

Analysis of the global spending with orphan drugs on the Portuguese National Health Service

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OBJECTIVES

This study aims to analyze the global spending with orphan drugs on the Portuguese National Health Service (NHS) between 2010 and 2015, and forecast the impact of these drugs on the Portuguese budget for the next five years.

METHODS

The global spending with orphan drugs with a Market Authorization was calculated through the analysis of data regarding the consumption of orphan drugs by the Portuguese NHS hospitals between 2010 and 2015 ^[1]. The global spending with orphan drugs for the next five years was estimated through the application of the methodology defined by Schey et al. (2011) ^[2].

RESULTS

In 2010 there were 57 orphan drugs with a Market Authorization, while in 2015 this number increased to 89. This increase occurred, probably, due to European legislation regarding orphan drugs. Between 2010 and 2015, the global spending with orphan drugs (Fig.1) floated between €72.184.094 (2012) and €82.802.658 (2015). The expenditure in this period was significantly influenced by the expenditures with Imatinib, but this medicine was removed from the Community register of orphan drugs in April 2012. An analysis without Imatinib was performed (Fig.1), and showed that the spending with orphan drugs went from €49.945.121 (2010) to €82.802.658 (2015).

The weight of orphan drugs on the total NHS budget (Fig.2) ranged between 6,79% (2015) and 7,95% (2011). Without the expenditures of Imatinib the analysis showed that the weight of orphan drugs on the Portuguese NHS went from 4,98% (2010) to 7,80% (2014) (Fig.2).

