wholesale to persons—
(a) who are themselves the holders of a wholesaler’s authorisation relating to those products,
(b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the wholesale distribution of those products,
(c) who are the holders of a manufacturer’s authorisation for use in the manufacture of medicinal products to which the said manufacturer’s authorisation relates,
(d) who are authorised or entitled to supply the said medicinal products to the public,
(e) who are lawfully entitled to administer those products to patients in the course of a professional practice or business as a hospital, or
(f) who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in a state other than an EEA State in accordance with the applicable legal and administrative provisions of the state concerned.
5. The authorisation holder shall provide and maintain such staff, premises, installations, equipment and procedures for the handling, storage and distribution of the medicinal products that he or she handles, stores or distributes under his or her authorisation, as are necessary to avoid deterioration of the products and he or she shall not use for such purposes premises other than those specified in his or her authorisation.
5A. The authorisation holder shall maintain a quality system setting out responsibilities, processes and risk management measures in relation to his or her activities.
6. (1) The authorisation holder shall at all times have at his or her disposal the services of a responsible person who possesses in the opinion of the Authority:
(a) knowledge of the activities to be carried out and of the procedures to be performed under the authorisation which is adequate for performing the functions of the responsible person; and
(b) experience in those activities and procedures which is adequate for those purposes.
(2) The functions of the responsible person shall be to ensure that in relation to medicinal products—
(a) the conditions under which the wholesaler’s authorisation has been granted have been, and are being, complied with, and
(b) the quality of the products that are being handled by the authorisation holder is maintained in accordance with the requirements of the marketing authorisation that are applicable to those products.
(3) The authorisation holder shall—
(a) notify the Authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of responsible person;
(b) notify the Authority of any change to the responsible person; and
(c) shall not permit any person to act as responsible person other than the person named in his or her authorisation as the responsible person, or subject to subparagraphs (4) and (5) any other such person whose name is notified to the Authority.
(4) Where, after giving the authorisation holder and the person acting as the responsible person the opportunity of making representations (either orally or in writing), the Authority is of the opinion that—
(a) the person so acting does not satisfy the provisions of subparagraph (1) as respects qualifications and experience, or
(b) he or she is failing to carry out the functions referred to in subparagraph (2) adequately or at all, and has notified the authorisation holder accordingly in writing, the holder shall not permit that person to continue to act as the responsible person so long as the said notification has not been withdrawn by the Authority.
(5) the Authority may require the authorisation holder to temporarily suspend the person acting as such responsible person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his or her
functions as referred to in subparagraph (2) and the authorisation holder shall not permit that person to act as the responsible person pending the determination of such proceedings. However, nothing in this paragraph shall affect the right of the responsible person pursuant to his or her contract of employment to receive full pay during the period of any such suspension.

7. The authorisation holder shall notify the Authority of any proposed structural alteration to, or discontinuation of use of, premises to which the authorisation relates or premises that have been approved from time to time by the Authority.
8. (1) The authorisation holder shall keep available for inspection by officers of the Authority, for a period of not less than five years, records giving for each transaction in respect of medicinal products received, dispatched or brokeredat least the following information:
— the date ofreceipt, supply or brokering,
— the name of the medicinal product,
— the quantityreceived, supplied or brokered, and
— the name and address of thesupplier, consignee or broker, as appropriate in the case of products required to bear safety features, the batch number of the medicinal product received, supplied or brokered.
(2) The records referred to in subparagraph (1) may be provided via image medium or other data medium, provided that the data, when made readable, match the original documentation in appearance and content, are available at all times, can be made readable without delay and can be analysed by automated means.
9. The authorisation holder shall have an emergency plan which will ensure the effective implementation of any recall from the market of any such product, or batch thereof, that may be ordered by the Authority or carried out in cooperation with the manufacturer or holder of the marketing authorisation for the medicinal product concerned.
10. The authorisation holder, in making a sale by wholesale to persons referred to inparagraph 4(d), (e) and (f)), 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 in the case of products required to bear safety features, the batch number of the medicinal product.
11. The authorisation holder shall, in respect of a medicinal product that has actually been placed on the market in the State and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product to the persons referred to in paragraph 4(d) and (e), so that the needs of patients in the State in respect of such medicinal product are covered.
