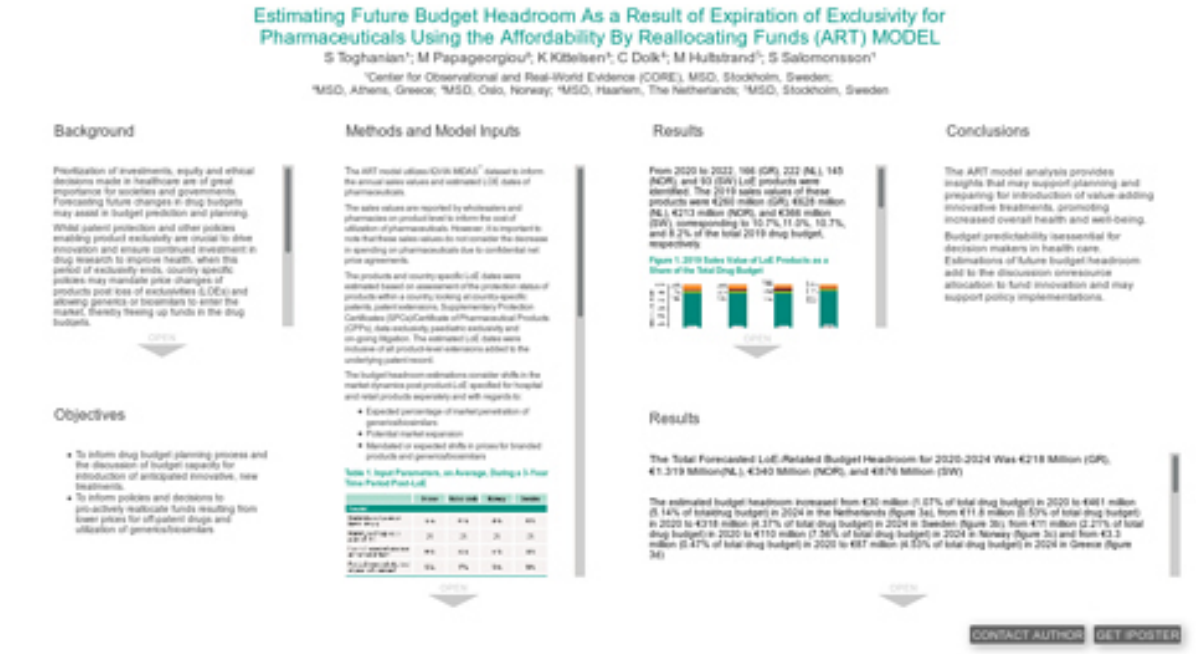
Estimating Future Budget Headroom As a Result of Expiration of Exclusivity for Pharmaceuticals Using the Affordability By Reallocating Funds (ART) MODEL



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PRESENTED AT:

BACKGROUND

Prioritization of investments, equity and ethical decisions made in healthcare are of great importance for societies and governments. Forecasting future changes in drug budgets may assist in budget prediction and planning.

Whilst patent protection and other policies enabling product exclusivity are crucial to drive innovation and ensure continued investment in drug research to improve health, when this period of exclusivity ends, country specific policies may mandate price changes of products post loss of exclusivities (LOEs) and allowing generics or biosimilars to enter the market, thereby freeing up funds in the drug budgets.

The ART model provides a structured analytical framework for estimating future budget headroom resulting from LOEs of drugs, highlighting areas where funds could be available to enable investment in innovation which could potentially lead to increase in overall health gains.

OBJECTIVES

- To inform drug budget planning process and the discussion of budget capacity for introduction of anticipated innovative, new treatments.
- To inform policies and decisions to pro-actively reallocate funds resulting from lower prices for off-patent drugs and utilization of generics/biosimilars

METHODS AND MODEL INPUTS

The ART model utilizes IQVIA MIDAS® dataset to inform the annual sales values and estimated LOE dates of pharmaceuticals.

