

A Budget Impact Analysis of the introduction of generics Ambrisentan and Tadalafil for the treatment of Pulmonary Arterial Hypertension in Greece

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Introduction and Objectives

The aim of this study was to estimate the potential budget impact from the introduction and uptake of the generic drugs Ambrisentan and Tadalafil for the treatment of Pulmonary Arterial Hypertension (PAH) in Greece.

Methods

A Budget Impact Model (BIM) was developed over a 5-year time horizon. Epidemiological data, clinical inputs and disease management information were obtained from published literature plus expert opinion. Cost parameters included medication costs, patient monitoring, inpatient costs, outpatient visits and adverse events and derived from official pricing and reimbursement lists. Outcomes of the analysis reflected total costs over the study horizon, under two scenarios: "world with" and "world without" the generics Ambrisentan and Tadalafil. Regarding market shares, the penetration of generics Ambrisentan and Tadalafil was illustrated by a forecasted annual increase against originators. A third-party payer perspective was employed.

The analysis was conducted by PAH functional class (Table 1), and the use of resources for each class was estimated. Medications included conventional therapy (namely oxygen therapy, diuretics, calcium channel blockers and Anticoagulation) and specialized therapy (endothelin receptor agonists, prostanoids, phosphodiesterase type 5 inhibitors and guanylate cyclase stimulator). Patient can receive monotherapy of specialized therapy, double combination or triple combination. Patient monitoring included visits to physicians or specialized personnel and a series of monitoring tests, such as electrocardiogram, liver function test, blood test and renal functional test. In addition, the frequency of hospitalization in general wards and in Intensive Care Unit for each class was taken into account, as well as the management of adverse events (headache, respiratory infection, rhinopharyngitis, elevated liver enzymes and lower limb swelling).

Results

The total 5-year costs were estimated EUR 70,708,971 for the scenario "world with" generics Ambrisentan and Tadalafil in the PAH therapy mix and EUR 72,991,812 for the scenario "world without" (Figure 1), representing a decrease of 3.13%. Total saving exceed EUR 2.0 million and reach a maximum of EUR 760,947 at the 5th year, while saving in the first years were lower, since the penetration of generics was lower too. Average savings per patient were calculated at EUR 6,199 (1,240 annually).

In addition, a deterministic sensitivity analysis (DSA) was performed, in which the value of BIM parameter was changed at a time, with the values of the rest parameters remaining constant. The DSA demonstrated that the introduction of generics will bring saving for the third party payer, in any change of parameters (Figure 3).

The contribution of the specialized therapy cost in the total cost for the management of patient with PAH was estimated 83.12%, followed by hospitalization cost. Finally, the model estimated that at an assumed budget of EUR 2 million, opting for generic Ambrisentan or Tadalafil allows 58 (166 vs 108) and 231 (661 vs 430) respectively, more patients to receive treatment, at an annual basis.

Table 1. Patient proportions by PAH functional class

| Patient proportions by PAH functional class | Prevalence |
|---|------------|
| PAH FC NYHA I phase | 8.23% |
| PAH FC NYHA II phase | 42.69% |
| PAH FC NYHA III phase | 38.85% |
| PAH FC NYHA IV phase | 10.23% |

