

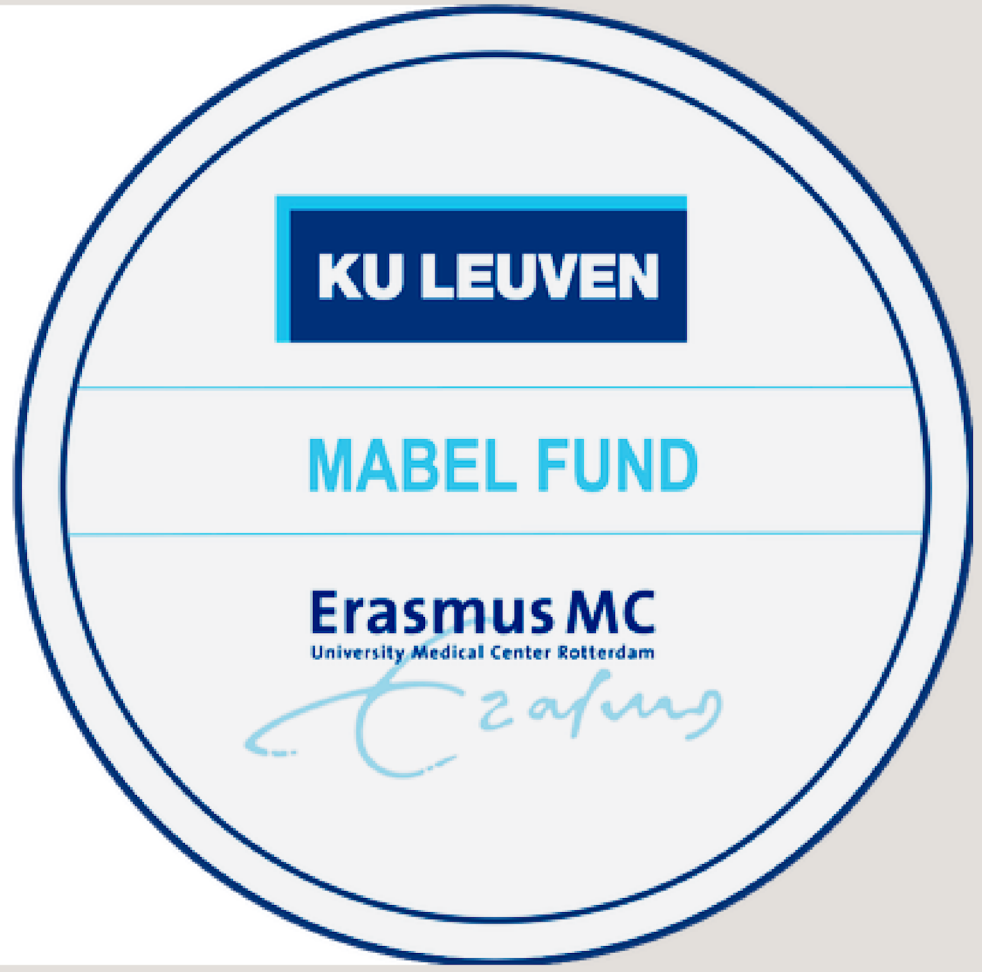
TNF-ALFA INHIBITOR THERAPIES:

Evaluating the Impact of Biosimilars Competition in Italy, Portugal and Spain

AUTHORS - HPR52

Barcina Lacosta, T¹
Vulto, AG^{1,2}
Huys, I¹
Simoens, S¹

1. KU Leuven (Belgium)
2. Erasmus University Medical Center (The Netherlands)



1. BACKGROUND

> **Biosimilars market entry** represents a cost-reduction opportunity.

> To seize this **cost-reduction opportunity** in the long term, it is needed to ensure a **sustainable competitive environment** for all market players.

BUT...

> The **level of competition generated by biosimilars varies** by country, care setting and molecule. Consequently, biosimilars contribution to attaining price reductions and increased access has varied.

2. OBJECTIVES

> **To capture market dynamics for TNF-alfa inhibitors and competing molecules in Southern European markets (2011-2020)**

> **To evaluate the benefits of the competition generated by the availability of biosimilars.**

5. LEARNINGS

> The availability of TNF-alfa inhibitor biosimilars in Southern-European markets led to **lowered NHS costs** within the drug class, **even after the increased utilisation of these therapies.**

BUT...

> The potential of marketed TNF-alfa inhibitor biosimilars to generate price competition outside their drug class has been limited.

> This limitation becomes especially relevant in the context of **observed drug utilisation shifts towards on-patent and higher-cost therapies**, even after loss of exclusivities for Remicade, Enbrel and Humira.



There is a need for strategies that support a level playing field between originator biologics and biosimilars, and that extend the benefits of biosimilar competition to the on-patent segment.

