

# Dwarfism: Accessibility of Somatropin Therapy for Patients with Growth Hormone Deficiency and Impact of its Cost on the State Budget in Ukraine

T. Germanyuk<sup>1</sup>, O. Kryvoviaz<sup>1</sup>, O. Toziuk<sup>1</sup>, O. Balicka<sup>1</sup>, T. Ivko<sup>1</sup>, Y. Polyshchuk<sup>1</sup>, L. Bobrytska<sup>2</sup>, V. Hrytsenko<sup>2</sup>, O. Shpychak<sup>3</sup>

<sup>1</sup>Department of Pharmacy, National Pirogov Memorial Medical University, Vinnytsya, Ukraine, <sup>2</sup>Department of Industrial Technology of Drugs, National University of Pharmacy, Kharkov, Ukraine, <sup>3</sup>Department of Drug Technology Named after D.P. Salo, National University of Pharmacy, Kharkov, Ukraine

## Abstract

**Aim:** Dwarfism is rare diseases with prevalence 1.1 per 10,000 children population in Ukraine. Considering the high cost of the treatment and its duration, it is very important to study socioeconomic accessibility therapy and its impact on the state budget. The purpose was scientific generalization of the results of the study of socioeconomic accessibility and its impact on the state budget. **The Material of the Study:** Pharmaceutical market of somatropin; Anatomical Therapeutic Chemical (ATC)/defined daily dose (DDD) index; the data of the state register of wholesale selling prices of August 09, 2017; the data of average salary; and the data of state statistics service. **Research Methods:** Analysis of the pharmaceutical market of somatropin, ATC/DDD methodology, liquidity ratio of price Cliq, and solvency adequacy ratio Ca.s, budget impact analysis. **Results and Discussions.** ATC/DDD methodology showed that the cost of DDD of somatropin ranged from 65.05 to 546.09 UAH. Liquidity ratio of price Cliq was 7.39, so price fluctuations were 739% of somatropin in the pharmaceutical market. Solvency adequacy ratio Ca.s varied from 44.1 to 370.6 which indicated a fluctuation in the cost of treatment from 44.1 to 370.6% of the salary of the population. It is established that the possible impact on the budget of Ukraine in context of the cost of somatropin analogues ranges from 20965289.75 to 176002076.6 UAH per year. Budget savings can be 155036786.85 UAH per year using the cheapest analogues of somatropin. **Conclusions:** Somatropin therapy for the Ukrainian population is economically inaccessible, and this makes a significant burden on the state budget of Ukraine.

**Key words:** Budget impact analysis, dwarfism, socioeconomic accessibility

## INTRODUCTION

Dwarfism (pituitary nanism), associated with a growth hormone somatropin hormone (STH) deficiency, refers to the so-called orphan diseases and according to researchers are common among children in Ukraine with a frequency of 1.1 per 10,000 child population.<sup>[1]</sup> At the same time, the prevalence of STH deficiency among children in the world is between 1:4000 and 1:20,000.<sup>[2,3]</sup> The Ministry of Health of Ukraine, through its order No. 778 of October 27, 2014 (as amended by order of the Ministry of Health No. 919 of December 30, 2015), established a list of rare (orphan) diseases to which pituitary nanism was introduced. Cost for the treatment of orphan diseases is provided on the state

budget by order «Fundamentals of the Ukrainian legislation on health care for the provision of prevention and treatment of rare (orphan) diseases» No. 1213-VII of October 27, 2014. Only genetically engineered analogues of STH are used for the treatment of pituitary nanism.<sup>[4]</sup> Hence, in the limited financing of the healthcare system in Ukraine,<sup>[5]</sup> it is very important to study socioeconomic accessibility of

### Address for correspondence:

Tanya Ivko, Department of Pharmacy, National Pirogov Memorial Medical University, Pirogov Street 56, Vinnytsya - 21018, Ukraine. Tel: 098-264-05-60. E-mail: ivkot1981@gmail.com

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STH deficiency therapy for the patients and its impact on the state budget.

The purpose was scientific generalization of the results of the study of socioeconomic accessibility of somatropin therapy for the patients with growth hormone deficiency and its impact on the state budget in Ukraine.

### Research objectives

To study the pharmaceutical market of Ukraine of genetically engineered analogues of growth hormone; to determine defined daily dose (DDD) of somatropin; to analyze socioeconomic accessibility of somatropin pharmacotherapy by liquidity ratio of price  $C_{liq}$  and solvency adequacy ratio  $C_{a.s.}$ ; and to perform budget impact analysis of somatropin pharmacotherapy.