Figure 1. Accumulative cost of each scenario

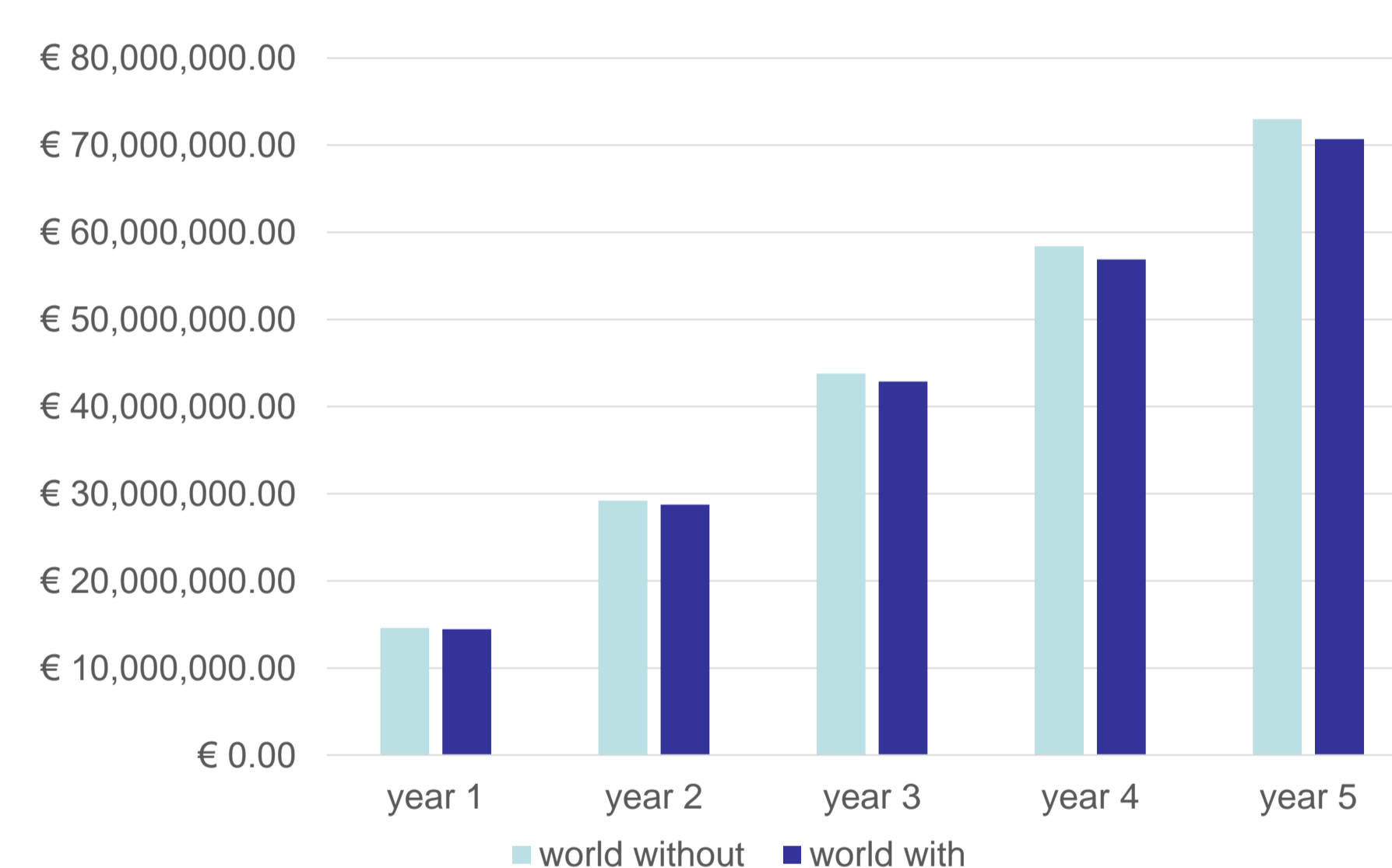


Figure 2. Accumulative savings from the introduction of generics

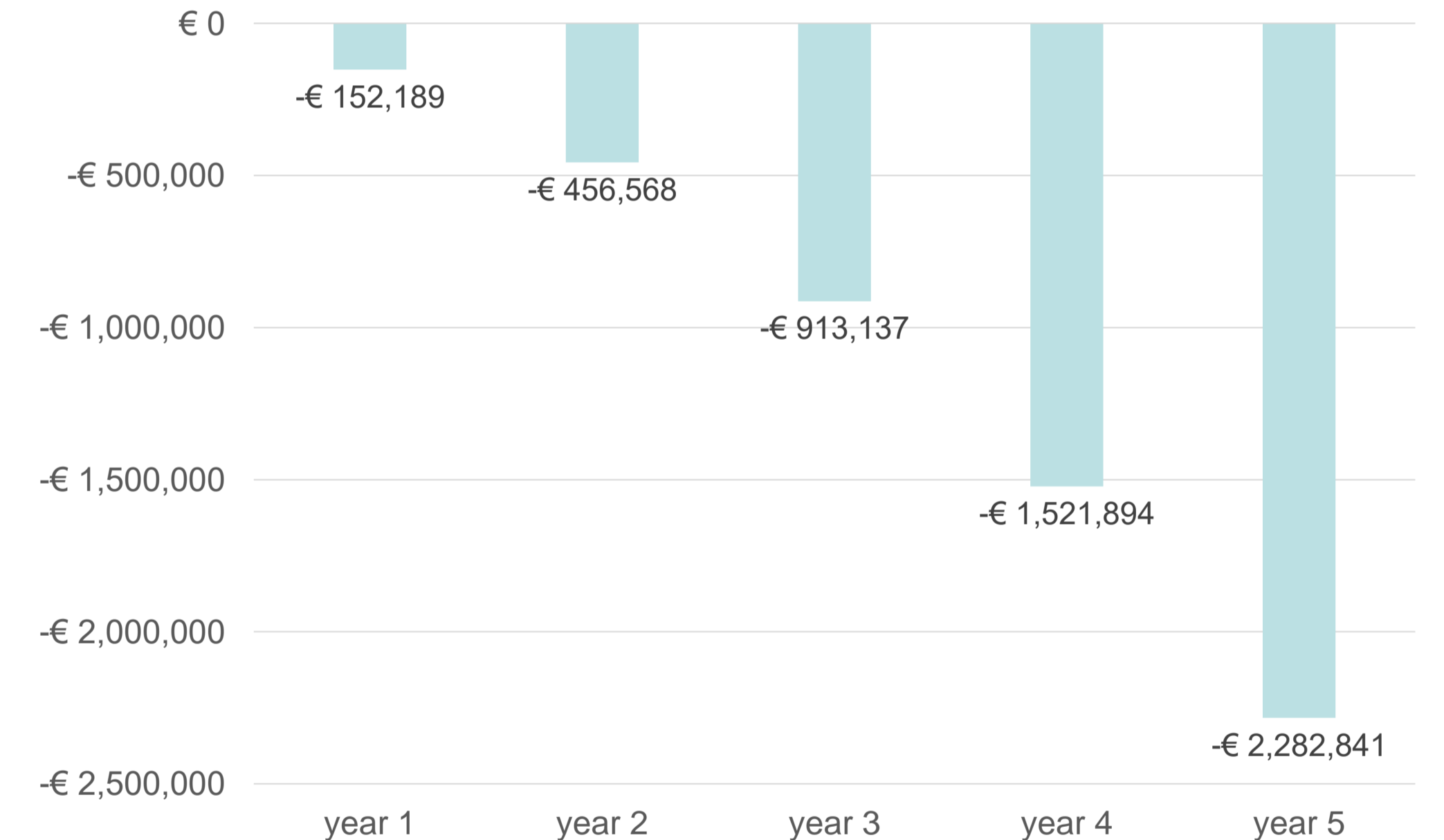


Figure 4. DSA results

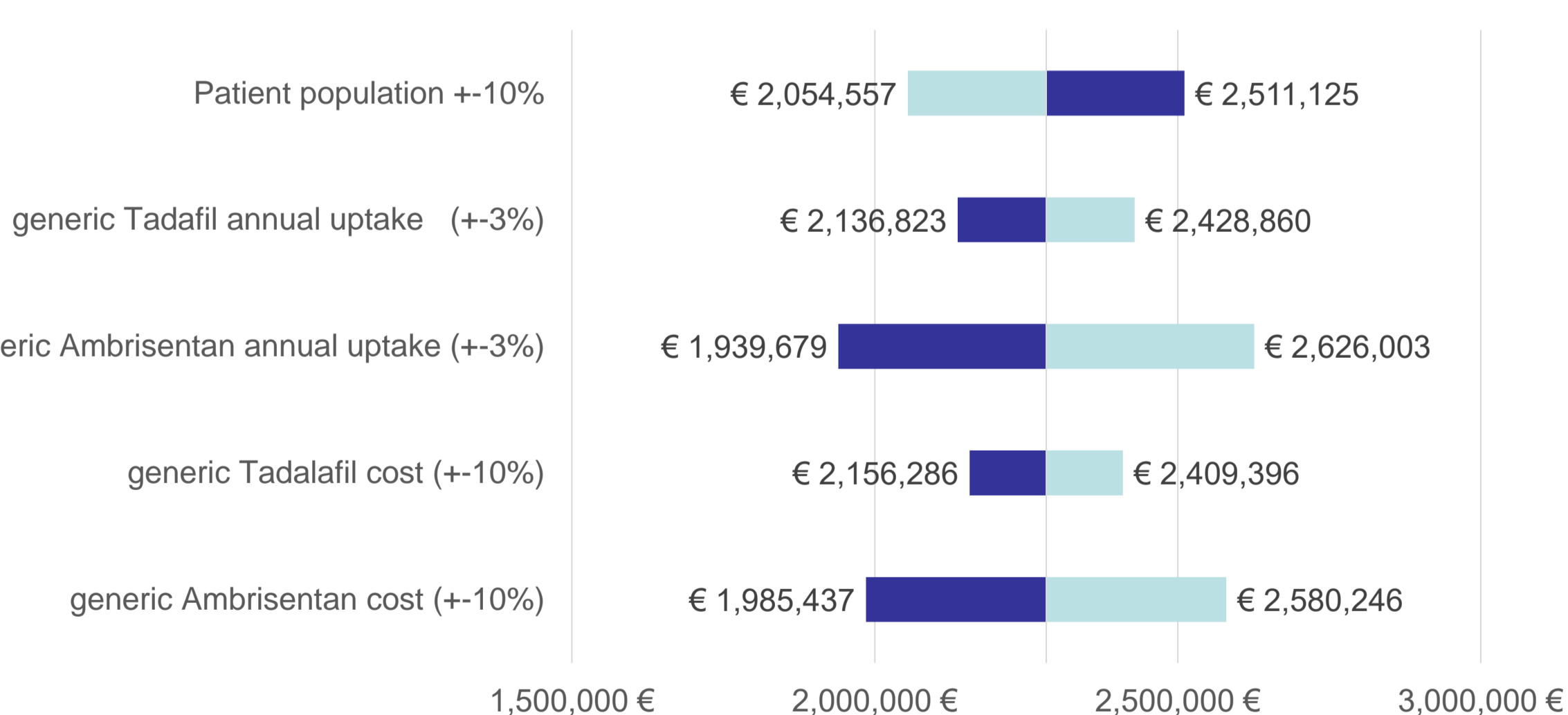
