



SUBMISSION TO THE COMPETITION COMMISSION
INQUIRY INTO THE PRIVATE HEALTHCARE SECTOR
NON-CONFIDENTIAL

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Introduction

This submission is made in response to allegations already made against Novo Nordisk South Africa to the Commission. No initial submissions were made by Novo Nordisk South Africa in October 2014, due to the fact that medicine prices in the Private Sector are regulated by the Department of Health, both in terms of existing products, as well as all new products. In addition, regulations from the Department of Health provide for a mechanism whereby prices of medication or devices could be declared unreasonable and in terms of utilisation, Companies face very effective managed care controls, imposed by private Medical Aid Schemes not only through formularies, co-payments, and an analysis of cost effectiveness but also through dispensing software that would immediately alert the dispenser and the patient that a product would not be funded at all, or only in part. In addition, for higher cost products there are stringent pre-prescription and pre-authorisation processes in place.

Novo Nordisk South Africa has, however, found that specific allegations and implications are made in relation to our products and the types of products which we sell within the South African market. Based on these allegations and implications Novo Nordisk South Africa deems it of the utmost importance that the Commission, and the Panel, is placed in a position to be in possession of accurate information in relation to the allegations and pricing of the Novo Nordisk Products in question. This information is provided as recommendations made by the panel may impact on our Company, and could have implications for the availability of medicines in the future, investment in our country, employment and skills development.

Novo Nordisk South Africa is therefore making this submission in exercising our rights to reply in relation to our products being mentioned by name, or implied. In doing so, we provide information to the Panel on matters pertaining to Novo Nordisk's policies and business principles within the South African Healthcare environment.

About Novo Nordisk South Africa

Novo Nordisk is headquartered in Denmark, and is a global healthcare company with affiliates in 75 countries and makes its products available in over 180 countries. Novo Nordisk has been operating in South Africa since 1959, employs 150 people from diverse backgrounds, 75 % of whom are female and 62 % are previously disadvantaged individuals.

Novo Nordisk South Africa has joined forces with other local private healthcare organisations to assist government in a number of health initiatives. Starting with the Social Compact Forum that established a Public Enhancement Health Fund (PHEF) which assists in

funding priority projects identified by the National Department of Health, these include the expansion of healthcare professionals, academy for leadership and management in healthcare and training of Masters and PHD students for combating TB, HIV and AIDS.

In exercising its values of having a patient centred business approach, Novo Nordisk South Africa has over the past 10 years invested more than R40 million in various projects aimed at programmes in diabetes and haemophilia education alone. These include, but are not limited to;

- Training of doctors and Nurses in a Diabetes and Haemophilia care.
- Diabetes Awareness Programme to members of the public.
- Partnership with various Academic Institutions to improve Diabetes and Haemophilia care.

Novo Nordisk is associated to numerous Pharmaceutical and Industry Associations within Europe, USA and South Africa. Some of the larger Associations to which Novo Nordisk subscribes are the European Federation of Pharmaceuticals Industries and Associations, The Danish Pharmaceutical Association, Pharmaceutical Researcher and Manufacturers of America and Innovative Pharmaceutical Association of South Africa.

Response to allegations made by Mediclinic that NovoSeven® is excessively priced compared to other named countries

Introduction to NovoSeven®

NovoSeven® is a recombinant factor Seven (VII) biological blood treatment primarily used in the treatment of a small subset of patients with the rare bleeding disorder (Haemophilia A and B) that develop antibodies to the replacement clotting factors. The rareness of this disorder is borne out by a reported incidence of 1 - 4 per 1 000 patient years¹. In South Africa, there is an estimated 100 known patients that seek treatment for acute bleeding episodes as a result of having this rare disorder. The majority of these patients (80-85%), are treated in the State sector and not the Private sector².