12. Where an authorisation holder proposes to import from another EEA State a medicinal product in respect of which he is not the holder of the relevant marketing authorisation or is not acting on behalf of such person, he or she shall notify the holder of the authorisation and—
(a) in the case of a marketing authorisation other than a Community marketing authorisation, notify the Authority and pay the appropriate fee to the Authority in respect of the notification, or
(b) in the case of a Community marketing authorisation, notify the Agency and pay the appropriate fee to the Agency, in accordance with Article 76(3) of the 2001 Directive.
13. The authorisation holder shall comply with the principles and guidelines of good distribution practice for medicinal products published by the Commission pursuant to Article 84 of the 2001
Directive.
14. The authorisation holder shall, on being informed by the Authority or by the holder of the marketing authorisation, that any batch of any medicinal product to which the wholesaler's authorisation relates, has been found not to conform as regards the provisions of the relevant marketing authorisation, or as regards the strength, quality or purity with the appropriate specification for that product, if so directed, immediately withhold such batch from sale or exportation, and if so directed by the Authority, insofar as may be reasonably practicable, immediately withdraw from sale any supplies of that batch held by him or her and immediately recall all supplies already sold or distributed from that batch.
15. The authorisation holder shall, on being informed by the Authority that a medicinal product to which the wholesaler's authorisation relates, has been found to give rise to concerns in regard to its safety or efficacy, if so directed by the Authority, immediately withhold such product from sale, supply or exportation and insofar as may be reasonably practicable, immediately recall all supplies already sold or distributed by him or her.
16. The authorisation holder shall permit at all reasonable times such inspections, by officers of the Authority, as may be required to satisfy the Authority that the conditions of the authorisation are being complied with.
17.
(1) Where and insofar as the wholesaler's authorisation relates to an exempt sourced medicinal products, the authorisation holder shall only source such products—
(a) in response to an order, or in anticipation of an order, which satisfies the requirements of paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2013 as amended; 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 consignment of an exempt sourced medicinal product received by him or her, 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 received;
(f) the batch number of the medicinal product which has been received; and
(g) the name and address of the manufacturer of that medicinal product in the form in which it was received and, if the person who supplied the medicinal product is not the manufacturer, the name and address of such supplier.
(3) Where the authorisation holder sells or supplies an exempt sourced medicinal product, he or she shall, in addition to those records mentioned in paragraph 8(1) and subparagraph (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 sourced medicinal product or make any representations 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 sourced medicinal product that has been sourced by him or her.
(6) The authorisation holder shall cease supplying an exempt sourced 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 sourced or supplied.
(7) The authorisation holder shall, on being informed by the Authority, or by the manufacturer or person who supplied the medicinal product to the holder of the authorisation, 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 receipt of a consignment of an exempt sourced medicinal product, notify the Authority of each such receipt. 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 the receipt of each such consignment.
(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 monograph in the current edition of the European Pharmacopoeia, 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.
18. In paragraphs 3(1)(b) and (c), 4, 6(2)(b) and 13, 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.19. (1) Subject to subparagraph (2), the authorisation holder shall verify that the medicinal products received are not falsified by checking any safety features on the outer packaging, in accordance with the measures adopted by the Commission pursuant to Article 54a(2) of the 2001 Directive.
(2) Subparagraph (1) shall not apply where a medicinal product is directly received from a third country but not imported into the State.
20. The authorisation holder shall immediately inform the Authority and, where applicable, the holder of the relevant marketing authorisation, certificate of registration certificate of traditional-use registration, or in the case of a product intended for a state other than an EEA State the holder of the relevant authorisation in that state if he or she receives, is offered or sells by wholesale a medicinal product and he or she knows, or subsequently becomes aware after having sold by wholesale the product, or there are sufficient grounds to suspect, that the product is a falsified medicinal product.
21. Where a medicinal product is obtained from another wholesale distributor, the authorisation holder shall verify that the supplying wholesale distributor—
(a) complies with the principles and guidelines of good distribution practice published by the Commission pursuant to Article 84 of the 2001 Directive, and
(b) holds a wholesaler’s authorisation, or an equivalent authorisation granted in another EEA State.
22. Where a medicinal product is obtained from a manufacturer or importer, the authorisation holder shall verify that the supplying manufacturer or importer holds an appropriate marketing authorisation, certificate of registration, certificate of traditional-use registration or in the case of a product obtained from a state other than an EEA State, the relevant authorisation issued in that state.
23. Where a medicinal product is obtained through brokering, the authorisation holder shall verify that the broker involved fulfils the requirements set out in these Regulations and the 2001 Directive.

This authorisation is subject to any other requirement specified as per the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 – 2013