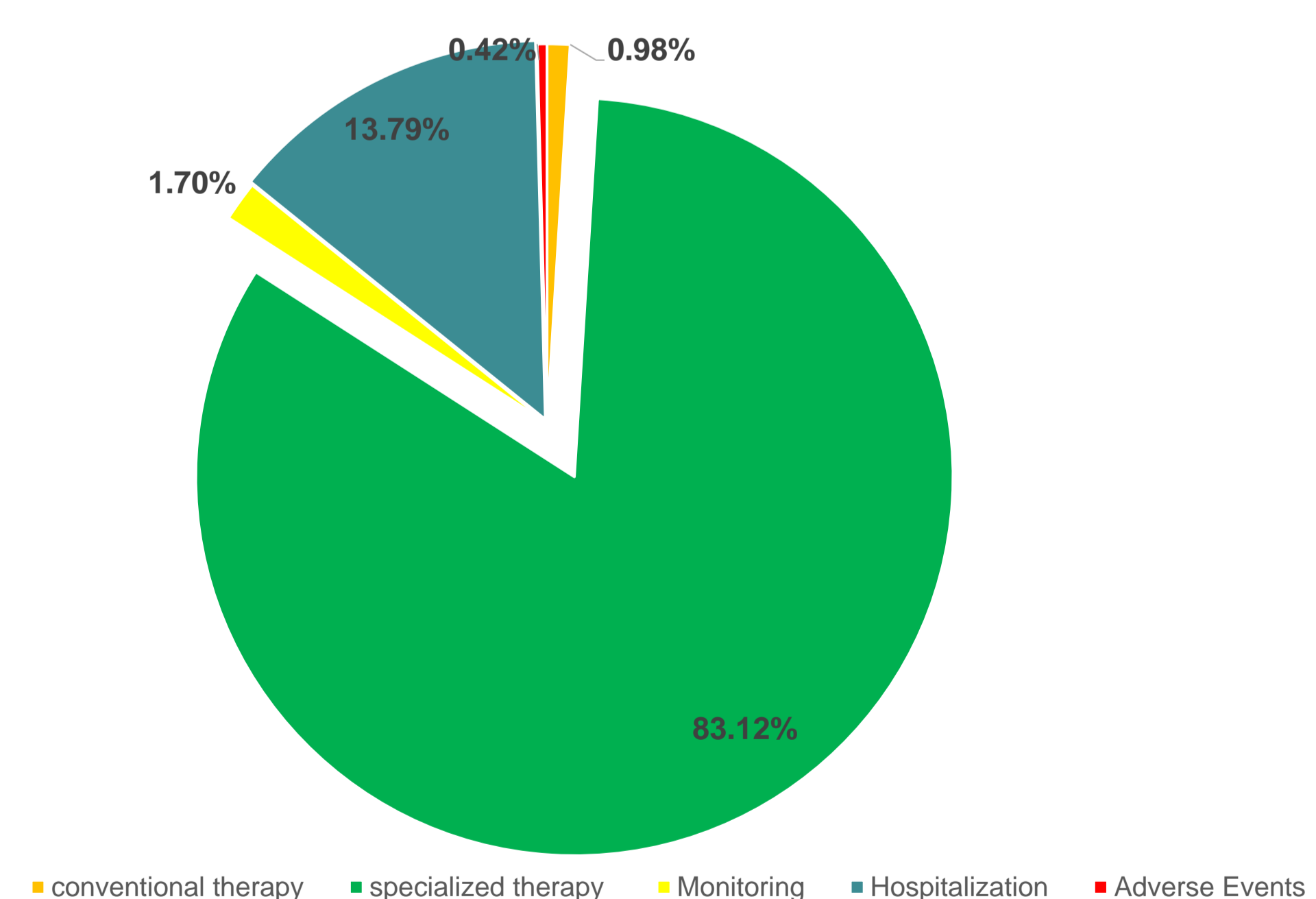


Figure 5. Contribution to total management cost of patients with PAH



Conclusions

The introduction and uptake of the generics Ambrisentan and Tadalafil in the treatment setting of PAH could result in significant budget savings for the Greek healthcare system, demonstrating the importance of the optimal resource allocation in the management of a rare disease. Moreover, the increase of the market share of the generics could lead to savings for the third part payer.

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