¹ Inhibitor development in previously treated haemophilia A patients: a systematic review, meta-analysis, and Meta-regression. Journal of Thrombosis and Haemostasis, 11: 1655–1662 (2013)

² South African Haemophilia Foundation Register

The allegations that NovoSeven® is significantly more expensive in the United Kingdom, Switzerland and UAE are factually incorrect. In the submission below, you will see a comparison of the patient acquisition prices of these products as supplied by Novo Nordisk. The following tables and graphics will highlight the price comparisons of NovoSeven® in the various countries under scrutiny as compared to South Africa:

NovoSeven®, is a medicine which supplied by Novo Nordisk South Africa, is specifically singled out in submissions, by Mediclinic, made to the Panel and therefore it is of paramount importance that correct information must be submitted to address these allegations.

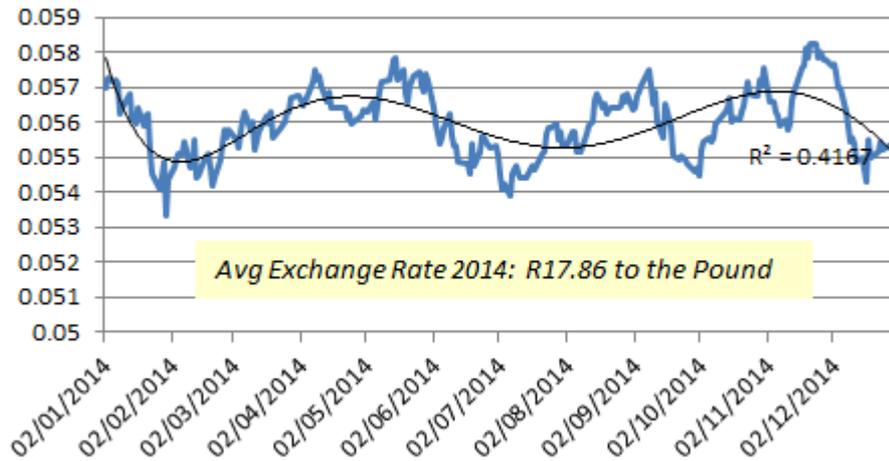
In this submission Novo Nordisk South Africa will provide a comparison of the patient acquisition prices, where available, of NovoSeven® between the countries specified in the allegation. It must however be noted that a direct comparison of prices across markets is a complex exercise compounded by the following factors:

1. The United Kingdom is in the European Union where NovoSeven® is manufactured (Denmark). This implies that there are little or no trade tariffs or duties imposed on exports between EU member state countries. Dubai uses a CIF (Cost, Insurance and Freight) system with no additional taxes and levies imposed on imports. Despite the significant customs and duties costs incurred by importing products such as NovoSeven® into South Africa, the patient acquisition price remains less than the countries referred to in the allegation.³
2. With respect, the South African pharmaceutical industry has been beset by an inefficient product regulatory authority. The inefficiencies are well documented and affect all companies both directly and indirectly. Further details relating to this will be supplied to the panel, if required.
3. Transport costs of manufactured NovoSeven®; a protein based biologic product from the country of manufacture (Denmark) to South Africa is significantly more expensive than transport costs to countries in closer proximity such as Switzerland and the United Kingdom. These costs are already expensive due to the special transport requirements for such protein based biological treatments.
4. The currency fluctuation in South Africa is far less stable than the currencies of United Kingdom, Switzerland and Dubai. Despite a depreciating Rand, NovoSeven® patient

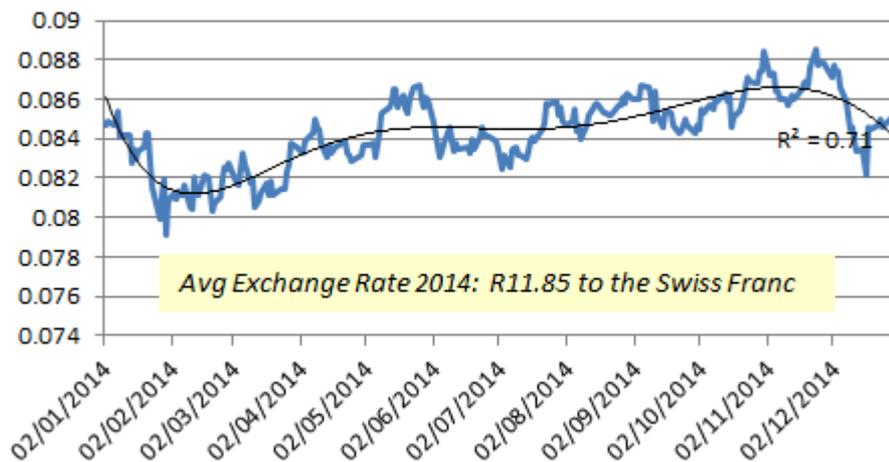
³ Pharmacy Selling Price (also known as the Public Price). PSP is price with or without Value Added Tax (VAT) that the patient or payers are paying. If the patient or payer is each only paying partial amounts, it is the full price paid by both before any rebates are applied. These Prices are listed in the public domain.

