

“English Translation/Original in German”

**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION
(MEDICINAL PRODUCTS FOR HUMAN USE AND/OR VETERINARY USE:
PLEASE NOTE ANNEX 1)**

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| 1. Authorisation number | DE_RP_01_WDA_2023_54.3/Novo/20230427 |
| 2. Name of authorisation holder | Novo Nordisk Pharma GmbH |
| 3. Legally registered address of authorisation holder | Brucknerstraße 1
D-55127 Mainz, Germany |
| 4. Address(es) of site(s)
(All sites should be listed, if not covered by separate authorisations) | Brucknerstraße 1
D-55127 Mainz, Germany |
| 5. Scope of authorisation
(complete for each site under 4) | Annex 1 |
| 6. Legal basis of authorisation | § 52 a Absatz 1 des Gesetzes über den Verkehr mit Arzneimitteln (Arzneimittelgesetz - AMG) in gültiger Fassung |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | Dr. Ilka Petry
Landesamt für Soziales, Jugend und Versorgung, Referat 54.3, Pharmazie, Schießgartenstraße 6, 55116 Mainz |
| 8. Signature | |
| 9. Date | April 27, 2023 |
| 10. Annexes attached: | <input checked="" type="checkbox"/> Annex 1: Scope of wholesale distribution authorisation
<input checked="" type="checkbox"/> Annex 3: Name(s) of responsible person(s)
<input checked="" type="checkbox"/> Annex 4: Date of Inspection on which authorisation was granted
<input checked="" type="checkbox"/> Annex 5: Product list |

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

Novo Nordisk Pharma GmbH, Brucknerstraße 1, D-55127 Mainz

1. MEDICINAL PRODUCTS

Medicinal Products for Human Use Medicinal Products for Veterinary Use

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

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

2.4 Export

2.5 Other activities(s): (please specify)

3. Medicinal products with additional requirements

3.1 Products according to Art. 83 of 2001/83/EC¹

Products according to Art. 67 of 2001/82/EC

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.1.4 Radiopharmaceuticals (including radionuclide kits)

3.2 Medicinal gases

3.3 Cold chain products (requiring low temperature handling)

3.4 Other products: (please specify here or make a reference to Annex 5) Medicines for the therapy areas diabetes, obesity, blood clotting disorders, growth disorders and post-menopause.

Any restrictions or clarifying remarks related to the scope of these wholesaling operations

Storage, distribution and order processing are performed by PharmLog Pharma Logistik GmbH, Siemensstraße 1, D-59199 Bönen. Customer service is provided by Vilua Vitartis Service GmbH, Gützkower Landstr. 36-40, 17489 Greifswald and for archiving Iron Mountain GmbH - Location Butzbach, Magnapark Unit 1, Kirchgöns, D-35510 Butzbach, was commissioned.

¹ Without prejudice to further authorisations as may be required according to national legislation

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

ANNEX 3

Name(s) of responsible person(s)

Thomas Reißer, PHD - for the field rare blood and endocrine diseases, hormone replacement therapy, GlucaGen® und NovoNorm®

Luise Weigand - for the field GLP-1 Receptor Agonist

Lars Winkler, PHD - for the field of insulins

ANNEX 4

Date of Inspection on which authorisation was granted	02/04/2019
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ANNEX 5

