we note a 30% switch in patients already treated by Remicade.

Inflectra was introduced with a −36% price in comparison with Remicade. Since 2015, vial cost has decreased (−40% for both biosimilar and originator).

Although the consumption grew, we observed an annual cost reduction of −15%. Since 2014, infliximab expenses diminish from € 8 50 000 to € 5 00 000 yearly. Due to the introduction of the infliximab biosimilar in our hospital, we estimate a cost savings of € 1.1 million in 3 years.

The maintenance rate is respectively 57% and 64% under Inflectra and Remicade.

Conclusion Since 2015, infliximab consumption has increased but a lower price and health authorities' promotion for biosimilars contribute to a cost reduction in both Remicade, Inflectra and, consequently, annual cost. This cost saving is helped by prescriptors's willingness: systematic treatment of naive patients by biosimilar and switch proposal to patients already treated. Biosimilar referencing and prescription are part of the cost-saving approach: less money is therefore spent on more treated patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-007 COST-MINIMISATION ANALYSIS OF LUNG CANCER PD-L1 POSITIVE TREATMENT

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Background A Therapeutic Positioning Report published by the Spanish Agency for Medicines and Healthcare Products concludes that there are no differences in efficacy and safety between nivolumab, pembrolizumab and atezolizumab for patients with lung cancer and PD-L1 expression >1%. The treatment must be chosen according to efficiency criteria.

Purpose To perform a cost-minimisation analysis and a simulation on the real population.

Material and methods For the cost-minimisation analysis, the price of atezolizumab, nivolumab and pembrolizumab were used, taking into account discounts and VAT (€ 2312.63/vial of 1200 mg, € 838.86/vial of 100 mg, € 1931.696/vial of 100 mg, respectively). The cost of treatment/day (CTD) was calculated for each alternative: atezolizumab 1200 mg/21 days; nivolumab 3 mg/kg/14 days and fixed doses of 240 mg/14 days for weight >80 kg; and pembrolizumab 2 mg/kg/21 days and pembrolizumab fixed dose of 200 mg/21 days. The costs were calculated for the range of 55–95 kg. A simulation to patients with nivolumab treatment from April 2016 to July 2018 was performed. The CTD and total treatment cost were calculated up to the time of analysis for each patient according to weight and number of cycles received, for the alternatives nivolumab and atezolizumab. The difference in cost per treatment was measured.

Results The CTD was: atezolizumab=€ 110.13, pembrolizumab 200 mg/21 days=€ 183.97, pembrolizumab 2 mg/kg=€ 91.99–€ 174.77, and nivolumab 3 mg/kg=€ 89.88–€ 143.80, remaining fixed for >80 kg. The difference in cost benefits of nivolumab up to 61.3 kg, weight for which the cost was equal. Twenty patients were treated with nivolumab during the study period. The average weight of the patients was 82 kg (range 52–100 kg). Eighty-nine per cent of the administrations were to patients over 61.3 kg. They received an average of four treatment cycles and a total of 100 administrations. The average CTD was € 132.95 for nivolumab with a total cost of € 285.191. The use of atezolizumab instead of nivolumab, would have entailed a total cost of € 231.263 (€ 53.298 less or −19%).

Conclusion At current prices, atezolizumab is more efficient than nivolumab when the patient's weight is above 61.3 kg. In our population, with a much higher average weight, the use of atezolizumab instead of nivolumab would have meant a reduction of one-fifth in the costs of treatment.

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https://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/docs/IPT-atezolizumab-Tecentriq-cancer-pulmon.pdf

No conflict of interest.

2SPD-008 RISK ANALYSIS ON CYTOTOXIC CIRCUIT IN A CENTRAL PHARMACY

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Background The manipulation of products with health risks is a source of concern for hospital pharmacy (HP) staff, even if good distribution practices require labelling of containers to identify them and secure their handling. This is particularly the case with cytotoxic products. Our HP, which ensures the supply and distribution of health products to 37 hospitals, is highly impacted by this risk even if cytotoxics are stored in specific areas and are subject to specific procedures in accordance with good HP practices. Therefore, we wanted to assess all the risks related to the handling of cytotoxics in our HP.

Purpose The objective is to establish a mapping of the risks associated with the cytotoxic circuit within our HP. The steps identified as most risky will be subject to action plans and corrective measures to secure the health products circuit.

Material and methods The scope of the study includes the reception and the storage of cytotoxics, preparation order, delivery to hospitals and disposal circuits. The Failure Mode, Effects and Criticality Analysis has been used to map risks. Failure modes with a criticality index (CI) greater than the average CI will be subject to a corrective action proposal.

Results The analysis reveals 51 failures with an average CI of 16 (min=2; max=48). Among these failures, 23 have a major criticality (CI higher than the average CI) and are mainly due to the lack of an identification label of the cytotoxic at different steps (n=13). The main steps at risk are the reception of unidentified packages arriving from suppliers or returning from hospitals, and the transport to hospitals. Breaks that can occur any time lead to a significant risk of contamination.

Conclusion The action plan to be set up requires working with suppliers, carriers and our logistics sectors, in such a way that everyone is aware of the risks incurred by each actor. The main focus of improvement concerns the identification of cytotoxics and staff training, especially in cases of product breakage. Finally, the disposal circuit is to be improved. A continuous evaluation process must allow the follow-up of the corrective actions.

