Biologics and Biosimilars in Albania; Consumption and Costs

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ABSTRACT

Biological therapies use proteins that have been produced with biological technology to generate targeted effects within the body, impact the body's immune system, and reduce inflammation at various stages. Biologics are used in the treatment of conditions such as rheumatoid arthritis, systemic lupus, ankylosing spondylitis, arthropathic psoriasis, and psoriatic arthritis. The aim of the study is to conduct a comprehensive review and analyze the market dynamics related to the use of these treatments in Albania. Methods: This is a retrospective and observational study based on FDSKSH’s data for 2023. Results: The total annual reimbursement cost for 2023 was ALL 188,208,780 (1 ALL = 0.01 USD). The average reimbursement cost per patient was ALL 20,982,026.79. The use of biologics and biosimilars represents 0.028% of all prescriptions and accounts for 1.56% of the total reimbursement costs for drugs. In 2023, the reimbursement cost covered by FDSKSH was 7.14% lower than in 2022. 87.17% of the patients were treated with Tumor Necrosis Factor (TNF) Inhibitors. Etanercept 25 mg (biosimilar) had the highest price reduction of 32.83% in 2024. The most expensive drug in 2023 was Secukinumab 150 mg. Biologics account for 61% of the total annual reimbursement cost, while biosimilars account for 39%. Conclusions: The prescription of biologics is lower compared to biosimilars, but they are associated with significant costs that impact the overall reimbursement costs. The prices of biologics and biosimilars were lower than those in Kosovo, Italy, Greece and will decrease in 2024. Cost-economic evaluations of the most expensive biologics and biosimilars are important for the management of financial resources.

KEYWORDS

Biological therapies, the total annual reimbursement cost, the average reimbursement cost per patient, prices, biosimilars

1. INTRODUCTION

Biological drugs have been used to treat diseases such as rheumatoid arthritis, systemic lupus, ankylosing spondylitis, arthropathic psoriasis and psoriatic arthritis. Tumor Necrosis Factor Inhibitor (Adalimumab, Etanercept, Infliximab, Golimumab), Interleukin-6 receptor antagonist (Tocilizumab) and Interleukin-17 receptor antagonist (Secukinumab) are available in the pharmaceutical market in Albania. Each type of biological drug has a different mechanism of action. Biologics have several potential advantages as they can, theoretically, be tailored to hit specific ‘targets’ in the human body [1]. Biologics are designed to act on specific proteins that cause
inflammation, and specifically affect the immune system. Biologics are more expensive than other treatment options for autoimmune diseases [2].

According to Albanian legislation in 2014, Law No.105/2014, 31.07.2014 “On drugs and pharmaceutical service”, amended: A biosimilar is a biological drug that is highly similar to another biological drug that already has a marketing authorization (reference biological product) and has the same active ingredient, dosage form and route of administration as the reference product, for which it is determined through a quality, safety and efficacy program. This drug doesn’t fulfill the criteria to be classified as a generic drug because it differs from the biological drug regarding the ingredients and manufacturing process and for these reasons, it is not substitutable[3].

In Albania, physicians are relatively free to select the clinically appropriate treatment option for their patients, although different options are reimbursed differently by the FDSKSH (Compulsory Health Care Insurance Fund) [4].

Success in drug discovery, development and healthcare delivery should also be measured by the level they are affordable to patients as determined by their costs [5]. Economic evaluations provide information on the costs of these expensive treatments to aid the optimal utilization of limited healthcare resources [6]. As this promising class of drugs continues to grow in number and popularity, their lifesaving power will be limited if costs make them inaccessible to patients who need them [7].

The study aims to analyze the market dynamics of these therapies in Albania; determine the reimbursement cost in 2023; evaluate the distribution of patients based on pharmacotherapy options; calculate the average reimbursement cost per patient; estimate the decrease in prices between 2023 and 2024; and examine the prevalence of biosimilars compared to biologics [8-13].