### The material of the study

Pharmaceutical market of genetically engineered analogues of STH; Anatomical Therapeutic Chemical (ATC)/DDD index 2017 of the WHO Collaborating Centre for Drug Statistics Methodology;<sup>[6]</sup> the data of the state register of wholesale selling prices of August 09, 2017;<sup>[7]</sup> the data of average salary from the official site of the state statistics service of Ukraine;<sup>[8]</sup> and the data of State Statistics Service of Ukraine.<sup>[9]</sup>

### Research methods

Analysis of the pharmaceutical market of genetically engineered analogues of STH in Ukraine, ATC/DDD methodology, liquidity ratio of price  $C_{liq}$ , and solvency adequacy ratio  $C_{a.s.}$ , budget impact analysis.

Liquidity ratio of price  $C_{liq}$  shows the relationship between maximum and minimum price of the drugs in the pharmaceutical market, and  $C_{liq}$  is calculated by the formula:<sup>[9]</sup>

$$C_{liq} = \frac{C_{max} - C_{min}}{C_{min}}, \text{ where}$$

$C_{liq}$  - liquidity ratio of price

$C_{max}$  - maximum cost of drugs

$C_{min}$  - minimum cost of drugs

Solvency adequacy ratio  $C_{a.s.}$  characterizes the ratio between the price of drugs and the solvency of the population in dynamics. Drugs are accessible when the solvency ratio  $C_{a.s.} < 1$ .  $C_{a.s.}$  is calculated by the formula:<sup>[10]</sup>

$$C_{a.s.} = \frac{P}{W_{a.w}} * 100\%, \text{ where}$$

$C_{a.s.}$  - solvency adequacy ratio

P - DDD cost per year

**Table 1: Cost of DDD of analogues of somatropin**

Trade name	Declared wholesale selling prices, UAH	Cost of DDD, UAH
SOMATIN 1.3 mg (4 IU) and 1.0 ml of solvent Biopharma (Ukraine, Bila Tserkva)	130.08	65.05
OMNITROPE 15 IU 5 mg/1,5 ml cartridge №1 Sandoz (Austria)	525.63	70.10
GROWTROPIN 16 IU 5.34 mg bottle 2 ml №10 Contract (Ukraine, Kiev)	8000	100
ZROSTA 15 IU bottle 1,5 ml №1 Farmak (Ukraine, Kiev)	759.25	101.23
ZROSTA 4 IU bottle 1,5 ml №1 Farmak (Ukraine, Kiev)	211.5	105.75
ZROSTA 4 IU bottle 1,5 ml №5 Farmak (Ukraine, Kiev)	1057.53	105.75
GROWTROPIN 4 IU 1.34 mg bottle 0,5 ml №10 Contract (Ukraine, Kiev)	2200	110
RASTAN 4 IU 1.3 mg №1 Biopharma (Ukraine, Bila Tserkva)	225	112.5
GENOTROPIN 36 IU/ml pre-filled pen №1 Pfizer (USA)	5467.46	280.38
ZOMACTON 12 IU 4 mg №1 Ferring (Germany)	2347.57	391.26
NORDITROPIN 30IU 10 mg/1,5 ml pre-filled pen №1 Novo Nordisk (Denmark)	6338.82	422.58
SAIZEN 8 mg №1 Ares Trading (Switzerland)	2062.03	515.50
GENOTROPIN 16 IU/ml pre-filled pen №1 Pfizer (USA)	4368.72	546.09