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https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

No conflict of interest.

2SPD-009 ANALYSIS OF OLAPARIB AND TALAZOPARIB AS POSSIBLE THERAPEUTIC ALTERNATIVES IN ADVANCED BREAST CANCER AND A GERMLINE BRCA MUTATION

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Background To date, the main treatment in advanced breast cancer (ABC) with BRCA mutation is a non-specific chemotherapy of the physician's choice.

Purpose To establish whether olaparib and talazoparib can be declared equivalent therapeutic alternatives (ETA) in patients with ABC and a BRCA mutation, through an indirect treatment comparison (ITC) using a common comparator.

Material and methods A bibliographic search was conducted to identify a phase III clinical trial with olaparib or talazoparib in a similar ABC population (with BRCA mutation), duration and endpoints. An ITC was done according to Bucher's method, using the ITC calculator from the Canadian Agency for Health Technology Assessment. Physician's choice (capecitabine, eribulin or vinorelbine) was used as a comparator. Delta value (Δ), maximum acceptable difference as a clinical criterion of no-inferiority, was set at 0.650 (and its inverse, 1.538). If the 95% CI deviated from the delta margin, this probability was calculated using the Shakespeare method.

Results Clinical trials included were: open-label, randomised, HER 2-negative, capecitabine, eribulin or vinorelbine as comparator, ECOG 0–1, pretreated with taxane, anthracycline or both, and if platinum was used without progression to this one. The primary end point was radiologic progression-free survival (PFS). Two trials were included, one of each drug. Both of them were open-label trials, randomised, in patients with HER2-negative ABC, ECOG 0–1 and pretreated with taxane, anthracycline or both. Differences were found in the percentage of patients with ECOG 0–1 (olaparib 72.2% vs. talazoparib 53.3%), excepting this characteristic the population of both studies was similar. The results of each trial, as well as the ITC conducted, are summarised in the following table 1:

Abstract 2SPD-009 Table 1

Reference	PFS: HR (95% CI)
Olaparib	0.58 (0.43–0.80)
Talazoparib	0.54 (0.41–0.71)
ITC	1.074 (0.71–1.626)

The 95% CI was broad (high level of uncertainty) and exceeds the equivalence margin, and the probability of a result falling out the delta margin was <4.5%.

Conclusion ITC showed no statistically differences in PFS between olaparib and talazoparib.

There is a probable clinical equivalence between both drugs. Although a fraction crosses the confidence interval, this is not statistically significant.

Olaparib and talazoparib could be considered as ETA in most patients with advanced breast cancer.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-010 INDIRECT COMPARISON OF PEMBROLIZUMAB PLUS CHEMOTHERAPY VERSUS PEMBROLIZUMAB IN LUNG CANCER

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Background Pembrolizumab (Pb) showed significant benefit in overall survival (OS) and progression-free survival (PFS) versus chemotherapy in patients with untreated metastasic non-small-cell lung cancer (NSCLC) and ≥50% PD-L1 expression. The pembrolizumab-chemotherapy combination (Pb-CT) also showed significant benefit in OS and PFS over chemotherapy in patients with untreated non-squamous NSCLC, regardless of PD-L1 value. It lacks clinical trials of Pb-CT vs. Pb alone.

Purpose To develop an adjusted indirect treatment comparison (ITC) between Pb and Pb-CT in non-squamous NSCLC with PD-L1 ≥50%.

Material and methods A bibliographic search was conducted to select phase III randomised clinical trials with Pb and Pb-CT in a similar non-squamous NSCLC population (without EGFR or ALK mutations and PD-L1 ≥50%), follow-up period and endpoints. ITC was elaborated using Bucher's method with hazard ratio (HR) and 95% CI.

Results Two trials were selected, one of each regimen. Limitations found: differences in control treatment – platin doublets with pemetrexed vs. several drugs (pemetrexed subgroup was selected for PFS comparison; subgroup data lack for OS comparison) – masking (double-blind vs. open-label design), included population (only patients with PD-L1 ≥50% vs. all patients, then subgroup data were used; and inclusion of 18% patients with squamous tumour). The follow-up period of Pb and Pb-CT trials were 11.2 and 10.5 months, respectively. The results of pivotal trials and ITC are shown below:

Abstract 2SPD-010 Table 1

Reference	PFS	OS
Pb-CT vs. CT	HR=0.36 (95% CI, 0.25 to 0.52, PD-L1≥50% subgroup)	HR=0.42 (95% CI, 0.26 to 0.68, PD-L1≥50% subgroup).
Pb vs. CT	HR 0.63 (95% CI, 0.44 to 0.91, subgroup platinum+pemetrexed).	HR 0.60 (95% CI, 0.41 to 0.89)
Pb-CT vs. Pb (ITC)	HR=0.57 (95% CI, 0.40 to 0.96)	HR=0.70 (95% CI, 0.38 to 1.30)

Significant differences in PFS between Pb-CT and Pb results were observed. No significant differences in OS results were found (broad 95% CI with a high level of uncertainty).

Conclusion Pb-CT showed benefit in PFS over Pb monotherapy for patients with non-squamous NSCLC and ≥50% PD-L1 expression receiving pemetrexed combinations. Overall survival benefit is doubtful because of potential bias and large