The impact of annual price revision based on external reference pricing on medicines between 2012 and 2023, in Portugal

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OBJECTIVES

External Reference Pricing (ERP) is a widely used price regulation tool to control drug costs and can contribute to regulating prices upwards and downwards, involving referencing prices from one or several countries to establish a **benchmark or reference price**[1-4]. In Portugal, the **Annual Price Revision** (APR), based on ERP, has been one of the **key pharmaceutical price regulation** measures implemented since 1990 for the outpatient market (and 2013 for the hospital market)[5]. The system did not allow upward price adjustments, even when price increases occurred in reference countries, nor did accommodate adjustments for inflation or rising production, distribution, and dispensing costs, which could potentially affect the sustainability of pharmaceutical supply chains. In 2023 small increase was allowed in the lowest prices.

- This study aims to **evaluate the impact of the APR on branded medicines** in the **outpatient market** in Portugal, from 2012 to 2023, as there was a major change in regulation of the ERP in 2012 due to the external intervention.

METHODS

- A **retrospective longitudinal study** with time series was conducted using national sell-out data for **branded medicines** subject to the APR between **2012 and 2023**.
- Data was retrieved from **several databases**: sell-out data of a panel of over 82% of community pharmacies and extrapolated to the national level, and the National Official Dictionary database (CITS) with characteristics of medicines, retail prices, and reimbursement levels.
- The impact was based on **two main outcomes**: (i)the annual impact; (ii)the cumulative impact; both analyzed at current and constant 2023 prices (adjusted for inflation)[6].
- The outcomes estimate **the isolated effect of retail price variations** resulting from **changes in the maximum retail price.**
- Additionally, the impact was assessed considering the inclusion of medicines in **Homogeneous Groups (HGs)** - for which generics are available on the market - and according to **payer segmentation**.

RESULTS

- The **annual impact** of APR ranged from a reduction of 128.4 million euros in 2012 (at constant prices) and an increase of 2.7 million euros in 2023 (Figure 1).
- The present value of the total **cumulative impact** of the APR between 2012 and 2023 (sum of the years) amounted to **5,300 million euros**, representing the direct income loss of the pharmaceutical sector (Figure 2).
- The impact was **more significant in innovative medicines** (not included in HGs) and revealed the greatest increase in this segment of innovative medicines, reaching 81.7% in 2023 (Figure3).
- The stratified analysis by payer/financing entity shows that the major effect of APR was observed on the **reduction of public expenditure component** (Figure 4). Overall, the public entities (NHS/RHS) captured 56.9% of the total price reductions.

Figure 1: Impact of Annual Price Revisions (at constant prices)

