TNF-ALFA INHIBITOR BIOSIMILARS:

Exploring Uptake Determinants in Southern European Hospital Markets

AUTHORS - HPR144

Barcina Lacosta, T[1]
Vulto, AG[1,2]
Huys, I[1]
Simoens, S[1]

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

KU LEUVEN
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1. OBJECTIVES

> Diverse policies and information campaigns have been launched in Italy, Portugal and Spain to support the adoption of TNF-alfa inhibitor biosimilars. Despite these measures, **intra-country biosimilars uptake heterogeneity is wide**, and **biosimilars utilisation** in certain regions is considerably **below the European average.**

> The aim of this study is to identify biosimilar uptake determinants in hospital environments in Italy, Portugal and Spain, using the class of TNF-alfa inhibitors as an example.

2. METHODS

> Mixed methods study based on: **(1) a literature review, (2) the quantitative analysis of biosimilars uptake data** for hospital-use TNF-alfa inhibitors in Italy, Portugal and Spain, and on **(3) the qualitative analysis of semi-structured interviews.** Learnings from the quantitative analysis were discussed with experts in semi-structured interviews. The narrative literature review conducted complemented findings from the quantitative and the qualitative analyses.

> QUANTITATIVE ANALYSIS - Regional uptake data

Regional biosimilars uptake (%) data were examined from 2016 to 2021 (Portugal, Spain) and from 2019 to 2021 (Italy)

Data provision: Osmed (Italy); Infarmed (Portugal); BioSim, MoH Department of Pharmaceuticals and Health Products (Spain)

> QUALITATIVE ANALYSIS - Biosimilar uptake determinants

10 interviews were conducted from November 2022 to March 2022. The purpose of conducting these interviews was to describe supply- and demand-side considerations that may have affected biosimilars adoption in clinical practice

3. RESULTS - Qualitative Analysis

Biosimilar uptake determinants:

1 **Standard of care evolutions**
(shifts in prescribing towards on-patent molecules)

2 **Late publication of official position statements on biosimilars interchangeability**

3 **Regulators' vague positioning on best switching practices**
(including multiple switches)

4 **Legal frameworks limiting the initiation of switching protocols**

5 **Inefficient purchasing procedures**
(limit biosimilars potential to generate market competition)

3. RESULTS - TNF-Alfa Inhibitor Biosimilars Uptake

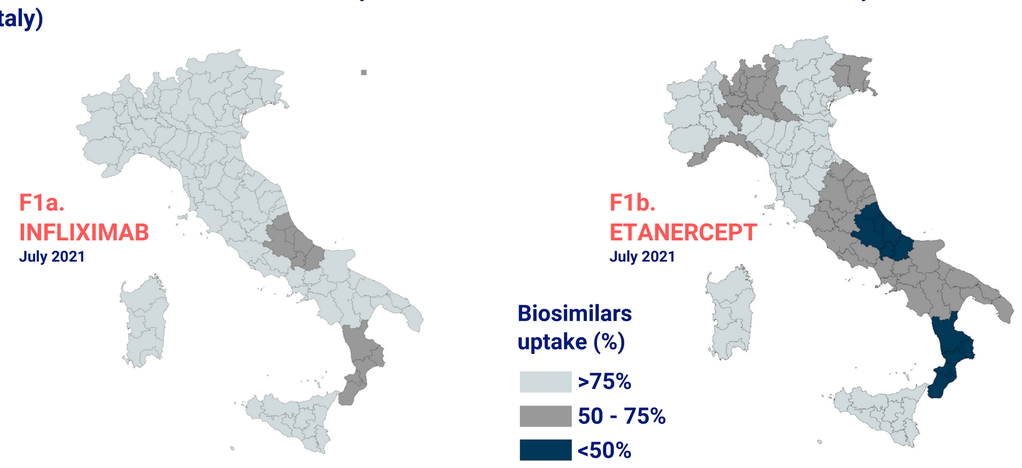
Regional-level analysis of uptake data:

Table 1. Infliximab, etanercept and adalimumab biosimilar market shares (%) in Italy, Portugal and Spain (2020)

		Italy	Portugal	Spain
Infliximab (IV)	Biosimilar market shares (%) National average 2020	91.2	84.5	75.5
	Biosimilar market shares (%) Intra-country variability range 2020	57.4 (Molise) - 100.0 (Aosta Valley)	73.9 (LVT) - 99.2 (Algarve)	49.2 (Extremadura) - 95.7 (Asturias)
Etanercept (SC)	Biosimilar market shares (%) National average 2020	65.8	45.1	48.7
	Biosimilar market shares (%) Intra-country variability range 2020	**7.8** (Molise) - 95.1 (Aosta Valley)	**10.4** (Algarve) - 63.8 (Center)	**0** (Melilla) - 91.1 (Asturias)
Adalimumab (SC)	Biosimilar market shares (%) National average 2020	64.8	33.7	42.9
	Biosimilar market shares (%) Intra-country variability range 2020	**10.8** (Calabria) - 96.0 (Trentino-South Tyrol)	**14.2** (LVT) - 53.4 (Center)	**26.5** (Melilla) - 96.5 (Asturias)

> After more than six years since TNF-alfa inhibitor biosimilars market availability, up to 91% variation in biosimilars uptake has been observed in Southern European markets.

> Uptake has been lower for biosimilars administered subcutaneously than for biosimilars administered intravenously **(see Figure 1a-b, the example of Italy)**



4. LEARNINGS

> Hospital pharmacists and managers have been primarily responsible for fostering the preferential prescription of 'best-value' TNF-alfa inhibitor biologics. In fulfilling this responsibility, they have been affected by the **absence of common policies to steer biosimilars adoption**, and by **limited benchmarking and coordination capabilities.**

> Health authorities' position regarding best-switching practices, the desirability of non-medical switching and how to manage multiple switches remains vague.

> The lack of guidance from the regulators' side has affected biosimilars adoption in clinical practice.

> This study highlights the need for policy frameworks supportive of measures already implemented locally to foster biosimilars. These frameworks should account for the particularities of off-patent biologic and biosimilar markets and should jointly address supply- and demand-side challenges.

3. RESULTS - Biosimilar Uptake Determinants

> The organisation of multi-stakeholder information campaigns supporting biosimilars use in Italy, Portugal and Spain has resulted in an increased familiarity of clinicians and patients with the prescription/use of these products. However, **barriers persist that impede high biosimilars uptake, especially in chronic patient populations eligible for a switch.**

> These barriers relate to: **(1)** Evolutions in the standard of care and prescribing shifts from off-patent TNF-alfa inhibitors towards on-patent molecules; **(2)** the late publication of official position statements on biosimilars interchangeability; **(3)** regulators' vague positioning on best switching practices; **(4)** the existence of policy frameworks that do not necessarily support the initiation of switching protocols; **(5)** the establishment of sometimes inefficient purchasing procedures that limit biosimilars potential to generate market competition.

> In the absence of national-level harmonised interchangeability and switching criteria, hospitals' success in rationalising biologics spending has strongly relied on: **(1)** Effectively raising awareness among HCPs on benefits offered by biosimilars; **(2)** the support of opinion leaders among clinical departments and the prescribers' community; **(3)** achieving sufficient participants for voluntary managed-switch programs; **(4)** establishing incentives that can align stakeholders' priorities. Our research suggests that primarily relying on these strategies, without having the support of a common comprehensive policy framework, has led to heterogeneous outcomes in the adoption of biosimilars.

5. CONTACT

Teresa Barcina Lacosta
teresa.barcina@kuleuven.be

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