**Abstracts**

**Background and importance** The introduction of biological drugs changed the pharmaceutical market, improving patients' prognoses and quality of life. Intravenous MabThera, authorised in January 1998, is the originator of the monoclonal antibody rituximab. In Italy, the regulatory agency approved the first rituximab biosimilar, Truxima, in July 2014, and the second, Rixathon, in December 2017. To describe the clinical case of a 38-year-old man with BRAF negative and PD-L1 positive metastatic ATC, treated with pembrolizumab. This drug is not indicated for ATC treatment but its off-label use in combination with lenvatinib is justified by one study and a few case reports.

**Aim and objectives** To describe the clinical case of a 38-year-old man with BRAF negative and PD-L1 positive metastatic ATC, treated with pembrolizumab. This drug is not indicated for ATC treatment but its off-label use in combination with lenvatinib is justified by one study and a few case reports.

**Material and methods** Regional consumption and costs data for rituximab between January and September 2017, 2018 and 2019 were collected and analysed, using Microsoft. ADR reports were extracted from the Adverse Drug Reactions National Report (ADRsNR) and stratified by gravity, gender of the patient and diagnosis.

**Results** In 2017, the number of intravenous MabThera dispensed packs was 10,017, with a progressive reduction over the years (552 in 2019). Truxima decreased from 2274 delivered packs in 2018 to 117 in 2019. Intravenous distributed pack numbers of MabThera decreased from 2017 to 2019 and was about —94.49%. Regarding costs, MabThera expenditure in 2017 was about 9,002, 232.64 €, in 2018 it was 3,590, 428.00 €, and in 2019 it was 613, 502.88 €. Truxima costs were 2,027, 695.38 € in 2018 and 91, 438.67 € in 2019. Rixathon expenditure was 2,066, 974.79 € in 2018 and 5,473, 728.71 € in 2019. A reduction of 93.80% was registered for MabThera expenditure from 2017 to 2019. From January 2002 to March 2020, ADRsNR rituximab ADRs were 2,865: 10.23% MabThera, 19.02% Truxima and 10.66% Rixathon. 50.3% of patients were men and 49.7% women. ADR gravity was 2.2% deaths, 39.1% serious and 57.8% not serious. Diagnoses principally concerned rash 7.9%, dyspnoea 7%, neutropenia 7.3% and pyrexia 7%.

**Conclusion and relevance** ADRsNR biosimilar data are still limited: greater collaboration between health professionals is needed to structure a system of more robust and adequate pharmacovigilance, to overcome the information gap relating to the security of the originator and biosimilar. Nonetheless, biosimilar drugs are a valid therapeutic alternative for patients, and a good way to reduce expenditure and to optimise available resources, ensuring good pharmaceutical governance. Biosimilar switch involves a multidisciplinary team composed by prescribers and pharmacists. Pharmacovigilance is important to discover and characterise ADRs in the post-marketing phase.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

**5PSQ-158** OFF-LABEL USE OF PEMBROLIZUMAB IN PD-L1 POSITIVE METASTATIC ANAPLASTIC THYROID CARCINOMA: A CASE REPORT

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10.1136/ehjpfr-2021-eahpconf.277

Background and importance Anaplastic thyroid carcinoma (ATC) is a rare aggressive carcinoma representing 1–2% of all thyroid carcinomas. For patients with metastatic ATC, systemic chemotherapy with taxanes, platinum compounds or adriamycin is recommended. Several studies have shown that BRAF mutated tumours have higher expression of programmed death ligand 1 (PD-L1) (82%) compared with BRAF wild-type tumours (13%). For patients with metastatic ATC, systemic chemotherapy with taxanes, platinum compounds or adriamycin is recommended.

Aim and objectives The aim of this study was to analyse and compare MabThera and its biosimilars in our region in the period 2017–2019 in terms of regional consumption, costs and adverse drug reactions (ADRs).

Material and methods Regional consumption and costs data for rituximab between January and September 2017, 2018 and 2019 were collected and analysed, using Microsoft. ADR reports were extracted from the Adverse Drug Reactions National Report (ADRsNR) and stratified by gravity, gender of the patient and diagnosis.

Results In 2017, the number of intravenous MabThera dispensed packs was 10,017, with a progressive reduction over the years (552 in 2019). Truxima decreased from 2274 delivered packs in 2018 to 117 in 2019; Rixathon increased from 3491 in 2018 to 9259 in 2019. Intravenous distributed packs in 2018 to 117 in 2019; Rixathon increased from 428 in 2019. Truxima decreased from 2274 delivered packs in 2018 to 9259 in 2019. From January 2002 to March 2020, ADRsNR rituximab ADRs were 2,865: 10.23% MabThera, 19.02% Truxima and 10.66% Rixathon. 50.3% of patients were men and 49.7% women. ADR gravity was 2.2% deaths, 39.1% serious and 57.8% not serious. Diagnoses principally concerned rash 7.9%, dyspnoea 7%, neutropenia 7.3% and pyrexia 7%.

Conclusion and relevance ADRsNR biosimilar data are still limited: greater collaboration between health professionals is needed to structure a system of more robust and adequate pharmacovigilance, to overcome the information gap relating to the security of the originator and biosimilar. Nonetheless, biosimilar drugs are a valid therapeutic alternative for patients, and a good way to reduce expenditure and to optimise available resources, ensuring good pharmaceutical governance. Biosimilar switch involves a multidisciplinary team composed by prescribers and pharmacists. Pharmacovigilance is important to discover and characterise ADRs in the post-marketing phase.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

**5PSQ-159** PALBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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10.1136/ehjpfr-2021-eahpconf.278

Background and importance Loss of cell cycle regulation due to pathway alterations in cyclin D-CDK4/6-Rb is common in breast cancer. Palbociclib is a CDK4/6 inhibitor, indicated in metastatic breast cancer (mBC).

Aim and objectives The aim of this study was to analyse the safety profile of patients with mBC positive hormone receptors receiving treatment with palbociclib.

Material and methods A retrospective descriptive study was conducted in patients with mBC receiving treatment with palbociclib from July 2019 to July 2020. Electronic prescription

Conflict of interest No conflict of interest