2. MATERIALS AND METHODS

This is a retrospective and observational study based on FDSKSH’s health administrative data for the period between January 1, and December 31, 2023. FDSKSH was utilized for gathering anonymous data on patients (number, age, gender), as well as the number of prescriptions, consumption and prices of biologics and biosimilars. The reimbursement cost per therapy option was calculated at the list price of 2023. Total and average annual costs per patient were retrieved from the database. A Microsoft Excel–based collection form was utilized for storing and manipulating data, calculating, data analysis, charting etc.

3. RESULTS

In 2023, there were 897 patients who received treatment with biologics and biosimilars. The reimbursement cost for 2023 amounted to ALL 186,523,409.9 (as shown in Table 1). The treatment as included in the protocol of FDSKSH is reimbursed at 100% of the cost, whereas if the patient wants to buy an expensive alternative any difference in price between the product and the first alternative with the lowest price is added. The total annual reimbursement cost was ALL 188,208,780 (this value takes into consideration the difference paid by the patients ALL 1685371.44). The average reimbursement cost per patient in 2023 calculated as the total accumulated sum of reimbursement costs divided by the number of patients was ALL 209820.2679.
Table 1. Costs of biologics and biosimilars

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug</th>
<th>Pharmac. form</th>
<th>Reimbursement Cost</th>
<th>No of prescriptions</th>
<th>Patient Cost</th>
<th>Total annual reimbursement Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>662/37</td>
<td>Etanercept 25 mg</td>
<td>pre-filled syringe</td>
<td>1,699,643</td>
<td>35</td>
<td>1,699,643</td>
<td></td>
</tr>
<tr>
<td>663/81</td>
<td>Etanercept 50 mg</td>
<td>pre-filled pen.</td>
<td>24,463,445</td>
<td>270</td>
<td>24,463,445</td>
<td></td>
</tr>
<tr>
<td>663/37</td>
<td>Etanercept 50 mg</td>
<td>pre-filled pen.</td>
<td>41,978,258</td>
<td>467</td>
<td>41,978,258</td>
<td></td>
</tr>
<tr>
<td>663/37a</td>
<td>Etanercept 50 mg</td>
<td>pre-filled syringe</td>
<td>13,645,315</td>
<td>178</td>
<td>13,645,315</td>
<td></td>
</tr>
<tr>
<td>631/56</td>
<td>Infliximab 100 mg</td>
<td>pulvis for inj.</td>
<td>2,798,978</td>
<td>30</td>
<td>642156.06</td>
<td>3,441,134</td>
</tr>
<tr>
<td>664/37</td>
<td>Adalimumab 40mg</td>
<td>pre-filled syringe</td>
<td>6,521,719</td>
<td>122</td>
<td>1043215.38</td>
<td>7,564,934</td>
</tr>
<tr>
<td>664/8</td>
<td>Adalimumab 40mg</td>
<td>pre-filled syringe</td>
<td>20,914,018</td>
<td>375</td>
<td>20,914,018</td>
<td></td>
</tr>
<tr>
<td>664/8a</td>
<td>Adalimumab 40mg</td>
<td>pre-filled pen.</td>
<td>936,749</td>
<td>31</td>
<td>936,749</td>
<td></td>
</tr>
<tr>
<td>760/43</td>
<td>Golimumab 50 mg</td>
<td>pre-filled pen.</td>
<td>25,562,911</td>
<td>159</td>
<td>25,562,911</td>
<td></td>
</tr>
<tr>
<td>752/41</td>
<td>Tocilizumab 162mg/0.9ml</td>
<td>pre-filled syringe</td>
<td>16,005,647</td>
<td>119</td>
<td>16,005,647</td>
<td></td>
</tr>
<tr>
<td>758/2</td>
<td>Secukinumab 150 mg</td>
<td>solu for inj.</td>
<td>31,996,726</td>
<td>308</td>
<td>31,996,726</td>
<td></td>
</tr>
</tbody>
</table>

Biologics and biosimilars, representing only 0.028% of all prescriptions, accounted for ALL 186,523,409 (calculated at an average exchange rate of 0.01 USD to ALL in 2023) or 1.56% of the total drug reimbursement cost in Albania in 2023.

Chart 1 indicates that approximately 1.56% of the drug reimbursement costs under FDSKSH is attributed to the total annual reimbursement cost of biologics and biosimilars, while the remaining 98.43% is attributed to the total annual reimbursement cost of other drugs.