DDD: Defined daily dose,

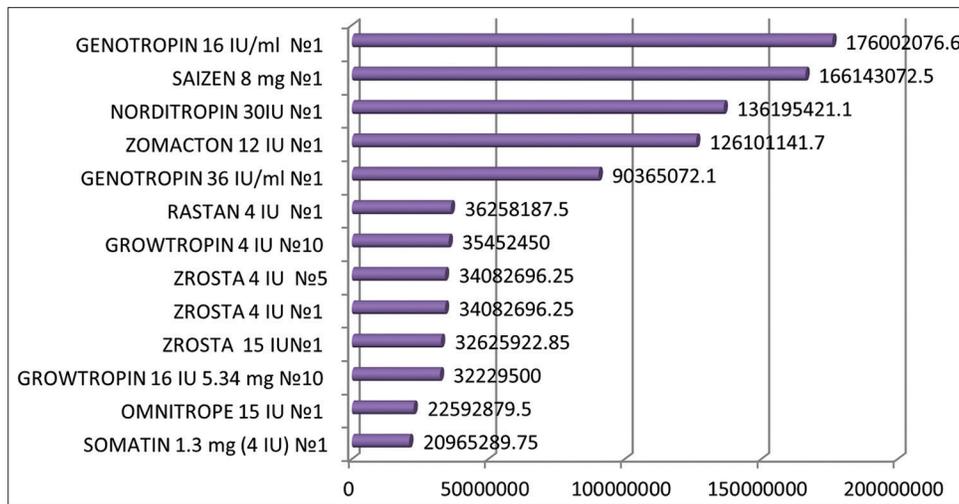


Figure 1: Budget impact analysis for analogues of somatropin

Table 2. Solvency adequacy ratio Ca.s for analogues of somatropin

Trade name	Solvency adequacy ratio Ca.s
SOMATIN 1.3 mg (4 IU) and 1.0 ml of solvent Biopharma (Ukraine, Bila Tserkva)	44.1
OMNITROPE 15 IU 5 mg/1,5 ml cartridge №1 Sandoz (Austria)	47.6
GROWTROPIN 16 IU 5.34 mg bottle 2 ml №10 Contract (Ukraine, Kiev)	67.9
ZROSTA 15 IU bottle 1,5 ml №1 Farmak (Ukraine, Kiev)	68.7
ZROSTA 4 IU bottle 1,5 ml №1 Farmak (Ukraine, Kiev)	71.8
ZROSTA 4 IU bottle 1,5 ml №5 Farmak (Ukraine, Kiev)	71.8
GROWTROPIN 4 IU 1.34 mg bottle 0,5 ml №10 Contract (Ukraine, Kiev)	74.6
RASTAN 4 IU 1.3 mg №1 Biopharma (Ukraine, Bila Tserkva)	76.3
GENOTROPIN 36 IU/ml pre-filled pen №1 Pfizer (USA)	190.3
ZOMACTON 12 IU 4 mg №1 Ferring (Germany)	265.5
NORDITROPIN 30 IU 10 mg/1,5 ml pre-filled pen №1 Novo Nordisk (Denmark)	286.8
SAIZEN 8 mg №1 Ares Trading (Switzerland)	349.8
GENOTROPIN 16 IU/ml pre-filled pen №1 Pfizer (USA)	370.6

Wa.w. - average salary per year (53788.20 UAH per year.

N - number of children aged 18 years in the country

Budget impact analysis calculates the economic benefits of using medical technology by the formula:<sup>[10]</sup>

n - prevalence of pituitary nanism.

BIA = Efec (1) - Efec (2), where

During the study, the cost of DDD was calculated from the data of the state register of wholesale selling prices August 09, 2017,<sup>[7]</sup> and the data of average salary we obtained from the official site of the State Statistics Service of Ukraine.<sup>[8]</sup>

BIA - economic benefits, UAH

Efec (1) – direct costs when using most expensive drugs, UAH

Efec (2) – direct costs when using cheapest drugs, UAH

Number of patients with pathology calculated by the formula:

K = N/n, where

K - number of patients

## RESULTS AND DISCUSSIONS

- There are 13 genetically engineered analogues of STH on pharmaceutical market of Ukraine.
- ATC/DDD methodology showed that the cost of DDD of somatropin analogues ranged from 65.05 to 546.09 UAH [Table 1].

Liquidity ratio of price Cliq was 7.39. It means that in the Ukraine pharmaceutical market the price fluctuations were 739% for the analogues of somatropin.

Solvency adequacy ratio Ca.s for analogues of somatropin ranged from 44.1 to 370.6 [Table 2].

It was found that the cost of treatment varied from 44.1 to 370.6% of the salary of the population in Ukraine. Hence, genetically engineered analogues of STH with INN somatropin for the Ukrainian population are economically inaccessible.

According to the researchers, the official data of State Statistics Service of Ukraine and our calculations,<sup>[1,11]</sup> there are 883 children with deficiency of STH in Ukraine. It was revealed that the possible impact on the budget of Ukraine in context of the costs for analogues of somatropin varies from 20965289.75 to 176002076.6 UAH per year. Budget savings can be 155036786.85 UAH per year using the cheapest analogues of somatropin [Figure 1].

## CONCLUSIONS

1. There are 13 genetically engineered analogues of growth hormone on pharmaceutical market of Ukraine.
2. ATC/DDD methodology showed that the cost of DDD of somatropin analogues ranged from 65.05 to 546.09 UAH.
3. Somatropin therapy for the Ukrainian population is economically inaccessible.
4. The burden on the state budget for the somatropin pharmacotherapy ranged from 20965289.75 to 176002076.6 UAH per year, corresponding to the cost of analogues of somatropin in the pharmaceutical market of Ukraine.
5. Budget savings can be 155036786.85 UAH per year using the cheapest analogues of somatropin.

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