Fig.1. Global spending with orphan drugs by the Portuguese NHS hospitals

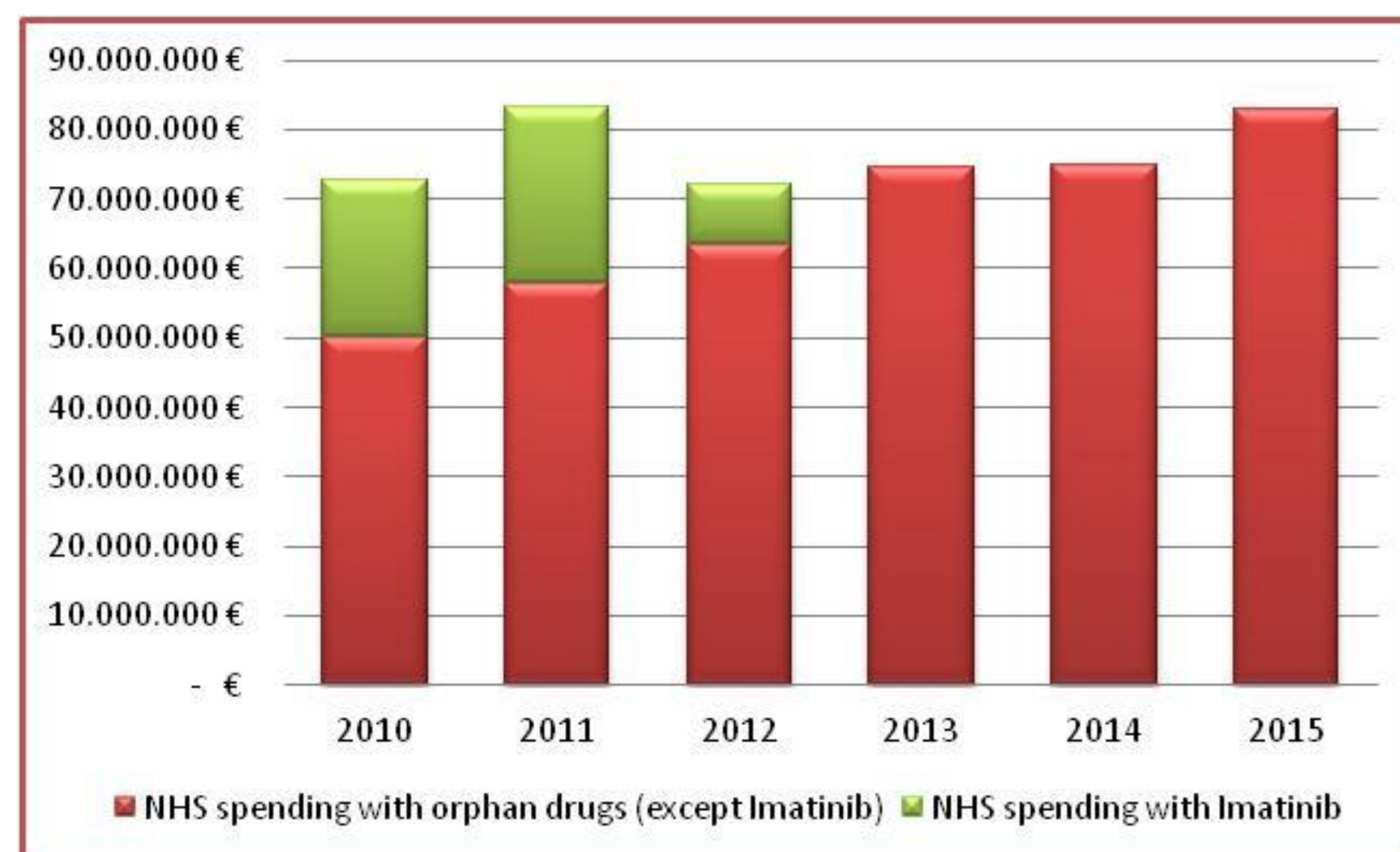
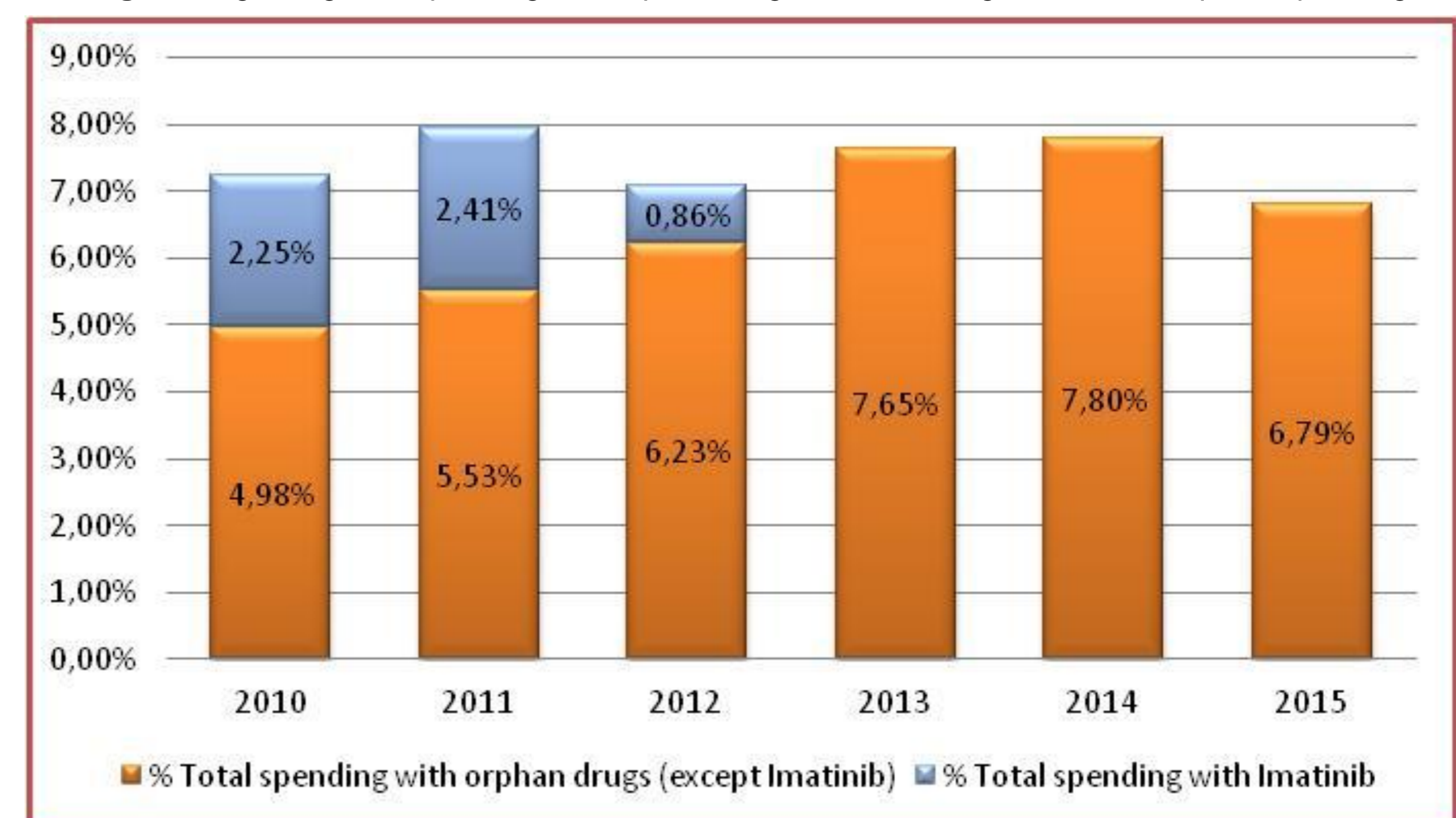