The sales values are reported by wholesalers and pharmacies on product level to inform the cost of utilization of pharmaceuticals. However, it is important to note that these sales values do not consider the decrease in spending on pharmaceuticals due to confidential net price agreements.

The products and country specific LoE dates were estimated based on assessment of the protection status of products within a country, looking at country-specific patents, patent extensions, Supplementary Protection Certificates (SPCs)/Certificate of Pharmaceutical Products (CPPs), data exclusivity, paediatric exclusivity and on-going litigation. The estimated LoE dates were inclusive of all product-level extensions added to the underlying patent record.

The budget headroom estimations consider shifts in the market dynamics post product-LoE specified for hospital and retail products seperately and with regards to:

- Expected percentage of market penetration of generics/biosimilars
- Potential market expansion
- Mandated or expected shifts in prices for branded products and generics/biosimilars

Table 1. Input Parameters, on Average, During a 3-Year Time Period Post-LoE

	Greece	Netherlands	Norway	Sweden
Hospital				
Market share of generics/ biosimilars (%)	52%	67%	80%	93%
Market growth/expansion post-LoE (%)	0%	0%	0%	0%
Post-LoE expected price level of branded product[a]	90%	53%	54%	38%
Post-LoE expected price level of generics/biosimilars[a]	59%	37%	54%	38%
Retail				
Market share of generics/ biosimilars (%)	40%	67%	80%	93%
Market growth/expansion post-LoE (%)	0%	0%	0%	0%
Post-LoE expected price level of branded product[a]	59%	43%	45%	71%
Post-LoE expected price level of generics/biosimilars[a]	59%	23%	45%	12%

[a]As a % of the branded product's price pre-LoE

Scenario analyses were conducted for Greece, the Netherlands, Norway and Sweden, including products losing exclusivity during the 3-year period from 2020–2022, with a forecast of the resulting budget headroom to 2024. For each country, the analysis spanned all therapeutic areas, and included drugs utilised in both hospital and retail sectors.

The results of the estimated budget headroom are calculated on annual bases as well as cumulatively during 2020-2024 and as share of the annual drug budget during the model time period highlighting the potentials for reallocating funds from off-patent sector to funding innovation leading to a potential increase in overall health gains.

Modeling Considerations and Limitations

The ART model does not consider the budget impact of introduction of new treatments.

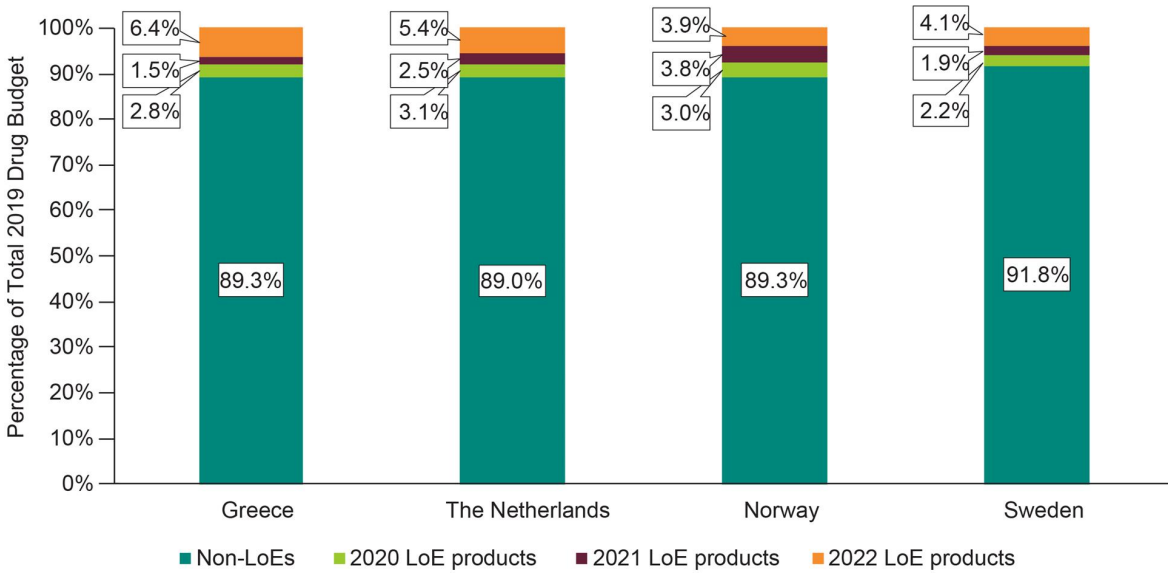
The results of this study provide a conservative estimate of the budget headroom due to several factors:

- The IQVIA MIDAS® dataset does not provide estimates for the LoE date for all products, with the data gap for the four countries varying between 57% and 75% depending on the country. The impact of these data gaps is expected to be limited, since products, for which the LOE date are missing, only account for 18% to 30% of the 2019 total sales value of pharmaceuticals in each country.
- The analysis does not consider the class effect of LoE which may lead to higher estimations of the budget headroom, i.e., the decrease in total sales values of other branded products in the same product class.
- The estimated budget headroom is dependent on the accuracy of the country specific model inputs, which are largely based on expectation informed by observations of historical changes in market dynamics post LOE
- The baseline annual sales values for LoE products are based on the most recent information on the MAT for each product and are not extrapolated to the timepoint of LoE date since this would add additional uncertainty in the calculations.

RESULTS

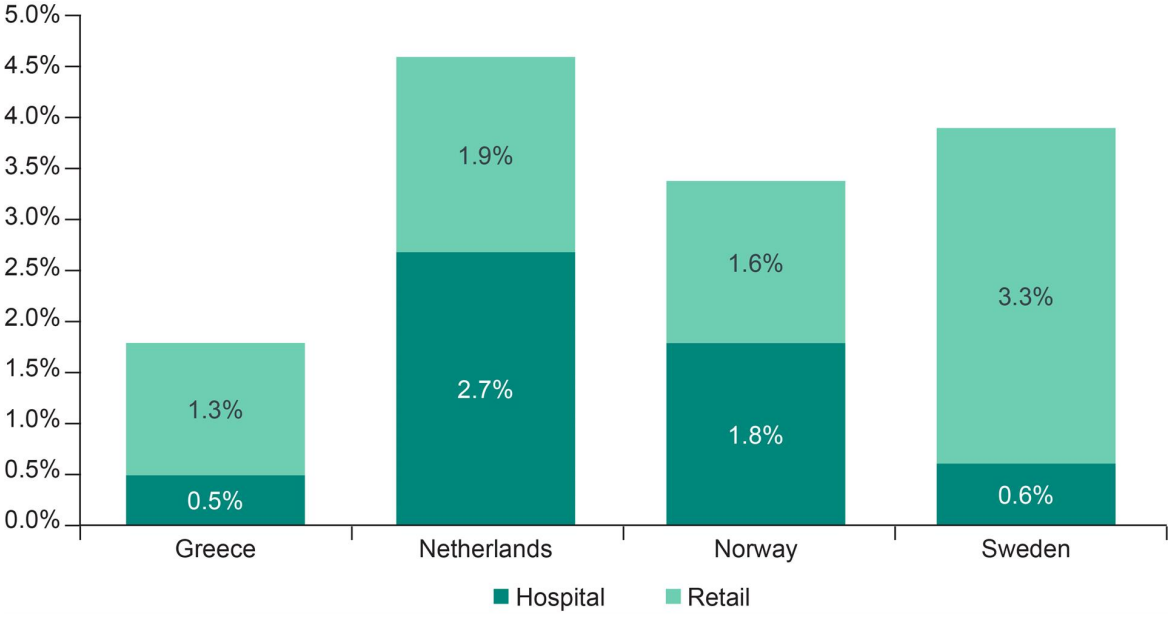
From 2020 to 2022, 166 (GR), 222 (NL), 145 (NOR), and 93 (SW) LoE products were identified. The 2019 sales values of these products were €260 million (GR), €628 million (NL), €213 million (NOR), and €366 million (SW), corresponding to 10.7%,11.0%, 10.7%, and 8.2% of the total 2019 drug budget, respectively.