acquisition price remains comparable or less than the countries referred to as comparators. Novoseven® is a fully imported product. Below are graphs depicting the varying exchange rate in 2014.

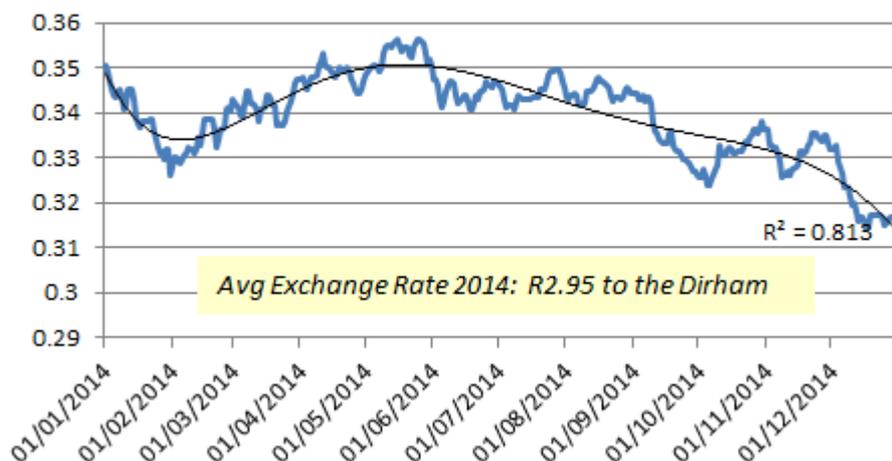
British Pound



Swiss Franc



UAE Dirham



NovoSeven® Comparison versus Switzerland:

In Switzerland, NovoSeven® is sold at the official prices and there are no special prices for any hospital/clinic. There are no volume based rebates or discounts. In Switzerland there are only two official prices (in Swiss Francs - CHF) which are Wholesale Purchase Price (WPP)⁴ and Pharmacy Selling Price (PSP)⁵. These systems are published in the public domain⁶. In Switzerland the normal process is that this product is sold directly to the hospitals. Hence PSP is rarely used as well as the 40 CHF dispensing fee is very low. From the table below, NovoSeven® Pharmacy Selling Prices (PSP) are 13% - 16% cheaper in South Africa.

Strength	Switzerland (ZAR)	South Africa (ZAR)	PSP Price Difference (ZAR)	% Difference
NovoSeven® 1 mg	10 741.88	9 228.10	- 1 513.78	-16%
NovoSeven® 2 mg	21 010.39	18 333.20	- 2 677.19	-15%
NovoSeven® 5 mg	51 778.58	45 648.48	- 6 130.10	-13%

*Exchange Rate: 1 CHF = ZAR 12.71*⁷

*South African DoH list price (SEP)*⁸

⁴ Wholesaler Purchase price or WPP is the publically available purchasing price by a wholesaler from Novo Nordisk in a certain country.

⁵ Pharmacy Selling Price (also known as the Public Price). PSP is price with or without Value Added Tax (VAT) that the patient or payers are paying. If the patient or payer is each only paying partial amounts, it is the full price paid by both before any rebates are applied.