Product list

Product name	Pharmaceutical dosage form	Active pharmaceutical ingredient(s)	Authorisation number
Actrapid® Vial, Penfill®, InnoLet®, FlexPen®	Solution for injection in a vial, in a cartridge, in a pen	Insulin human	EU/1/02/230/001-017
Protaphane® Vial, Penfill®, InnoLet®, FlexPen®	Suspension for injection in a vial, in a cartridge, in a pen	Insulin human, Isophan-Insulin Suspension (NPH Insulin)	EU/1/02/234/001-017
Insulatard® Vial, Penfill®, InnoLet®, FlexPen®	Suspension for injection in a vial, in a cartridge, in a pen	Insulin human, Isophan-Insulin Suspension (NPH Insulin)	EU/1/02/233/001-017
Actraphane® 30 Vial, Penfill®, InnoLet®, FlexPen®	Suspension for injection in a vial, in a cartridge, in a pen	Solved Insulin human 30% und 70% Isophan-Insulin	EU/1/02/229/001-013,030-037
Actraphane® 40 Penfill®	Injektionssuspension in einer Patrone	Solved Insulin human 40% und 60% Isophan-Insulin	EU/1/02/229/014-016
Actraphane® 50 Penfill®	Injektionssuspension in einer Patrone	Solved Insulin human 50% und 50% Isophan-Insulin	EU/1/02/229/017-019
Mixtard® 30 Vial, Penfill®, InnoLet®, FlexPen®	Injektionssuspension in einer Durchstechflasche, in einer Patrone, im Fertigpen	Solved Insulin human 30% und 70% Isophan-Insulin	EU/1/02/231/001-004,011-013,030-037
Mixtard® 40 Penfill®	Suspension for injection in a cartridge	Solved Insulin human 40% und 60% Isophan-Insulin	EU/1/02/231/014-016
Mixtard® 50 Penfill®	Suspension for injection in a cartridge	Solved Insulin human 50% und 50% Isophan-Insulin	EU/1/02/231/017-019
NovoRapid® Vial, Penfill®, InnoLet®, FlexPen®, FlexTouch®, PumpCart®	Suspension for injection in a vial, in a cartridge, in a pen	Insulin aspart	EU/1/99/119/001,003,006,008-015, 017-025
NovoMix® 30 Penfill®, FlexPen®	Suspension for injection in a cartridge, in a pen	Soluble Insulin aspart/ Insulin aspart-Protamin-Kristalle im Verhältnis 30/70	EU/1/00/142/004,005,009,010,023-025
NovoMix® 50 Penfill®, FlexPen®	Suspension for injection in a cartridge, in a pen	Soluble Insulin aspart/ Insulin aspart-Protamin-Kristalle im Verhältnis 50/50	EU/1/00/142/011-016
NovoMix® 70 Penfill®, FlexPen®	Suspension for injection in a cartridge, in a pen	Soluble Insulin aspart/ Insulin aspart-Protamin-Kristalle im Verhältnis 70/30	EU/1/00/142/017-022
Fiasp® Vial, Penfill®, FlexTouch®, PumpCart®	Solution for injection in a vial, in a cartridge, in a pen	Insulin aspart	EU/1/16/1160/001-013
Levemir® Penfill®, FlexPen®, InnoLet®, FlexTouch®	Solution for injection in a cartridge, in a pen	Insulin detemir	EU/1/04/278/001-016

Tresiba® 100 E/ml Penfill®, FlexTouch®	Solution for injection in a cartridge, in a pen	Insulin degludec	EU/1/12/807/001-005,007,008
Tresiba® 200 E/ml Penfill®, FlexTouch®	Solution for injection in a cartridge, in a pen	Insulin degludec	EU/1/12/807/006,009-016
Ryzodeg® Penfill®, FlexTouch®	Solution for injection in a cartridge, in a pen	Insulin degludec/ Insulin aspart im Verhältnis 70/30	EU/1/12/806/001-005,007,008
Xultophy®	Solution for injection in a pen	Insulin deglugec/Liraglutid	EU/1/14/947/001-004
Ozempic® 0,25 mg	Solution for injection in a pen	Semaglutid	EU/1/17/1251/002
Ozempic® 0,5 mg	Solution for injection in a pen	Semaglutid	EU/1/17/1251/003,004
Ozempic® 1,0 mg	Solution for injection in a pen	Semaglutid	EU/1/17/1251/005,006
Ozempic® 2,0 mg	Solution for injection in a pen	Semaglutid	EU/1/17/1251/010,011
Rybelsus® 3 mg	Tablets	Semaglutid	EU/1/20/1430/001-004,011
Rybelsus® 7 mg	Tablets	Semaglutid	EU/1/20/1430/005-007,012,014
Rybelsus® 14 mg	Tablets	Semaglutid	EU/1/20/1430/008-0010,013,015
Wegovy® 0,25 mg	Solution for injection in a pen	Semaglutid	EU/1/21/1608/001, 006
Wegovy® 0,5 mg	Solution for injection in a pen	Semaglutid	EU/1/21/1608/002,007
Wegovy® 1 mg	Solution for injection in a pen	Semaglutid	EU/1/21/1608/003, 008
Wegovy® 1,7 mg	Solution for injection in a pen	Semaglutid	EU/1/21/1608/004, 009
Wegovy® 2,4 mg	Solution for injection in a pen	Semaglutid	EU/1/21/1608/005, 010, 011
Victoza®	Solution for injection in a pen	Liraglutid	EU/1/09/529/001-005
Saxenda®	Solution for injection in a pen	Liraglutid	EU/1/15/992/001-003
NovoNorm® 0,5 mg	Tablets	Repaglinid	EU/1/98/076/004-007,023
NovoNorm® 1 mg	Tablets	Repaglinid	EU/1/98/076/011-014,024
NovoNorm® 2 mg	Tablets	Repaglinid	EU/1/98/076/018-022
Prandin® 0,5 mg	Tablets	Repaglinid	EU/1/00/162/003-005,021
Prandin® 1 mg	Tablets	Repaglinid	EU/1/00/162/009-011,020
Prandin® 2 mg	Tablets	Repaglinid	EU/1/00/162/015-017,019
GlucaGen® 1 mg/ml	Powder and solvent for producing a solution for injection	Glucagon	21794.00.00
GlucaGen® HypoKit 1 mg/ml	Powder and solvent for producing a solution for injection	Glucagon	28288.00.00
Norditropin® FlexPro® 5mg/1,5 ml	Solution for injection in a pen	Somatropin	78464.00.00