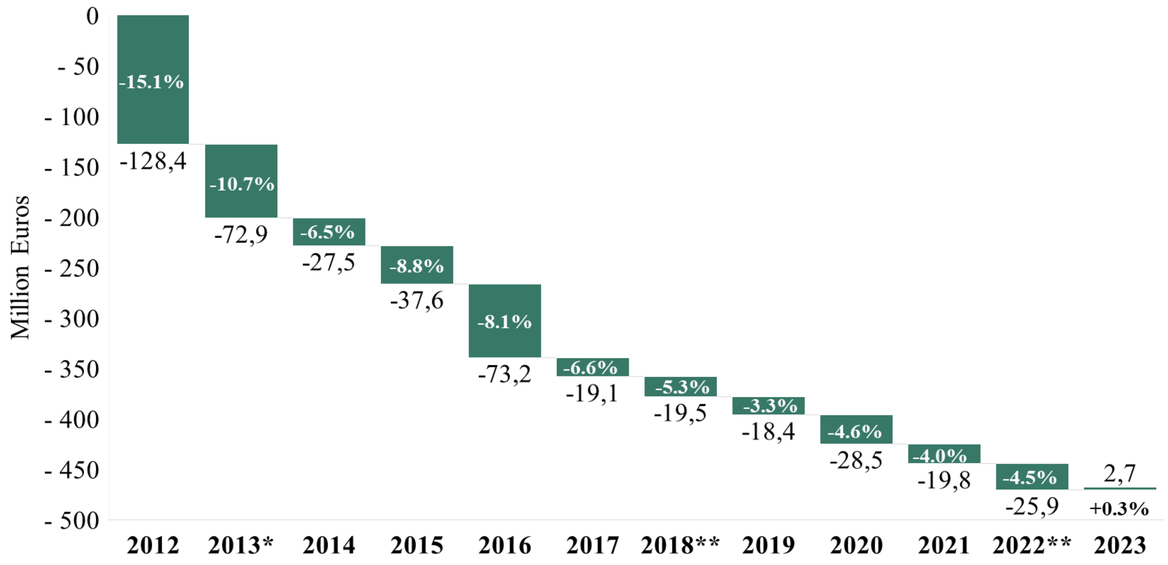


Figure 2: Impact of cumulative Price Revisions (at constant prices), since 2011

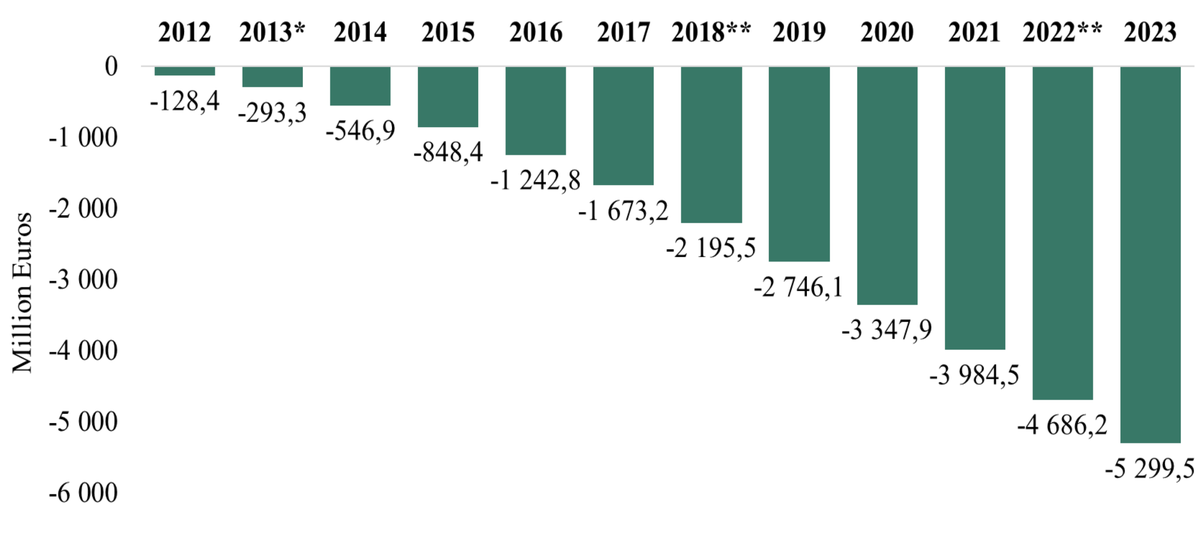


Figure 3: Impact of Annual Price Revision by Homogeneous Groups segmentation

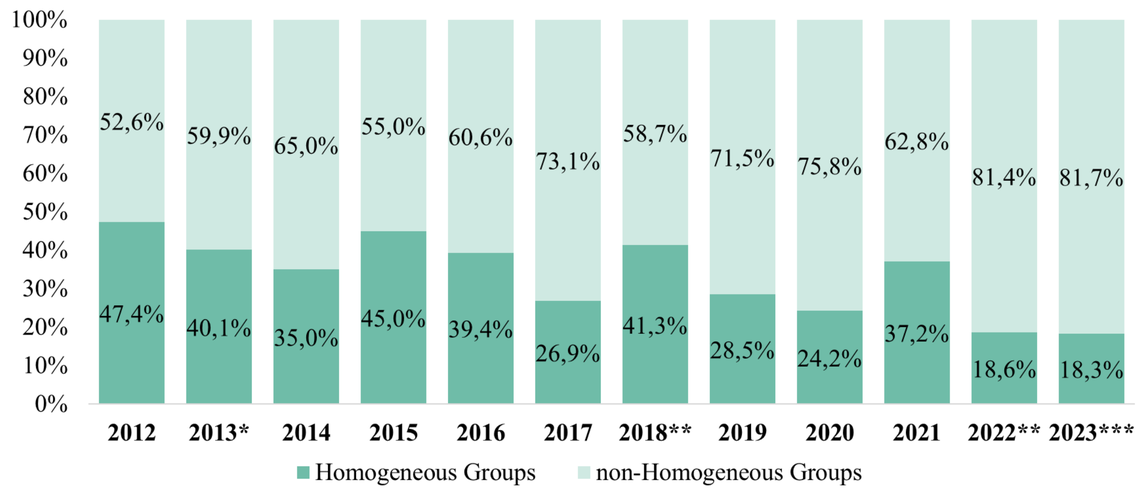
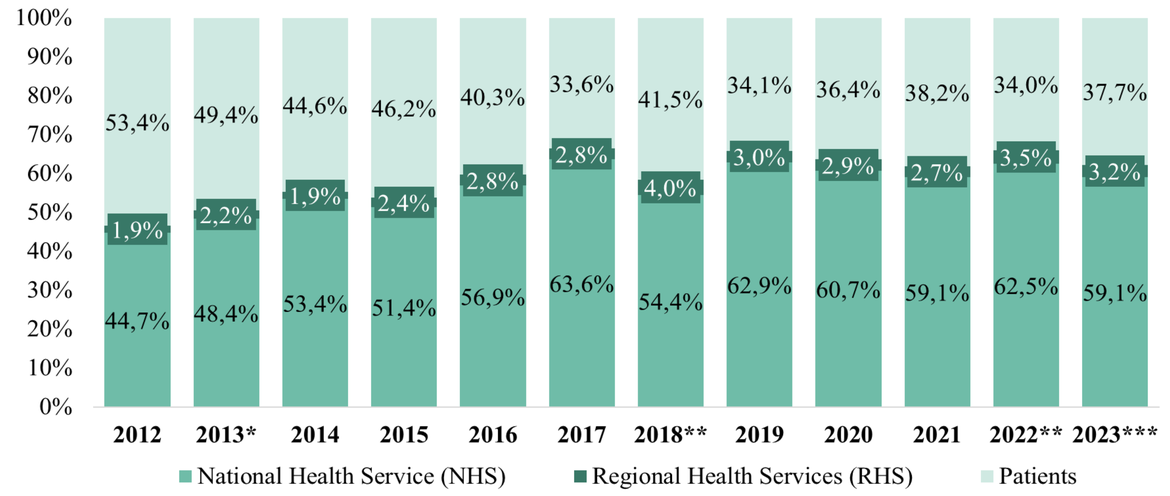


Figure 4: Impact of Annual Price Revision by payer



Note: All figures are computed based on constant prices; the annual duration corresponds to 12 months except: *9 months (2013 period); **13 months (2018 and 2022 period); ***Including only price reductions to allow comparisons

CONCLUSIONS

- Policymakers should carefully consider the **complex trade-offs** when implementing External Referencing Pricing systems, ensuring a balance between benefits and negative effects.
- This study provides a valuable contribution to the **evaluation of price regulation measures based on ERP** and can support decision-making by helping to identify and select specific criteria for future price revisions.

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