⁶ <http://www.spezialitaetenliste.ch/ShowPreparations.aspx>

⁷ <https://www.resbank.co.za/research/rates/pages/selectedhistoricaexchangeandinterestrates.aspx>

⁸ <http://www.pbb.co.za>

NovoSeven® Comparison versus UAE:

In the UAE, NovoSeven® is sold at the official prices and there are no special prices, discounts or rebates for any hospital/clinic. From the table below, NovoSeven® Pharmacy Selling Prices (PSP) are 18% - 20% cheaper in South Africa than the UAE.

Strength	United Arab Emirates (ZAR)	South Africa (ZAR)	PSP Price Difference (ZAR)	% Difference
NovoSeven® 1 mg	10 923.30	9 228.10	- 1 695.20	-18%
NovoSeven® 2 mg	21 848.08	18 333.20	- 3 514.88	-19%
NovoSeven® 5 mg	54 622.42	45 648.48	- 8 973.94	-20%

Exchange Rate: 1 AED = ZAR 3.46⁹

South African DoH list price¹⁰

NovoSeven® Comparison versus the United Kingdom:

The Pharmacy Selling Price (PSP) in the United Kingdom to the best of our knowledge is not publically available. What is in the public domain is the Pharmacy Purchase Price (PPP). A comparison of this publicly listed price indicates that NovoSeven® is 23 % less expensive in South Africa.

Strength	United Kingdom (ZAR)	South Africa (ZAR)	PPP Price Difference (ZAR)	% Difference
NovoSeven® 1 mg	9 380.05	7 606.60	- 1 773.45	-23%
NovoSeven® 2 mg	18 760.11	15 213.20	- 3 546.91	-23%
NovoSeven® 5 mg	46 900.27	38 032.98	- 8 867.29	-23%

Conclusion on Novoseven® Pricing

The Public Domain pricing data evidently shows that the Mediclinic's claim that Novo Nordisk South Africa is more expensive than the referenced countries is inaccurate and misleading. As is clearly evident from the data provided above, it is inaccurate to claim that NovoSeven® is more expensive in South Africa, both at the patient or payer acquisition level.

We conclude that the acquisition price of Novoseven® in South Africa is cheaper than that of Switzerland the UAE and the UK both at payer and patient level.

⁹ www.oanda.com

¹⁰ <http://www.pbb.co.za>

Parity on Pricing between Public and Private Sectors in response to the allegations by Transpharm and MediRite in their submission.

Addressing the call for Public/Private sector pricing parity, Novo Nordisk submits that it is wholly inappropriate to refer to Public sector pricing in determining the price of a medicine in the Private Sector.

Notwithstanding that a number of parties have called for parity of medicines in the Private and Public sectors, Novo Nordisk is of the opinion that this is out of scope of the Panel's mandate and therefore, with respect, should not be included as part of this focus. Given that the stakeholders submissions in this respect are superficial Novo Nordisk does not believe that the Panel is placed in the position to make any meaningful comment in respect thereof and respectfully, should avoid doing so without a detailed consideration of the Public sector and how it interrelates with the Private sector.

It must also be noted that in most countries Private sector prices of medicines are not regulated, and regulatory measures are limited to the Public sector systems of health services. This can be evidenced from many of the submissions already made to the Panel.

In the non-confidential submission made to the commission by Transpharm and MediRite, amongst many assumptions and allegations, Estrofem[®], a Novo Nordisk product is listed as an example of price cross subsidisation between the private and public sectors. The allegation of cross subsidisation between the public and private sector is addressed below as it pertains to Estrofem[®].

Estrofem[®] Tablets

Estrofem[®] is a Hormone Replacement Therapy (HRT). It contains the female hormone estradiol. Estrofem[®] is used in postmenopausal women, particularly in women who have had their womb removed (have had a hysterectomy) and therefore do not require combined oestrogen/progesterone therapy. Estrofem[®] is used for: Relief of symptoms occurring after menopause and Prevention of osteoporosis.

