Transfer Pricing Documentation {{ year }}

{{ entity_name }}, {{ country }}

Local file

STRICTLY PRIVATE AND CONFIDENTIAL

CONTENT

1. Local Company Analysis

{{ entity_name }} is a limited risk sales company and an affiliate of the NN group of companies with the parent company being NNAS a resident of Denmark.

1.1. Legal structure

{{ entity_name }} was established in 1990. It is a 100% owned subsidiary of Novo Nordisk Region Europe A/S a holding company which is a 100% owned subsidiary of NNAS, the parent company of the NN Group. Thereby the affiliate is 100% indirectly owned by NNAS.

{{ entity_name }} is domiciled at {{ address }}, {{ country }}.

Tax registration number: A-28081495

1.2. Affiliate history

The history of {{ entity_name }} in {{ country }} starts with the company "Laboratorios Capitol", which was acquired by the Novo Nordisk Group in 1958.

When the merger between Nordisk Gentofte A/S and Novo Industry A/S took place in 1989, {{ entity_name }} was founded as the result of the merger of NOVO ESPAÑA, S.A. and NORDISK HISPANIA, S.A., effective as of 15th of January 1990.

Market activities in {{ country }} were concentrated in the insulin market, according to the world strategy adopted by the new company.

As of 1st May,2013 the distribution activities have been outsourced to Logista Pharma. In October 2017 distribution activity has been moved from Logista Pharma to Alloga Logística España S.L.

In {{ year }}, {{ entity_name }} has 300 employees, 162 of which are commercial agents working in the promotion of Diabetes, Obesity, GHT and Haemostasis products.

A brief description of the history of {{ entity_name }} from incorporation up to 2019 follows:

- **Regarding products:**

1. 1996 Launch of NovoSeven®
2. 1998 Launch of Repaglinida (NN)
3. 1998 Out-licensing ISDIN
4. 2002 Co-marketing Prandin (Menarini)
5. 2002 Launch of analogues (NovoRapid® y NovoMix®)
6. 2004 Stop commercialisation of Human Insulin (Penfill)
7. 2005 Launch of Levemir®
8. 2006 Stop commercialisation of Human Insulin (NovoLet®)
9. 2009 Launch of NovoSeven® RTS (change in vial dose)
10. 2009 Launch of High Mixes Analogues (Novomix® 50 and Novomix® 70)
11. 2011 Launch of Victoza®
12. 2013 Vials excluded from the Government reimbursement
13. 2015 Launch of Novoeight®
14. 2016 Launch of Tresiba® and Saxenda®
15. 2018 Launch of Fiasp®
16. 2019 Launch of Ozempic®
17. 2020 Launch of FlexTouch® 3x3ml
18. 2020 Launch of Fiasp® 100 U/ml 5 cartuchos 3 ml
19. 2020 Launch of Fiasp® 100 U/ml vial 10 ml
20. 2020 Launch of Esperoct®
21. 2020 Launch of Refixia®

- **Others:**

1. 90's – Split between Diabetes and Pharmaceuticals (Diabetes and Biopharma)
2. 1998 Medical Department – Significant increase in R&D activities
3. 2006 – New warehouse
4. 2007 – New offices
5. 2010 - Change of General Manager.

6. 2016 - Change of General Manager.