Figure 1. 2019 Sales Value of LoE Products as a Share of the Total Drug Budget



The average budget headroom per year from 2020 to 2024 is estimated at €44 million (GR), €264 million (NL), €68 million(NOR), and €175 million (SW), corresponding to 1.8%, 4.6%, 3.4%, and 3.9% of the total annual drug budget in each country.

Figure 2. Estimatated Average Budget Headroom per Year as Share of Annual Drug Budget During 2020-2024 byCountry and Hospital/Retail Sector



CONCLUSIONS

The ART model analysis provides insights that may support planning and preparing for introduction of value-adding innovative treatments, promoting increased overall health and well-being.

Budget predictability is essential for decision makers in health care. Estimations of future budget headroom add to the discussion on resource allocation to fund innovation and may support policy implementations.

RESULTS

The Total Forecasted LoE-Related Budget Headroom for 2020-2024 Was €218 Million (GR), €1.319 Million(NL), €340 Million (NOR), and €876 Million (SW)

The estimated budget headroom increased from €30 million (1.07% of total drug budget) in 2020 to €461 million (5.14% of totaldrug budget) in 2024 in the Netherlands (figure 3a), from €11.8 million (0.53% of total drug budget) in 2020 to €318 million (4.37% of total drug budget) in 2024 in Sweden (figure 3b), from €11 million (2.21% of total drug budget) in 2020 to €110 million (7.56% of total drug budget) in 2024 in Norway (figure 3c) and from €3.3 million (0.47% of total drug budget) in 2020 to €87 million (4.53% of total drug budget) in 2024 in Greece (figure 3d)

Figure 3a. Estimated Budget Headroom per Year 2020-2024 (million euro) – The Netherlands

