

EXPENDITURE AND CONSUMPTION DESCRIPTIVE ANALYSIS: RITUXIMAB ORIGINATOR VERSUS BIOSIMILAR IN AN ITALIAN DISTRICT

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BACKGROUND AND IMPORTANCE

The introduction of biological drugs changed pharmaceutical market, improving patients' prognosis and quality of life. Intravenous MabThera[®], authorized in January 1997 figures as the originator of the monoclonal antibody rituximab. In Italy, the Regulatory Agency approved the first rituximab biosimilar Truxima[®] in July 2014, while the second had been Rixathon[®] in December 2017.

AIM AND OBJECTIVES

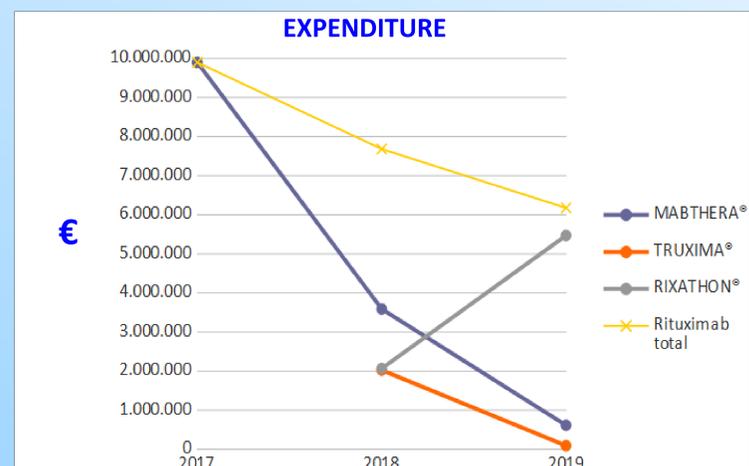
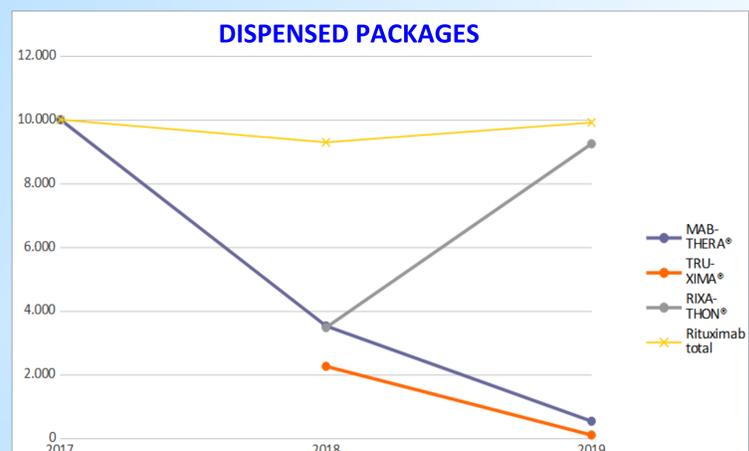
The objective was to analyse and compare MabThera[®] and its biosimilars in our region in the period between 2017 and 2019 in terms of regional consumption, costs and Adverse Drug Reactions (ADRs).

MATERIALS AND METHODS

Regional consumption and costs data of rituximab between January and September 2017, 2018 and 2019 were collected and analysed, using Microsoft[®] software. ADRs reports were extracted from Adverse Drug Reactions National Report (ADRsNR) and stratified by gravity, gender of patients, diagnosis.

RESULTS

In 2017, intravenous MabThera[®] dispensed packages were 10.017, with a progressive reduction over the years (552 in 2019). Truxima[®] passed from 2.274 delivered packages in 2018 to 117 in 2019; Rixathon[®] increased from 3.491 in 2018 to 9.259 in 2019. Intravenous distributed packages number of MabThera[®] decreased from 2017 to 2019 and was around -94.49%. Discussing about costs, MabThera[®] expenditure in 2017 was about 9,902,232.64€, in 2018 3,590,428.00€ and 613,502.88€ in 2019. Truxima[®] was 2,027,695.38€ in 2018, in 2019 91,438.67€. Rixathon[®] expenditure was firstly 2,066,974.79€ in 2018, then 5,473,728.71€ in 2019. A -93.80% of reduction was registered of MabThera[®] expenditure from 2017 to 2019. From January 2002 to March 2020 ADRsNR rituximab ADRs were 2.865, concerning respectively 10.23% MabThera[®], 19.02% Truxima[®] and 10.66% Rixathon[®]. Patients were 50.3% males and 49.7% females. ADRs gravity was 2.2% deaths, 39.1% serious, 57.8% not serious. Diagnoses principally concerned itch 7.9%, dyspnea 7.0%, neutropenia 7.3%, pyrexia 7.0%.



Drug	2017		2018		2019	
	Packages	Expenditure	Packages	Expenditure	Packages	Expenditure
MABTHERA[®] 500 mg/50ml + 100 mg/10ml	10,017	€ 9,902,232.64	3,541	€ 3,590,428.00	552	€ 613,502.88
TRUXIMA[®] 500 mg/50ml + 100 mg/10ml	N.A.	N.A.	2,274	€ 2,027,695.38	117	€ 91,438.67
RIXATHON[®] 500 mg/50ml + 100 mg/10ml [®]	N.A.	N.A.	3,491	€ 2,066,974.79	9,259	€ 5,473,728.71
TRUXIMA[®] + RIXATHON[®]	N.A.	N.A.	5,765	€ 4,094,70.17	9,376	€ 5,565,167.38
TOTAL	10,017	€ 9,902,232.64	9,306	€ 7,685,098.17	9,927	€ 6,178,670.26

Table 1. Total number of packages dispensed and spending trends of MabThera[®], Truxima[®], Rixathon[®] and rituximab total from 2017 to 2019 (N.A.: not available)

Graphs 1,2: respectively showed trends of dispensed packages and expenditure of MabThera[®], Truxima[®], Rixathon[®] in the period between January and September, respectively for the years 2017, 2018 and 2019.

CONCLUSION

ADRsNR data of biosimilars are still limited: one is desirable greater collaboration between health professionals in order to structure a system of more robust and adequate pharmacovigilance, able to overcome the information gap relating to security of the originator and biosimilar. Nonetheless, biosimilar drugs are a valid therapeutic alternative for patients, a good way to reduce the expenditure, and to optimize the available resources, ensuring a good pharmaceutical governance. The biosimilar switch involves a multidisciplinary team composed by prescribers and pharmacists. Pharmacovigilance is important to discover and characterize ADRs in postmarketing phase.

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