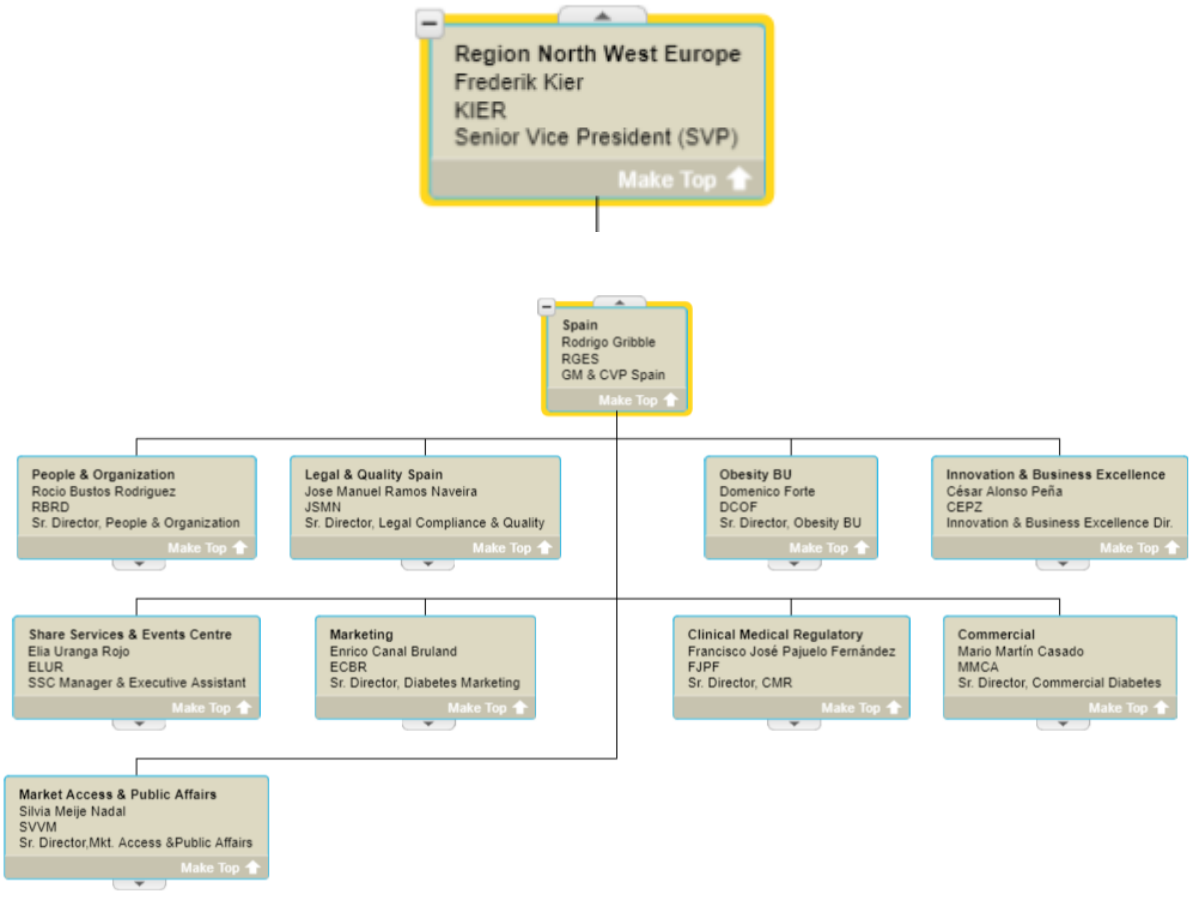
7. 2017- Launch of Business Area concept and structure.

8. 2018 – Business Area concept is replaced by Large Business Unit concept.

9. 2020 – Change of General Manager.

1.3. Organisational structure

{{ entity_name }} is organised as a legal entity with a Managing Director who is responsible for registrations and compliance according to local regulations reporting to the SVP for Region Europe. The company is organised as follows and a brief description for each department follows:



Commercial Department:

It is responsible for sales in accordance global strategy for the affiliate for Diabetes, Obesity and Biopharm therapies.

Marketing Diabetes Obesity and Biopharm:

Responsible for the preparation of local strategy and execution of strategic and tactical plans in accordance with the global framework set up by the IPR owners, in collaboration with medical, market access and commercial departments.

Finance & Strategic Operations:

It is responsible for co-ordinating different areas of the department, logistics, legal, reporting and accounting.

Market Access/Public Affairs: Responsible for ensuring the reimbursement for medical products set with the local authorities has been achieved and the conditions for the same are being adhered to.

Clinical, Medical & Regulatory (CMR): Responsible for the local co-ordination and execution of Clinical Trials. This involves meeting local regulatory requirements and providing medical information to the rest of the organisation.

P&O Department:

It is responsible for for all related employment matters such as recruitment, training.

1.4. Significant organisational changes since last report

No significant changes.

1.5. Affiliate business

The affiliate is classified as a limited risk sales and distribution company and is engaged in providing services and functions to NNAS and other NN affiliates.

In {{ year }} the services and functions performed were:

Service and functions performed
Sales and distribution of NN products
IT and administrative services
New product launch services
Clinical trials services
Financial transactions

The transactions are described in chapter 3 and an economic analysis for each transaction is included in chapter 3. A brief description follows:

In respect of the sales and distribution activities, {{ entity_name }} is directly responsible for the sale of diabetes related products, including insulin, oral diabetics and needles. These products are acquired from NNAS and are completely ready for sale in the local market.

{{ entity_name }} is also directly responsible for the sale of Growth Hormone Therapy products in the local market. These products are purchased from NNHCAG and are completely ready for sale in the local market.

{{ entity_name }} is also directly responsible for the sale of Hormone Replacement Therapy products in the local market through a distributor (Isdin). These products are purchased from NNHCAG and are distributed locally completely ready for sale.

Additionally, {{ entity_name }} performs clinical trial services and renders new product launch services when requested by NNAS and NNHCAG. These services include coordinating clinical research and studies which may be subcontracted to third parties with the relevant expertise such as hospitals, doctors and universities and providing other clinical trial related support.

Along with the services and functions performed the affiliate operates as a cash pool participant.