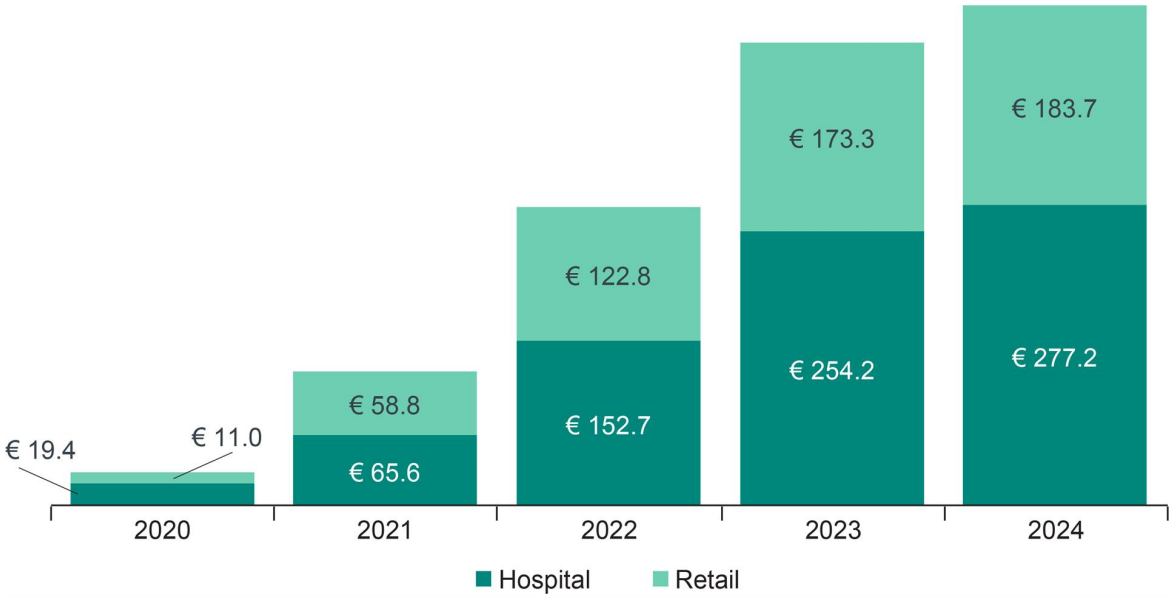


Figure 3b. Estimated Budget Headroom per Year 2020-2024 (million euro) – Sweden

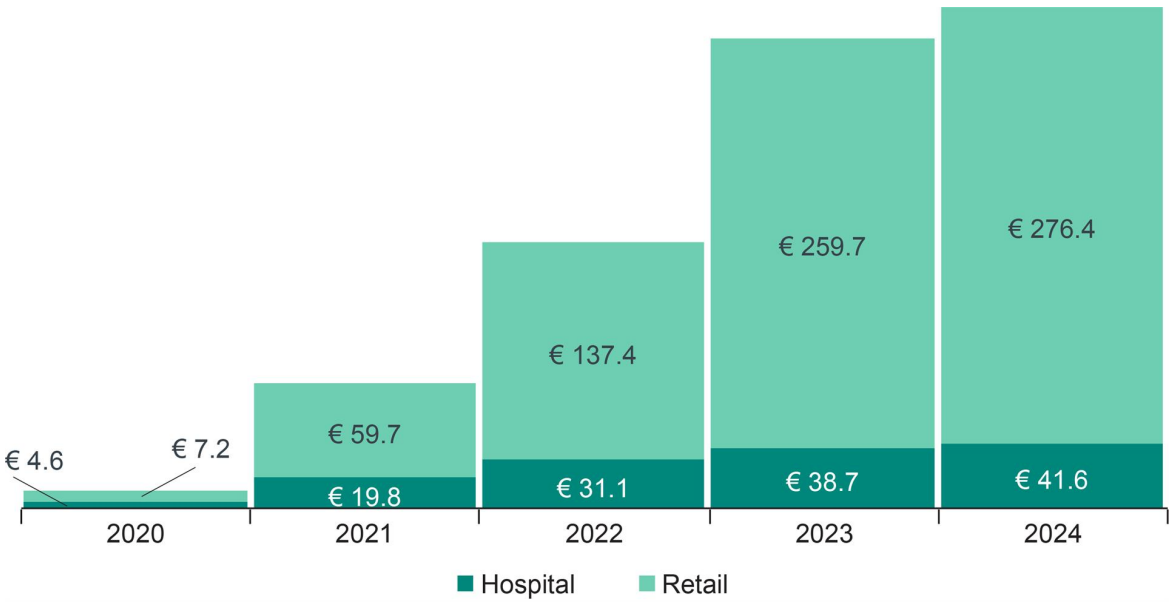


Figure 3c. Estimated Budget Headroom per Year 2020-2024 (million euro) – Norway