Novo Nordisk is a supplier of HRT products in South Africa which includes the widest range of products of any manufacturer in this therapeutic area. These include at least 6 different products¹¹ with varying dosage strengths. Of this portfolio of six products, three are available on tender in the public sector¹², including Estrofem[®]. Novo Nordisk South Africa is

¹¹ ACTIVELE[®], TRISEQUENS[®], VAGIFEM[®], ESTROFEM[®], KLIOGEST[®], NOVOFEM[®]

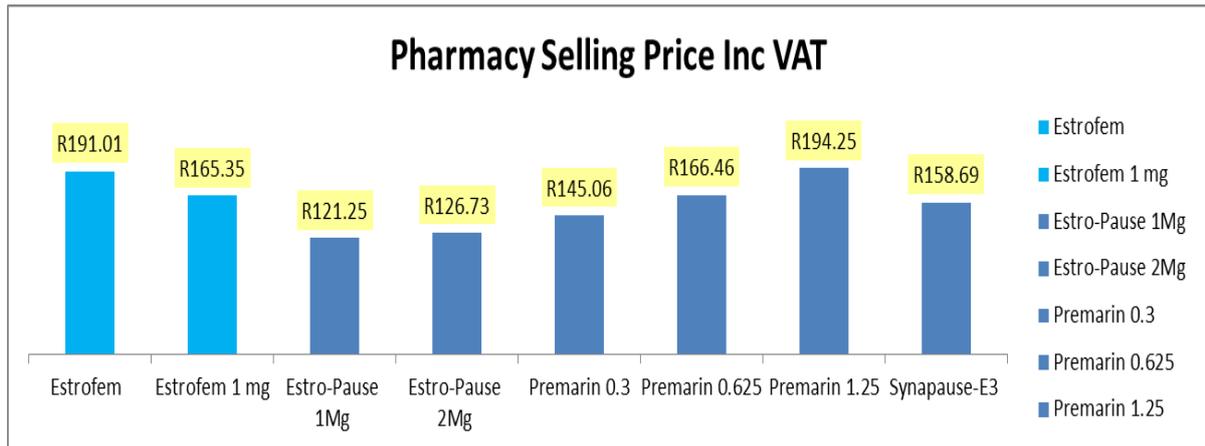
¹² ACTIVELE[®], ESTROFEM[®], KLIOGEST[®]

perplexed that Estrofem® is the **only** HRT Product within the portfolio that is cited as a cost driver of healthcare inflation in South Africa arising from an alleged assumption that price disparities are as a result of cross subsidisation. It appears that the allegations relating to this specific product, have with respect, been cherry picked to support the allegation relating to drug acquisition costs.

Public Private Price differentials

It is evident that there is a price difference between the Public and Private sectors when procuring medicines. Novo Nordisk South Africa bids in in the Public sector tender process adjudicated by the Department of Health as permitted by PFMA, with the intention of being the winning bidder, as is the intention of all other bidders, in therapeutic areas in which we supply medicines. The following comments and questions are raised in argument to test the validity of the allegations raised of cross subsidisation in the various submissions:

1. The tender period is fixed and limited and not continuous compared to the continuum of Private sector price adjustments that is granted by Department of Health, if at all.
2. The range of scheduled medicines required by the State and procured through the tender system are limited when compared to the Private sector. The tender process is restricted to more basic medicines that are geared toward public health objectives and primary care.
3. As there is often more than one drug competing in a tender, how would winning a tender make a product / treatment competitive in the private sector if the prices were then inflated by a cross subsidization premium? The graphic below shows that Estrofem® is indeed competitively priced in the private sector when compared to other similar treatments that have not been awarded a public sector tender.



*South African DoH list price (SEP)*¹³

Conclusion

We submit that Novoseven® in South Africa is cheaper than that of Switzerland the UAE and the UK both at payer and patient level. The allegation that Novoseven® is excessively priced is therefore inaccurate.

Estrofem® is competitively priced in the Private sector when compared to other similar treatments. Estrofem® pricing in the Public sector is in accordance to the PFMA bidding procedures.

Novo Nordisk South Africa welcomes this enquiry and can be contacted for further information, should it be required, on the above submission at:

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¹³ <http://www.pbb.co.za>