1.6. Local market conditions and outlook

The following information is sourced from the relevant therapy marketing plans/reports agreed with the relevant therapy principal. [1]

Tresiba®

Tresiba® U100 was launched in January 2016 with a good uptake, although the existing "visado" (limiting prescription) is creating minor local access issues.

In January 2020, Tresiba® U200 was launched with a direct positive impact in Tresiba® brand MS uptake (+1.2pp {{ year }} vs PY).

Additionally, Tresiba® growth continue being positive (+8,5% MAT21) although its main competitor Glargine U300 (Sanofi) doesn´t have market access restrictions (no visado) and the price 35 % lower than Tresiba®.

NovoEight®/Esperoct®

FVIII franchise performance closed in line with target, plus a 28% growth vs LY.

The strategy to protect FVIII franchise consolidated during {{ year }} with 30 patients being switched from NovoEight® to Esperoct®.

Esperoct® performance exceeded expectations and ended the year with 49 new prophylaxis patients and an uptake of 5.89% MS (MAT Value).

Victoza®

Victoza® lost its leadership in the GLP-1 class to Dulaglutide, launched in December 2015, as no promotion of Victoza® was in place during Tresiba® exclusivity period.

Since Ozempic® and Rybelsus® launch presents a negative growth trend due to Ozempic® cannibalization. At the end of the year Victoza® represents the 14.6% of MS in GLP1 (-8.7 pp vs PY).

Ozempic®

Ozempic® was launched in June 2019 and since its launch we reached a value market share of 43.6% (MAT, value) in the GLP-1 market.

Currently, Ozempic® leads the GLP.1 market growth (79% of growth vs PY).

Fiasp®

Fiasp® is a new generation fast insulin to compete in the fast insulin segment where our product NovoRapid® is already leading the market (Fiasp® 13.3% MS MAT Dec 21 vs NovoRapid® 46,5% MS MAT Dec 21).

Modern Insulins

Market share is impacted by continuous switch from Human Insulins to Modern Insulins and New Generation Insulins where NN capture rate is lower than competition, mainly in the Basal and Premix segment.

Basal segment growth is impacted by Biosimilars and New Generation Insulins.

NovoSeven®

Positive performance mainly due to leverage of AH cases which summed up to 40 by the EOY. Three of which were high consuming patients.

Saxenda®

Saxenda® consolidated its leadership in the antiobesity market despite not being reimbursed by Ministry of Health. Five years after launch the product has an uptake of 82% MS and 51% Value MAT Growth.

Saxenda® {{ year }} strong performance vs LY was mainly driven by the co-promotion partnership which let the product to penetrate within a Primary Care target.

1.7. Financial overview

The total turnover has ended with an increase this year of 2,6% compared to last year.

Key financial information	{{ year }} MEUR	{{ year }} MEUR	{{ year }} MEUR
Diabetes turnover			

Haemophilia turnover			
HRT turnover			
GHT turnover			
Total turnover			
Total Operating profit			
Composite ROS			

Source: Local Statutory Accounts

1.8. Advanced Pricing Agreement ("APA") Programmes

Novo Nordisk Pharma S.A has no unilateral or bilateral APA. Further there are no other tax rulings, related to controlled transactions described above, to which the local tax jurisdiction is not a party.

1.9. Related entity transactions

During {{ year }} the entity undertook controlled transactions with the following related entities. The material transactions are described in depth in chapter 3 and the economic analysis for each transaction is included in chapter 3.

Name of company	Country	Relationship	Type of Agreement	Description of transaction	VALUE M EUR	I/C Contract Ref# or Effective date *

Name of company	Country	Relationship	Type of Agreement	Description of transaction	VALUE M EUR	I/C Contract Ref# or Effective date *

*This is the reference for the contract in the Contract Management System (CMS) if it is available.

2. Local Industry Analysis

This section provides an overview of the industry in which {{ entity_name }} operates.

2.0 Competition {{ entity_name }} main competitors are:

Insulin: Sanofi Aventis, Lilly and Mylan.

Total Insulin Volume Market Share:

- Sanofi Aventis: 47,9%
- Lilly: 18.2%
- NN: 33.5%
- Mylan:0.4%

2. OAD: Accord Healthcare, Almirall, Almus Farmaceutic, Alter, Apotex, Aristo Pharma, Astrazeneca, Aurobindo, Aurovitas, Bayer, Bcnfarma, Bexal, Bluefish, Boehringer Ingel, Cinfa, Combix, Difarmed, Ecofar, Elam Pharma, Esteve, Faes Farma, Fardi, Ferrer, Generfarma, Kern Pharma, KRKA, Lacer, Mabo Farma, Melyfarma, Menarini, Merck & Co, Merck Sharp Dohme, Mundipharma Int, Neuraxpharma, Normon, Novartis, Novo Nordisk, Pfizer, Profas, Sanofi, Sandoz, Rubio, Servier, Stada, Sun Pharma, Takeda, Teva, Uxafarma, Viatris, Vifor Pharma, Vir , Zentiva.

