Biosimilars and originators: utilization and costs in Lombardy Region

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Background

Biosimilar medicines have improved the management of chronic diseases, including dermatological, rheumatological and gastroenterological ones, with a super-imposable safety and efficacy profile than biological/originator drugs

Despite the growing number of biosimilars approved, clinicians' comfort in prescribing originators against biosimilars, patients caution, and hesitation to switch from an originator to a biosimilar, are the major factors responsible for their current low utilization

Objective

To provide an overview of the available real-world data about the use of biosimilar and originator drugs in Lombardy Region, for the treatment of rheumatological, dermatological and gastroenterological diseases, also defining the economic savings generated in case of higher biosimilars' utilization

Methods

An observational study, based on Pharmacy Departments databases, was conducted in 5 hospitals

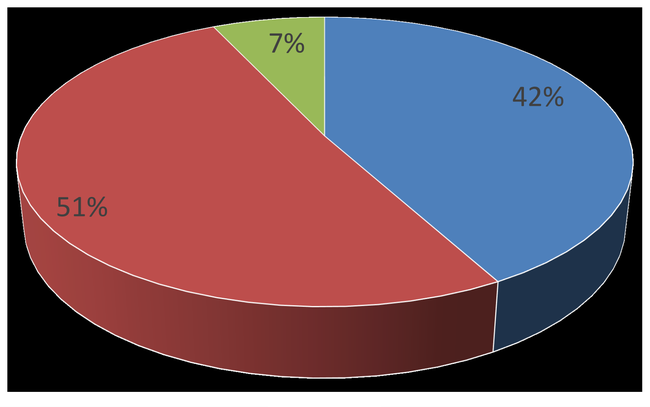
Data about the typology of administered drugs, number of drugs prescribed, diagnosis, and related treatment costs were collected, considering treatment-naïve patients, affected by rheumatological, dermatological or gastroenterological diseases, who received an originator or a biosimilar in 2018-2019, assuming a 24-month follow-up

The potential economic savings generated from switching between originator and biosimilar drugs of the same class (focusing on Anti-TNFα), was defined

The sample under assessment

The sample was composed of 1,885 patients, 51% of whom affected by dermatological disease

Most patients were treated with an originator (85%) and for 24 months (61%)



Nature of the administered drug	N.	%
Biosimilar	288	15%
Originator	1,597	85%
Totale	**1,885**	**100%**

Biosimilars' use in the clinical practice

Biosimilars are mainly used in the gastroenterological setting (51%), whereas a lower utilization rate emerged in both the dermatological (6%) and the rheumatological area (20%)

Nature of the administered drug	Dermatological setting	Gastroenterological setting	Rheumatological setting
Biosimilar	6%	51%	20%
Originator	94%	49%	80%

Patients' Follow-up period	Dermatological setting	Gastroenterological setting	Rheumatological setting
Patients treated for a 24-month time period	45%	43%	54%
Patients treated for a 24-month time period, and experiencing a therapeutical switch within the first year	5%	17%	12%
Patients treated for a 24-month time period, and experiencing a therapeutical switch within the second year	2%	11%	6%

A focus on the therapeutical switch	Dermatological setting	Gastroenterological setting	Rheumatological setting
% therapeutical switch – overall	8%	30%	20%
% therapeutical switch from an originator to a biosimilar drug	21%	72%	28%

Economic evaluation

Considering the drugs' acquisition hospital costs, patients treated with biosimilars require lower economic resources, for all the investigated setting, with a saving per patient, ranging from 71% to 89%

Follow-up period	Nature of the administered drug	Dermatological setting	Gastroenterological setting	Rheumatological setting
12-month treatment	Patients treated with an originator drug	6,396 €	7,265 €	4,344 €
	Patients treated with a biosimilar drug	680 €	1,177 €	1,261 €
	Difference (%)	**-89%**	**-84%**	**-71%**
24-month treatment	Patients treated with an originator drug	15,176 €	16,418 €	13,803 €
	Patients treated with a biosimilar drug	3,237 €	2,931 €	4,062 €
	Difference (%)	**-79%**	**-82%**	**-71%**

If a therapeutical switch would have been applied from the originators to their biosimilars (considering adalimumab, etanercept, infliximab and rituximab therapeutical principles), hospitals would benefit from economic savings equal to -47% for the rheumatological setting, -58% for the dermatological one and -34% for gastroenterological patients

	Dermatological setting	Gastroenterological setting	Rheumatological setting
AS IS Scenario (current biosimilars' use)	770,584.48 €	719,507.10 €	2,564,518.31 €
TO BE Scenario (higher biosimilars' use)	325,490.84 €	471,641.94 €	1,371,523.49 €
Difference (Euro)	**-445,093.64 €**	**-247,865.16 €**	**-1,192,994.83 €**
Difference (%)	**-58%**	**-34%**	**-47%**

Conclusions

Despite biosimilars represent both a clinical and a financial opportunity, a low biosimilar penetration could suggest area of resources efficiency, in particular concerning the possibility to apply a switch within different therapeutical class.

This information would play a double role, giving support:

- in educating key-stakeholders to ensure the safe, effective, and cost-effective use of biosimilars in clinical practice
- for the adequate understanding of the drugs' regional/national flows, that are always presented in an integrated manner and did not provide important information such as diagnosis, specific pathology, technological switch rate and follow-up period

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