Norditropin® FlexPro® 10mg/1,5 ml	Solution for injection in a pen	Somatropin	78465.00.00
Norditropin® FlexPro® 15mg/1,5 ml	Solution for injection in a pen	Somatropin	78466.00.00
Sogroya® 5 mg/1,5 ml	Solution for injection in a pen	Somapacitan	EU/1/20/1501/003,004
Sogroya® 10 mg/1,5 ml	Solution for injection in a pen	Somapacitan	EU/1/20/1501/001,002
NovoEight® 250 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa, humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/13/888/001
NovoEight® 500 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa, humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/13/888/002
NovoEight® 1000 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa, humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/13/888/003
NovoEight® 1500 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa, humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/13/888/004
NovoEight® 2000 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa, humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/13/888/005
NovoEight® 3000 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa, humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/13/888/006
Refixia® 500 I.E.	Powder and solvent for producing a solution for injection	Nonacog beta pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor IX	EU/1/17/1193/001
Refixia® 1000 I.E.	Powder and solvent for producing a solution for injection	Nonacog beta pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor IX	EU/1/17/1193/002
Refixia® 2000 I.E.	Powder and solvent for producing a solution for injection	Nonacog beta pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor IX	EU/1/17/1193/003
Refixia® 3000 I.E.	Powder and solvent for producing a solution for injection	Nonacog beta pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor IX	EU/1/17/1193/004
NovoSeven® 1 mg (50 KIE)	Powder and solvent for producing a solution for injection	Eptacog alfa (activated), rekombinanter Blutgerinnungsfaktor VIIa	EU/1/96/006/004,008
NovoSeven® 2 mg (100 KIE)	Powder and solvent for producing a solution for injection	Eptacog alfa (activated), rekombinanter Blutgerinnungsfaktor VIIa	EU/1/96/006/005,009
NovoSeven® 5 mg (250 KIE)	Powder and solvent for producing a solution for injection	Eptacog alfa (activated), rekombinanter Blutgerinnungsfaktor VIIa	EU/1/96/006/006,010
NovoSeven® 8 mg (400 KIE)	Powder and solvent for producing a solution for injection	Eptacog alfa (activated), rekombinanter Blutgerinnungsfaktor VIIa	EU/1/96/006/007,011

Esperoct® 500 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/19/1374/001
Esperoct® 1000 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/19/1374/002
Esperoct® 1500 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/19/1374/003
Esperoct® 2000 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/19/1374/004
Esperoct® 3000 I.E.	Powder and solvent for producing a solution for injection	Turoctocog alfa pegol, PEG konjugierter humaner rekombinanter Blutgerinnungsfaktor VIII	EU/1/19/1374/005
NovoThirteen® 2500 I.E.	Powder and solvent for producing a solution for injection	Catridecacog, rekombinanter Blutgerinnungsfaktor XIII	EU/1/12/775/001
Activelle® Filmtabletten	Film coated tablets	Estradiol, Norethisteronacetat	43555.00.00
Novofem® Filmtabletten	Film coated tablets	Estradiol, Norethisteronacetat	47567.00.00
Estrifam® 1 mg Filmtabletten	Film coated tablets	Estradiol	40226.00.00
Estrifam® 2 mg Filmtabletten	Film coated tablets	Estradiol	40226.01.00
Kliogest® N	Film coated tablets	Estradiol, Norethisteronacetat	26118.00.00
Trisequens®	Film coated tablets	Estradiol, Norethisteronacetat	6529829.00.00

This translation complies with the original document bearing the signature of the competent authority.