3. GLP1: Sanofi Aventis, Astra, Lilly and GSK.

Total GLP1 value Market Share:

- NN: 58.3%
- Sanofi Aventis: 0.6%

- Lilly: 39.0%
- AstraZeneca:2.1%

4. Haemophilia: Takeda, Bayer, Sanofi/Sobi, Roche, Octapharma, CSL Behring, Pfizer.

5. GHT: Ferring, Pfizer, Lilly, Merck Serono, Ipsen, Sandoz.

GHT Value Market Share:

- Ferring 1.0%
- Pfizer 22.6%
- Lilly 12.2%
- Merck Serono 24.3%
- Ipsen 6.7%
- Sandoz 28.3%

6. Obesity: Orlistat, Mysimba

- Saxenda® 81.9% MS Value MAT
- Orlistat (120 MG) 17,7% MS Value MAT
- Mysimba 0.4% MS Value MAT

2.1. Regulatory influence

By controlling which products are admitted to the pharmaceutical market, the public regulatory process provides ultimate control of what can and cannot be sold. The market is also affected by public reimbursement schemes and price control.

2.1.1. Product approval

The pharmaceutical market is a highly regulated market and all products need to be approved by either Local Authorities or European Authorities depending on the procedure followed. The different procedures are: NP (National procedure), MRP (Mutual recognising Procedure) DP (decentralized procedure), and CP (centralized procedure).

Both European guidelines and regulations are followed in relation to the Pharmaceutical Industry and medicaments.

Most of NNPH, S.A. products sales are made to wholesalers and Hospital Pharmacies.

The promotion of medicaments is regulated by Law and we follow the Spanish Code of Ethics.

The Spanish Code of Ethics follows the Code of the Promotion & Prescription on medicines of the EFPIA.

2.1.2. Price influence

NNAS determines the minimum price at which NNPH, S.A. can sell its products. On the other hand, Spanish Authorities establish a public purchasing price for the sale of Novo Nordisk Pharma, S.A. products in {{ country }}. Margins for wholesalers and Pharmacies are regulated by law. Final price intervention applies only for units sold to NHS allowing free pricing for units sold in a different setting.

2.2. Industry threats

The main industry threats are:

Generic and Biosimilar Products

The oral antidiabetics products (from 2010 onwards) sold by the Spanish affiliate lost the patent 2010. Generic products were launched in the Spanish market at the end of 2010; consequently a significant decrease in sales has been experienced.

Growth Hormone Biosimilar has been launched in {{ country }} in year 2013.

RD8/2010, of 20 May included different measures to control the public pharmaceutical expenditure. A compulsory rebate of 7.5% or 15% was established for the price of non-generic medicines which are dispensed in pharmacies and charged to the pharmaceutical service of the National Health System. This 7.5% or 15% rebate is affecting most of the products sold by the Spanish affiliate.

The Spanish economy recession and the government deficit had significant impacts on the Spanish economy in 2012. Royal Decree RD9/2011 establishes a number of measures on the Pharma sector. There are three main measures given their impact in the short term: the progressive price reduction until reaching the established reference price, generalization of international non property names prescription and the 15% rebate for medicines over 10 years of existence but not having a generic or biosimilar in the market.

Insulin Glargine Biosimilar has been launched in {{ country }} in year 2015.

Public Tenders (GHT)

Haemophilia and GHT products are sold through Hospital channels and are subject to price competition via Public Tenders. This implies an erosion of the average price of these products sold by the affiliate, which is not compensated with an increase of volumes sold.

3. Controlled Transactions

The purpose of this section is to demonstrate and conclude that arm's length conditions are applied to the transactions under review.

{{ entity_name }} engages in the following controlled transaction types:

Service and functions performed
Sales and distribution of NN products
General services
New product launch services
Clinical trials services
Financial transactions

A description for each transaction type, including a function and risk analysis relevant for {{ entity_name }} as well as a description of the transfer pricing policies applied.

The distribution and service transactions are each supported by a benchmark of comparable companies performing similar activities; these are attached as appendices.

The comparables have been found using recognised and widely used databases. The comparability search will for each type of transaction be provided in the below sections "Benchmark analysis" and "Arm's length conclusion":

3.1. Assumptions

Following assumptions have been taken while preparing the transfer pricing documentation.

1. The contractual terms for the companies selected as comparables are similar to contractual terms for NN Group companies

2. The comparables are working under similar economic conditions/ business and technological environment.

{{ transaction_modules }}