Fig.2. Weight of global spending with orphan drugs on the Portuguese NHS hospitals spending



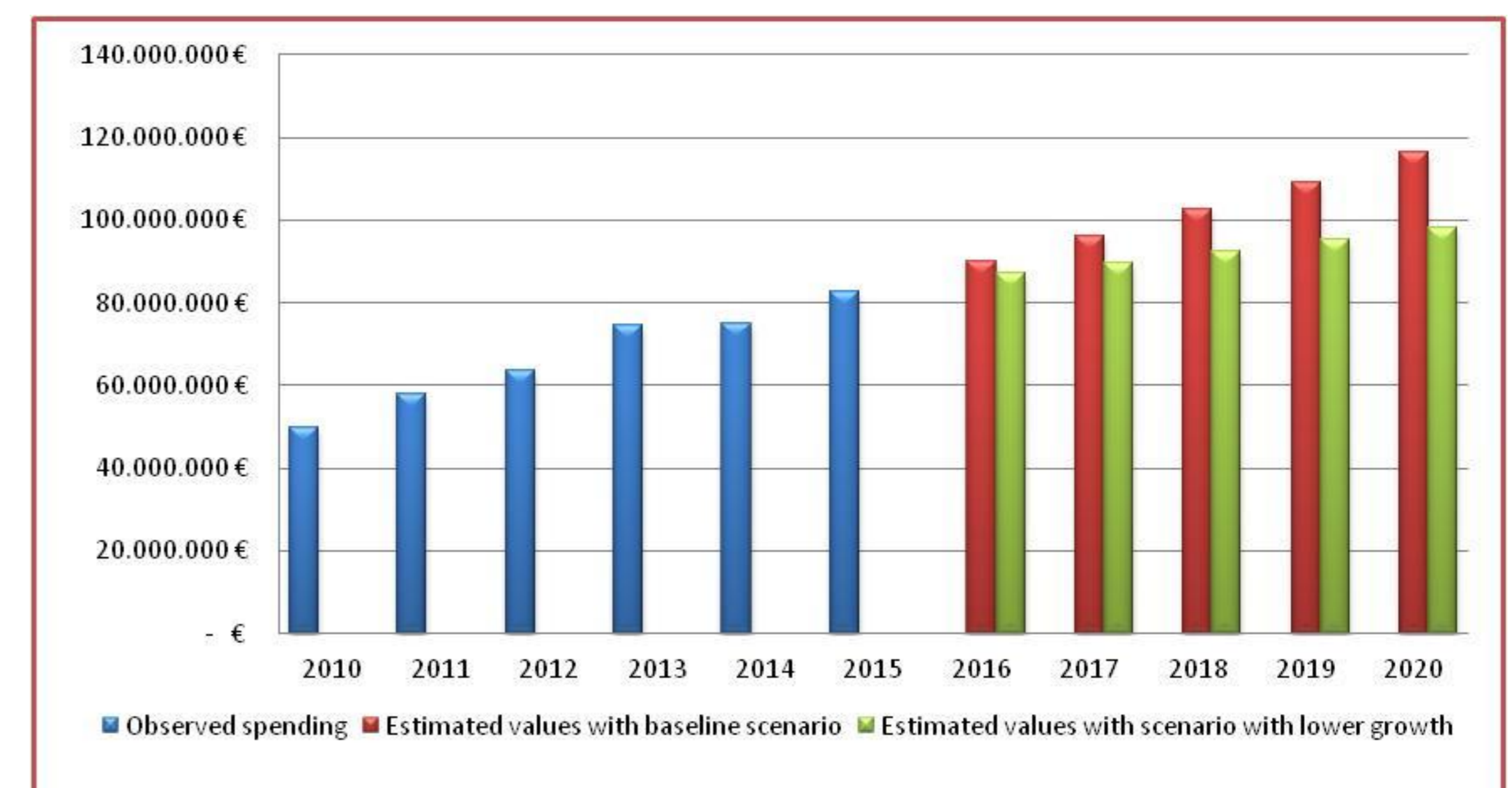
The expenditures with orphan drugs in each administrative region (district) were analyzed and it was clear that, during the period under study, the districts with the highest weight were Lisbon, Porto and Coimbra. Between 2010 and 2012 the hospitals in Lisbon showed the highest spending, however between 2013 and 2015 the highest expenditure came from the hospitals in Porto (Fig.3).