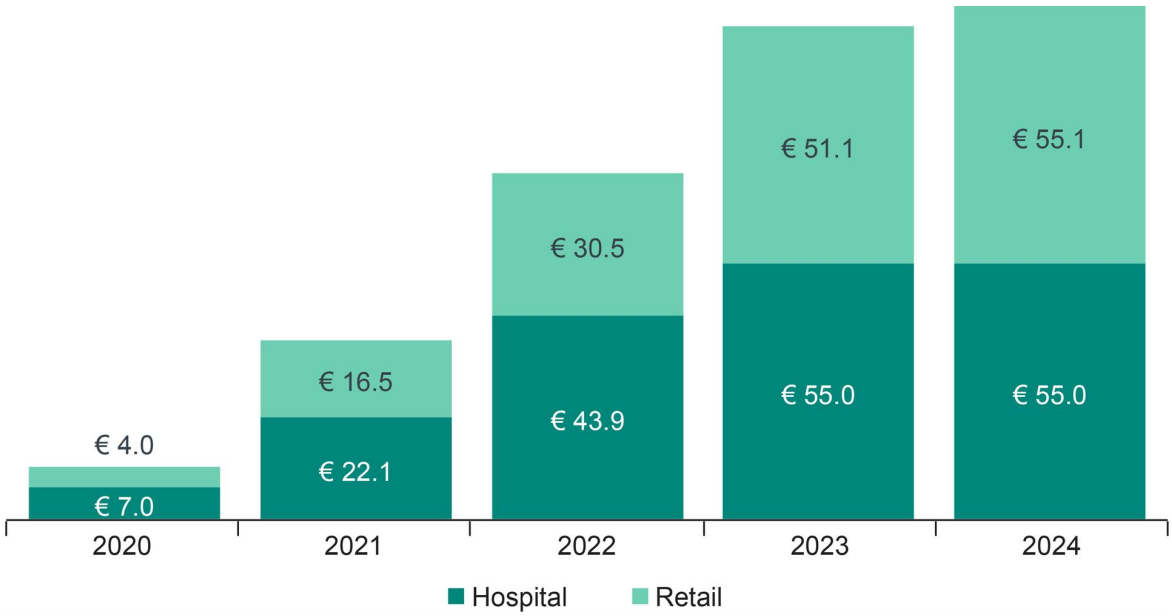
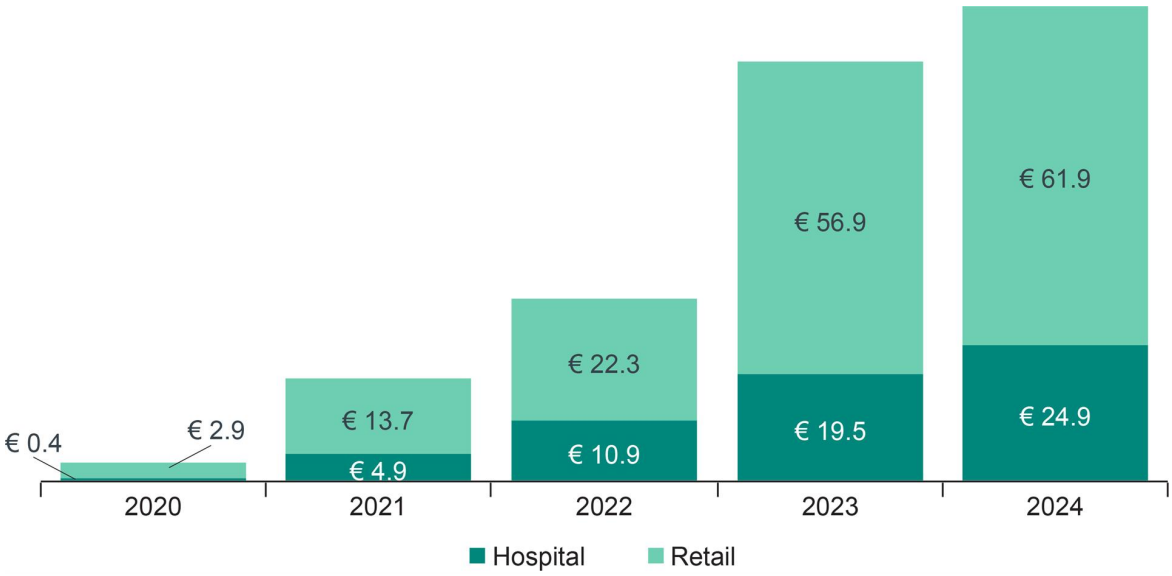


Figure 3d. Estimated Budget Headroom per Year 2020-2024 (million euro) – Greece



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