3. METHODS - Market Data Analysis

This study is based on a **literature review** examining market characteristics for TNF-alfa inhibitors and competing immunomodulators, and on the **quantitative analysis of market data** (consumption volume and NHS costs) for these molecules in Italy, Portugal and Spain.

Inclusion of molecules in the analysis: n=16; adalimumab, abatacept, anakinra, apremilast, baricitinib, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, rituximab, secukinumab, tocilizumab, tofacitinib, ustekinumab, vedolizumab

Data provision: Infarmed, Reuma.pt (Portugal); Spanish MoH Department of Pharmaceuticals and Health Products; Osmed (Italy)

EVOLUTION OF CONSUMPTION VOLUMES

Market growth (fold change in consumption volume) | 2017-2020

Shifts in prescribing within the TNF-alfa inh. class (market composition expressed as a share (%) of the total volume of TNF-alfa inhibitors) | 2011-2020

Prescribing shifts in rheumatology: The case of Portugal

> Evolution in No. of patients receiving each molecule (expressed as a share (%) of the total volume of patients treated with biologics) | 2011-2017

INTERPLAY OF VOLUME AND COST EVOLUTIONS

Yearly percent units change in costs in relation to yearly percent units change in consumption volume | 2018-2020

4. RESULTS - Impact of biosimilars availability on volume trends

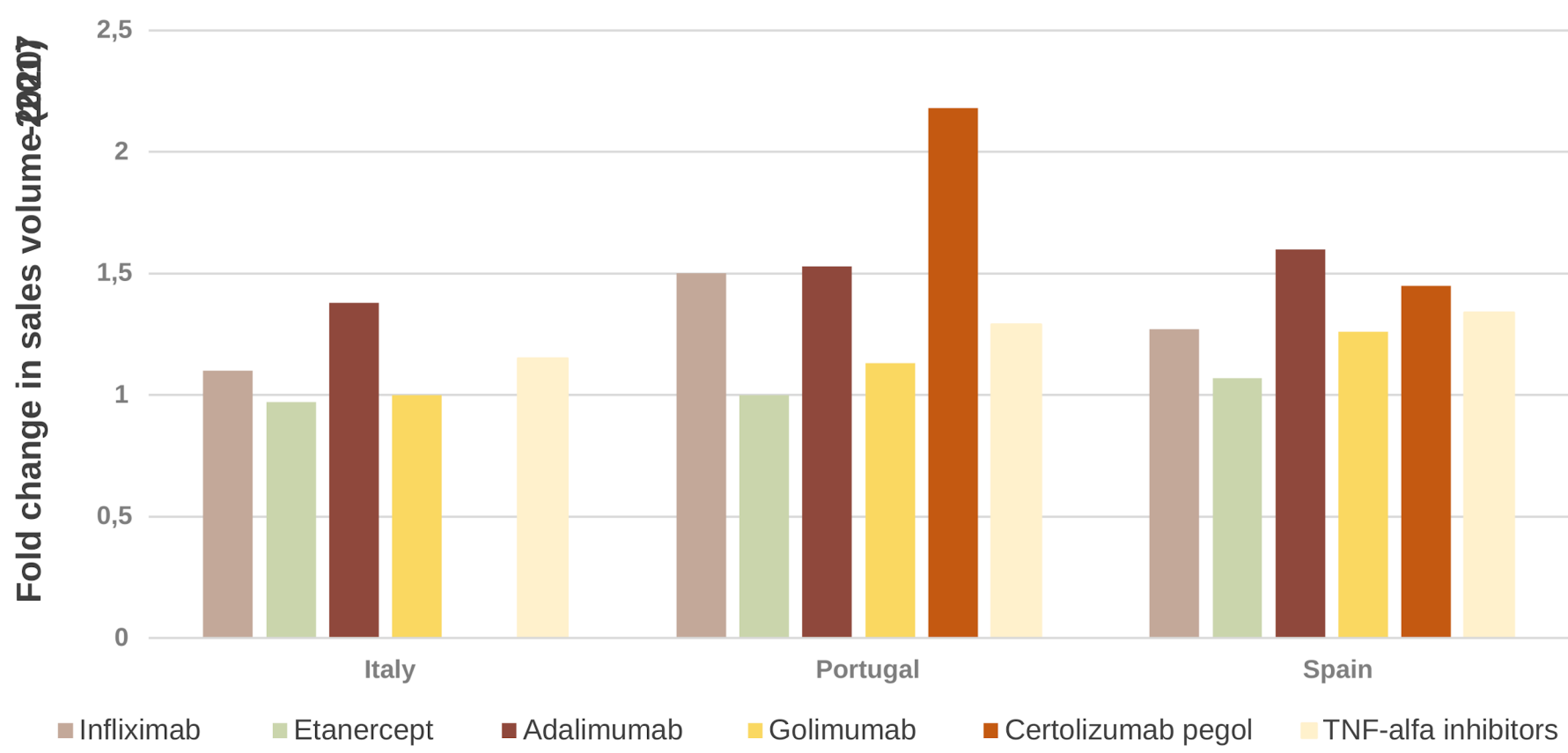


Figure 1

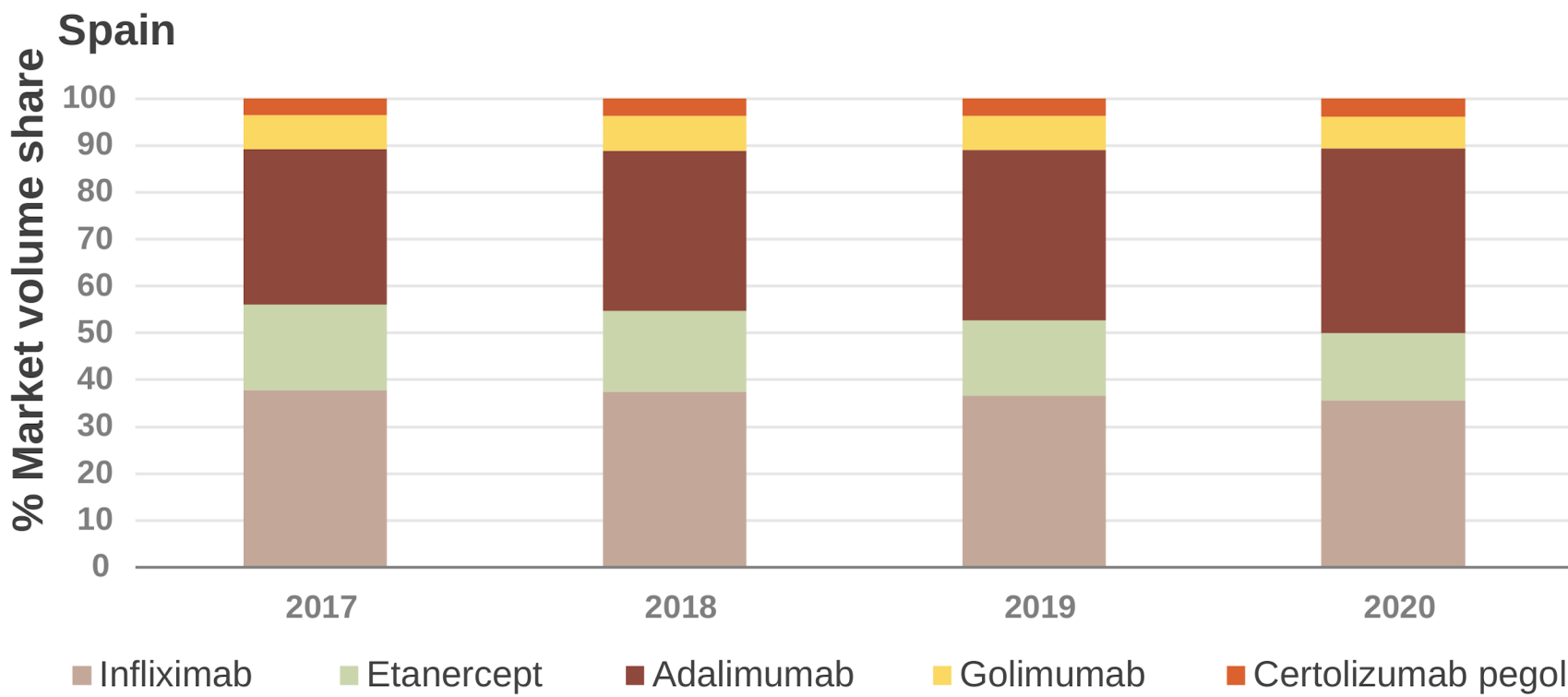
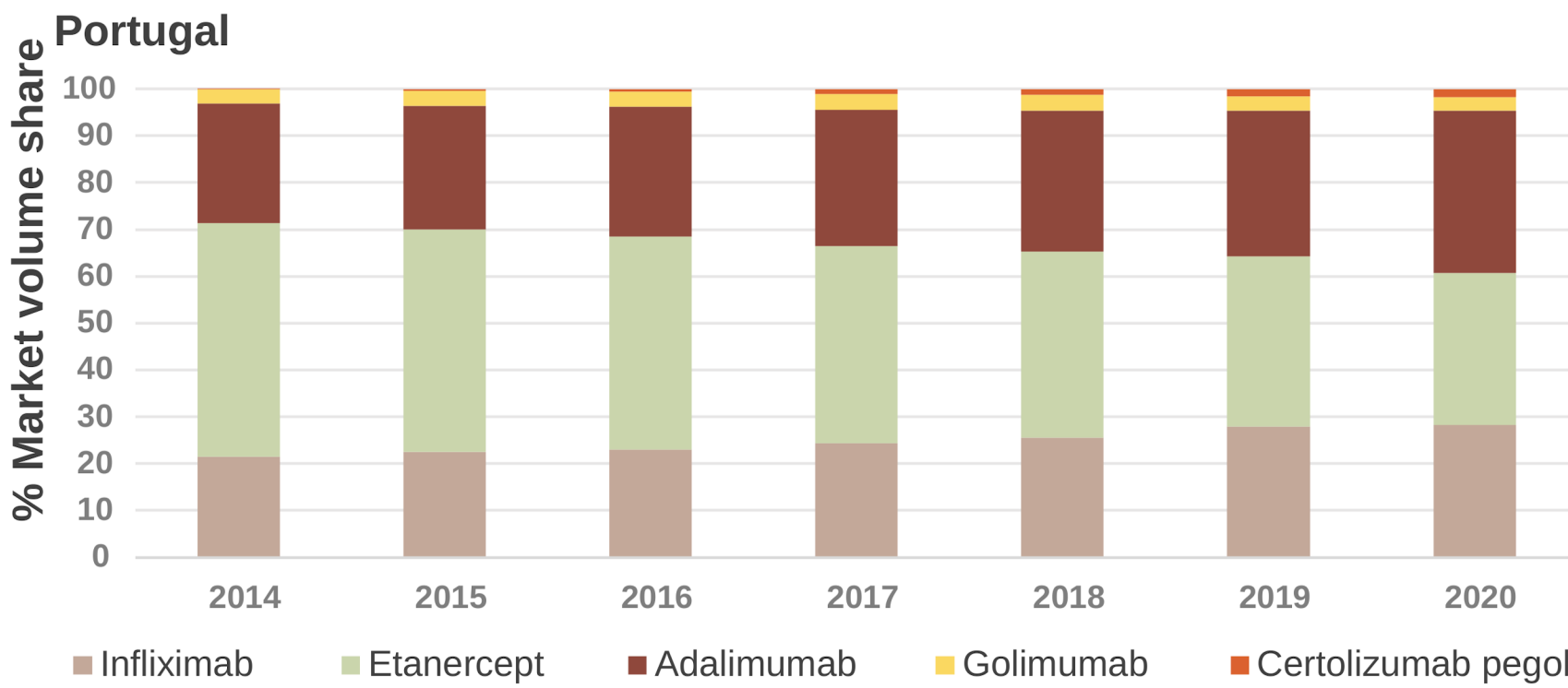
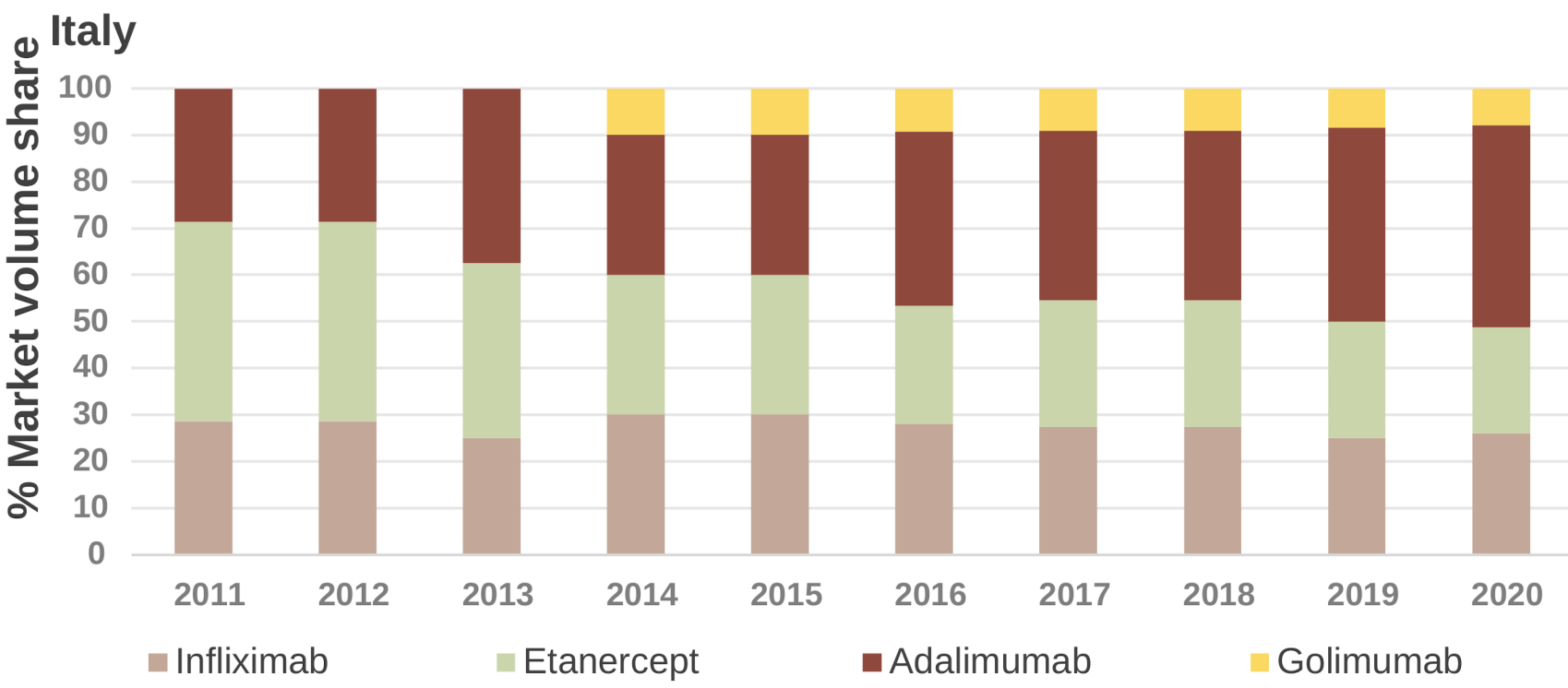