In order to estimate the global spending of orphan drugs for the next five years the study of Schey et al. (2011) ^[2] was analyzed. This study estimated the budget impact of orphan medicines in Europe from 2010 to 2020 and the share of this medicines in the general pharmaceutical market. Therefore, they estimated that the budget impact of orphan drugs would increase from 3,3% in 2010 to a peak of 4,6% in 2016, which represents a growth rate of 39%. These values were compared with the ones observed in Portugal, where the values of 4,98% and 6,79% have been reached in 2010 (without Imatinib) and 2015, respectively, which represents a growth rate of 36%. Assuming a weight of orphan drugs for 2016 of 6,94% (which represents an increase of 39% since 2010) and for the next few years, two estimates were calculated: a) assuming an annual growth rate of 6,6% in pharmaceutical market (baseline scenario); b) assuming a scenario with a lower growth rate (3%) in pharmaceutical market, as in Schey et al. (2011) ^[2]. In the baseline scenario the global spending with orphan drugs by the Portuguese NHS hospitals estimated for 2020 is €116.436.737, and in the scenario with lower growth the global spending with orphan drugs is €98.059.602 (Fig.4).

Fig.3. Weight of Top 3 districts in global spending with orphan drugs by the Portuguese NHS hospitals

		Year					
		2010	2011	2012	2013	2014	2015
District	Coimbra	16%	15%	13%	13%	14%	13%
	Lisbon	33%	34%	35%	35%	32%	34%
	Porto	31%	31%	33%	37%	42%	41%

Fig.4. Predicted global spending with orphan drugs by the Portuguese NHS hospitals



CONCLUSION

The analysis showed the total spending with orphan drugs has increased consecutively during the studied period, if not considered Imatinib. The forecast over the following five years can be affected by changes in: success rate for orphan drugs approvals (Market Authorization) and average cost of orphan drugs. The collection of data carried out through this study will support a more detailed analysis, which will be published in a Master's thesis. The objective is create a dynamic forecasting model that takes into account all orphan drugs designations, approvals (Market Authorization) and the ones that will be removed from the Community register of orphan drugs within the next few years.

REFERENCES

[1] Data available in May 2016 by INFARMED - National Authority of Medicines and Health Products, I.P.

[2] Schey C, Milanova T, Hutchings A. Estimating the budget impact of orphan medicines in Europe: 2010–2020. Orphanet J Rare Dis. 2011; 6:62