Reimbursement costs for biologics and biosimilars covered by the FDSKSH (without taking into consideration the patient cost) have been consistently decreasing annually since 2021, with a 7.14% reduction in 2023 compared to 2022 (according to Chart 2). The number of patients receiving treatment with biologics and biosimilars was 696 in 2021 and 897 in 2023.

More biosimilar options will drive competition, lower prices, reduce costs and increase patient access. Biosimilars with lower prices are more affordable for patients who need treatment with biologics [14].
In 2023, Table 2 indicates that 87.17% of the patients were treated with Tumor Necrosis Factor (TNF) Inhibitor drugs. The access of patients to different pharmacotherapy options is higher when the reimbursement costs of the treatment options increase.

### Table 2. The distribution of patient by pharmacotherapy option

<table>
<thead>
<tr>
<th>Pharmacotherapy option</th>
<th>Patient (No)</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Necrosis Factor (TNF) inhibitor</td>
<td>782</td>
<td>87.17949</td>
</tr>
<tr>
<td>IL-6(Interleukin-6 receptor antagonist)</td>
<td>36</td>
<td>4.013378</td>
</tr>
<tr>
<td>IL-17A(Interleukin 17A receptor inhibitor)</td>
<td>79</td>
<td>8.807135</td>
</tr>
</tbody>
</table>
The data in Table 3 presents an analysis of the pricing for biologic drugs and biosimilars in use in Albania, as reported on the official FDSKSH website. It is notable that the prices of these drugs in 2024 have decreased significantly compared to those in 2023, leading to anticipated reductions in reimbursement costs. Specifically, the biosimilar drug Etanercept 25 mg experienced the most substantial price reduction at 32.83%. Notably, the biologic drug Secukinumab 150 mg was the most expensive drug in 2023.

The prices of the biologic drug etanercept (Enbrel) were compared between Kosovo, Greece, Italy, and Albania, and it was found that the prices were lower in Albania [15-17]. All costs were converted to 2023 euros for comparison purposes (see Chart 3). Policies about drug pricing could promote lower prices for biosimilars and cost reduction. This difference in prices also provides information about the different levels of reimbursement between countries.

The use of biologics and biosimilars in Albania is shown in Chart 4. Biologics account for 61% of the total annual reimbursement cost, while biosimilars account for 39%. Biosimilars were developed to lower the cost of biologic drugs by promoting competition. Biologics are expensive due to their complexity, development process, administration route, competition, and market demand [18]. Biosimilar drugs are becoming more accessible to patients and their expenditure on reimbursement is increasing [19].

In Albania, are authorized for marketing both biologics and biosimilar but the issue is that in Albania we need regulations that govern the interchangeability/substitutability of biosimilars and the extrapolation of their indications [20-21].
4. LIMITATIONS

Our analysis was limited on costs because FDSKSH did not record any treatment outcomes or effectiveness. Also, this study includes a short period of time and studies in the future for longer periods of time, will have even more significant results. Other future studies comparing the cost-effectiveness (C/E) of biosimilars vs biologics will be important for the relevant healthcare institutions.
5. CONCLUSIONS

In Albania, the prescription of biologics is lower compared to biosimilars, but they are associated with significant costs that impact the overall reimbursement costs.

In 2023, the majority of patients received treatment with tumor necrosis factor (TNF) inhibitor biosimilars such as etanercept, infliximab, adalimumab and golimumab. Biosimilars of interleukin-6 receptor antagonist (tocilizumab) and interleukin-17 receptor antagonist (secukinumab) are not available on the Albanian pharmaceutical market.

The prices of biologics and biosimilars were lower than those in Kosovo, Italy, Greece and will decrease in 2024.

The class of biologic drugs is growing widely in number and variety but their use in Albania will be limited if costs make them inaccessible to patients. Our analyses revealed that the biologic costs are important to understand for optimal management of financial resources. Further studies on costs and effectiveness should be useful for physicians, pharmacoeconomics specialists and policymakers to guide decision-making for biologics and their biosimilars.

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REFERENCES

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