Figure 2

4. PORTUGAL - Prescribing shifts

PsA

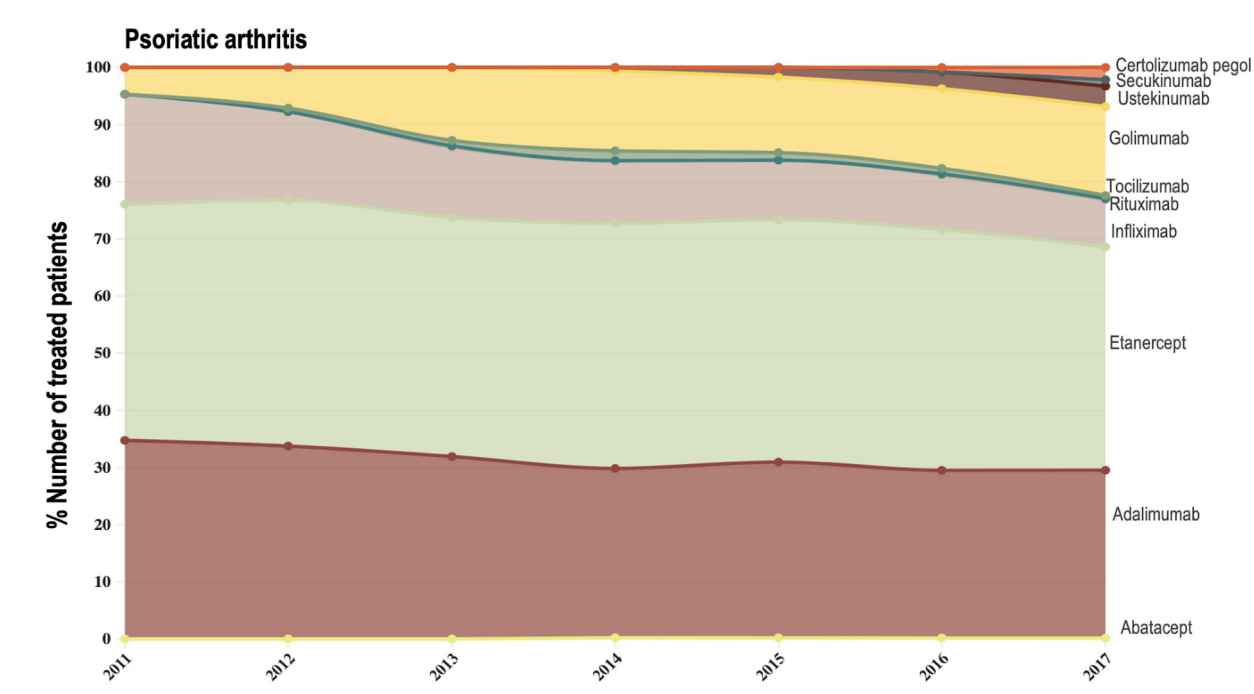


Figure 3a

AS

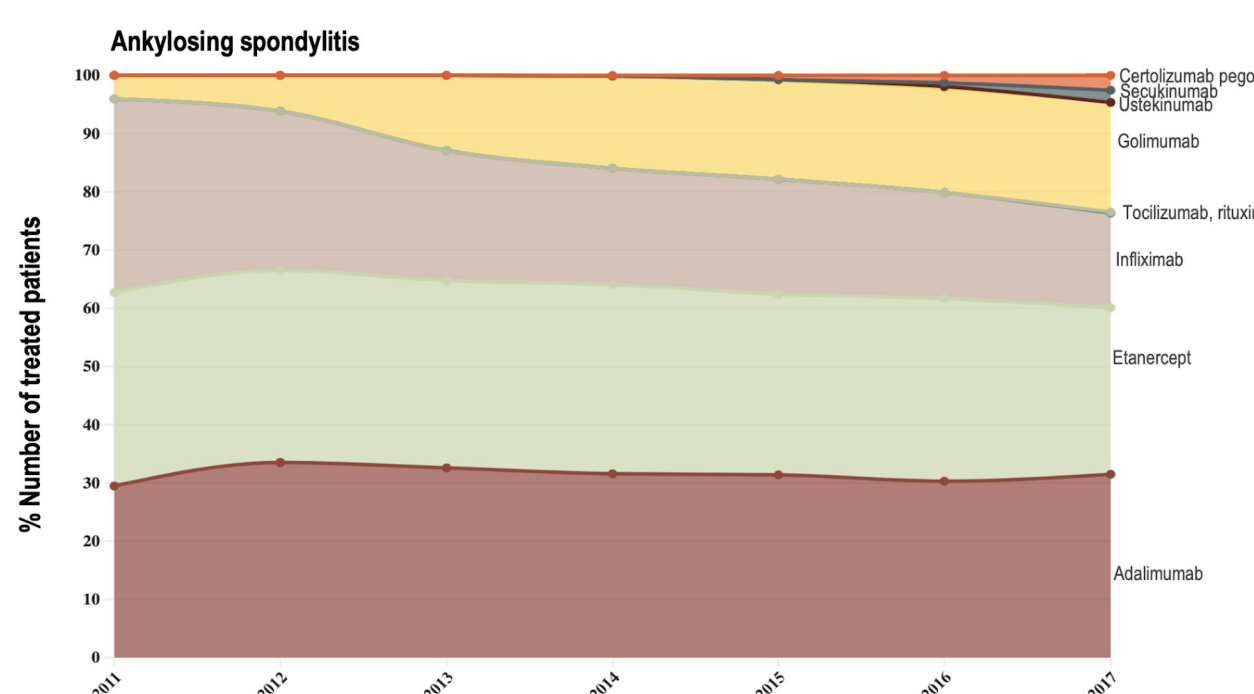


Figure 3b

RA

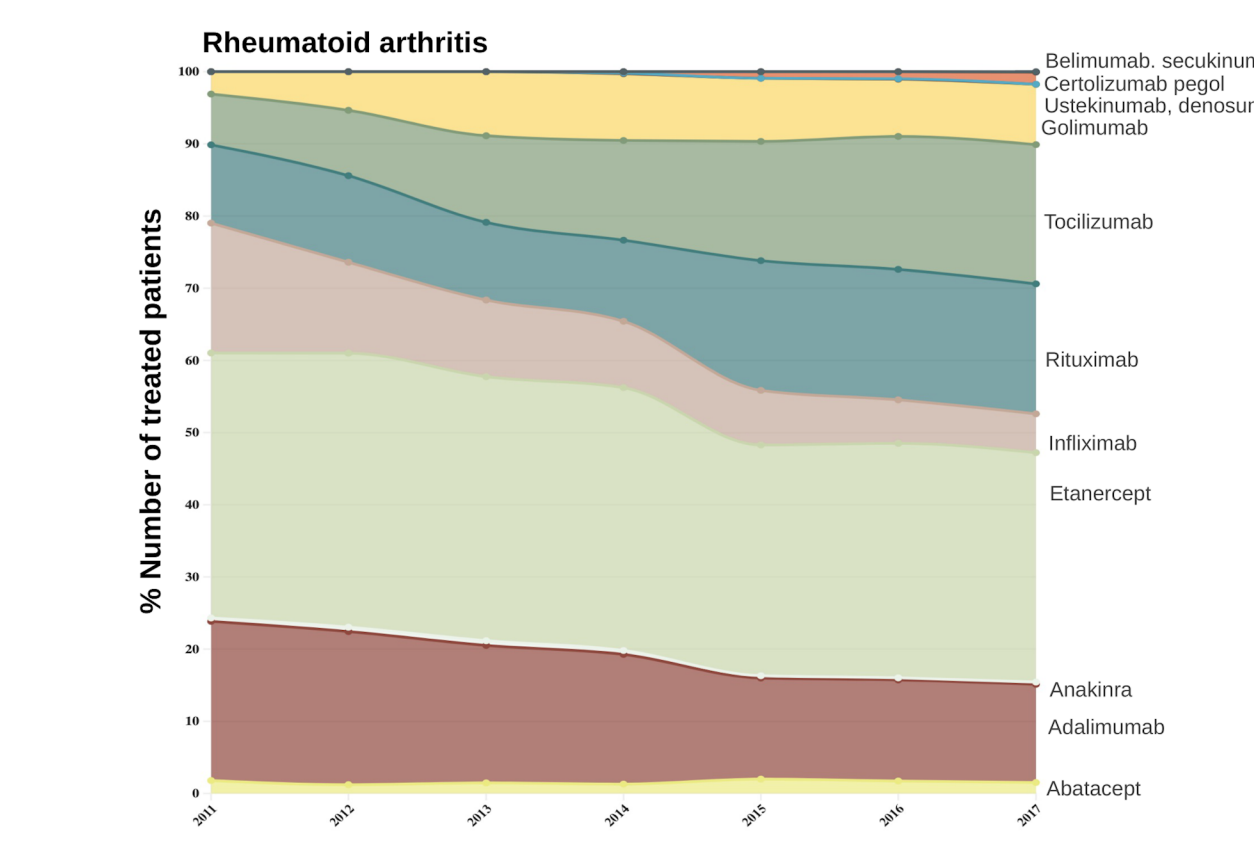


Figure 3c

4. RESULTS - Interplay of volume and cost evolutions

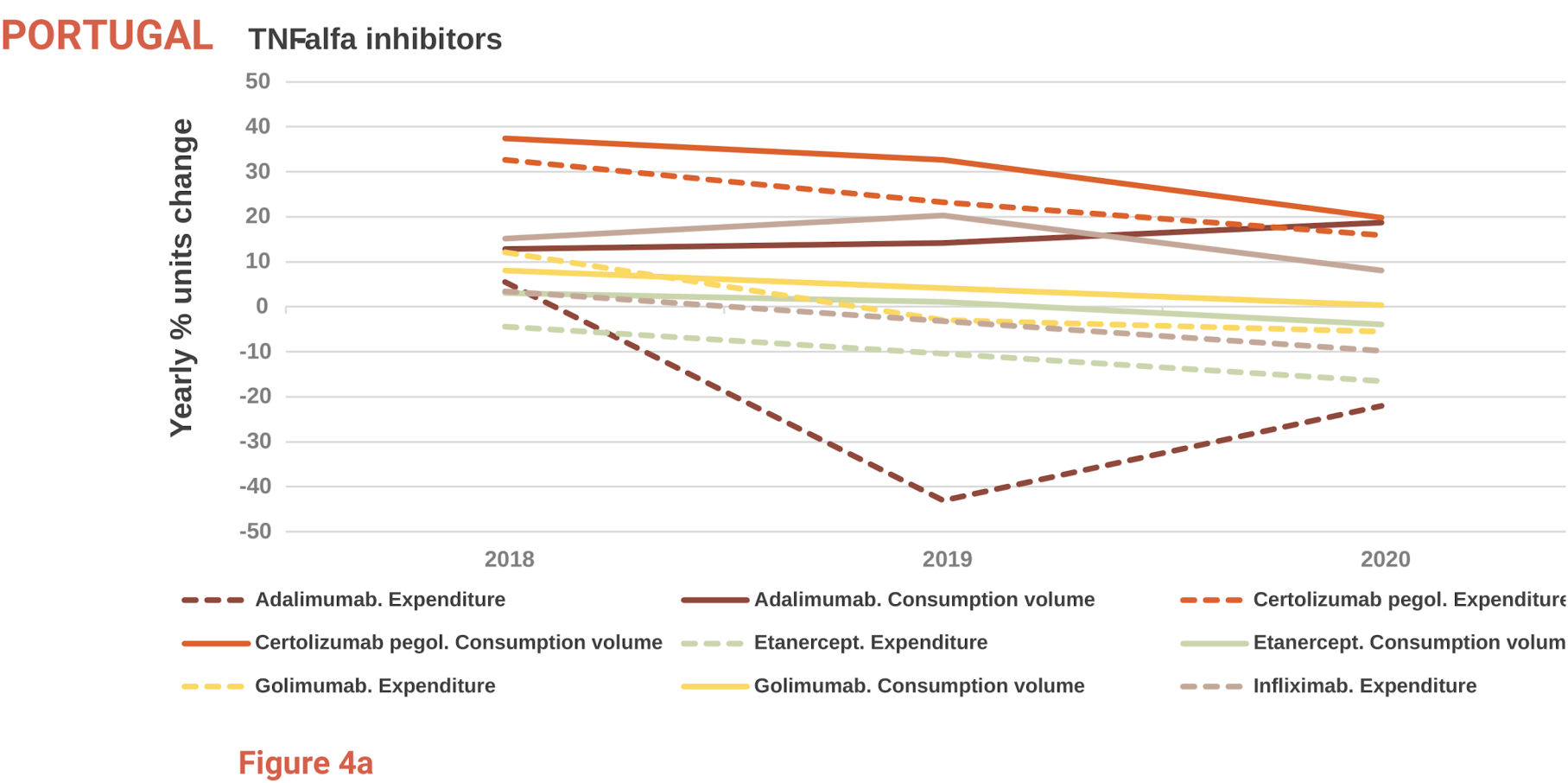


Figure 4a

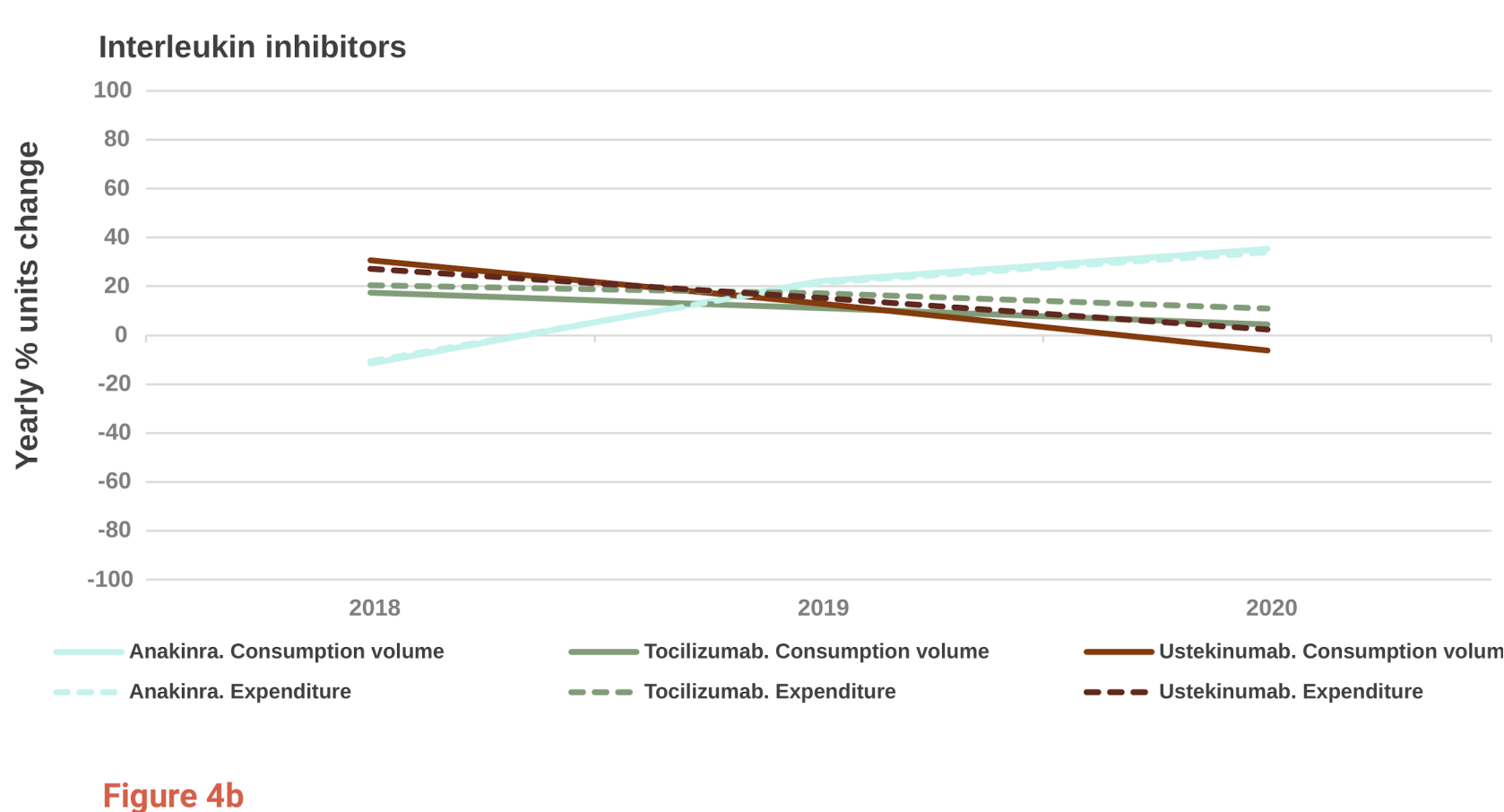


Figure 4b

> Following biosimilars availability, **NHS costs for adalimumab and infliximab in the countries of study were lower than in previous years**, even after the increased utilisation of these molecules. Biosimilars potential to generate competition outside their own drug class appeared limited.

6. REFERENCES

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7. CONTACT

Teresa Barcina Lacosta
e-mail: teresa.barcina@kuleuven.be

