with bevacizumab with an average age of 62 (ranging 45–79). 40 treatments were reviewed (one patient received two different bevacizumab regimens during the monitoring process), 42.5% of which followed the indications authorised by the EMA. The regimens that didn’t fit to the technical data (57.5%) were as follows: 46% bevacizumab in monotherapy 15 mg/kg/21 days, 54% bevacizumab associated with other cytostatics different from paclitaxel or capetitabine. Combinations with bevacizumab not indicated in the technical data were: 37% bevacizumab 15 mg/kg + liposomal doxorubicin 75 mg/m²/21 days, 37% bevacizumab 15 mg/kg/21 days + vinorelbine 25 mg/m²/2 days 1 and 8, 10% bevacizumab 15 mg/kg/21 days, 10% bevacizumab 10 mg/kg + irinotecan to 125 mg/m²/15 days and 6% bevacizumab 15 mg/kg + docetaxel 100 mg/m²/21 days.

Conclusions Despite the extension of the bevacizumab indications in 2011 by the European Medicines Agency (EMA) the off-label use of bevacizumab remains high, probably due to the clinical evidence with bevacizumab, which has evolved rapidly in recent years. In this sense, the importance of pharmacists’ role should be stressed in evaluating the use of medicine in relation to the recent evidence of the MBC.

No conflict of interest.

[GRP-179] SURFACE CONTAMINATION WITH ANTEINOPLEISTIC DRUGS IN SEVEN FRENCH HOSPITAL PHARMACIES

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Background Due to their carcinogenic, mutagenic and teratogenic properties, handling cytotoxic drugs presents a risk of occupational exposure for healthcare workers.

Purpose To evaluate and limit occupational risk, environmental monitoring was conducted in 7 French hospital pharmacies that prepare formulations of carboplatin, cisplatin and oxaliplatin. Platinum was used as the tracer (~20% of the production).

Materials and Methods From 2010 to 2012, 7 cytotoxic drug preparation units were investigated. Different types of surface were evaluated: the external surface of vials containing cytotoxic materials, workplace surfaces and the surfaces of antineoplastic drug preparations. Surfaces were sampled with a moistened swab. After pre-concentration by cloud point extraction, the quantity of elements was determined by graphite furnace atomic absorption spectrometry. The lower limit of detection corresponded to 2 ng of platinum per sample.

Results A total of 518 samples analysed had various levels of contamination and we found a frequency of cytotoxic contamination of more than 57% of samples (>2 ng). Contamination was found on 58% of vials of cisplatin, carboplatin and oxaliplatin from different manufacturers (n = 111, max 66 ng), 56% of cytotoxic preparations (n = 18, max 78 ng) with 29% of packagings (n = 24, max 15 ng) and 56% of workplace surfaces (n = 365) contaminated. Surfaces inside isolators were the most contaminated area (59%, n = 169) compared with storage areas (26%, n = 89), controlled areas (15%, n = 55), control laboratories (24%, n = 25) and other areas (4%, n = 27). However the highest level of contamination was found inside storage boxes of vials containing cytotoxic with more than 20,000 ng of Pt.

Conclusions Regarding environmental monitoring, two major sources of contamination were identified: the outer surface of vials of cytotoxic material and handling cytotoxic drugs inside the isolator. Other contamination spreads from these initial points of contamination. Thus, it seems necessary to use effective individual protective equipment but also to use efficient cleaning protocols to limit chemical contamination and thus, to prevent occupational exposure.

No conflict of interest.

[GRP-179] SWITCH FROM CERA TO EPO ZETA IN PATIENTS WITH ANAEMIA AND CHRONIC KIDNEY DISEASE

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Background As the result of a possible shortage of methoxy polyethylene glycol epoetin beta (CERA) within Italy, with the agreement of the EMA, AIFA (the Italian Medicines Agency) prepared a document inviting prescribers to switch patients who were undergoing treatment with different doses of CERA to any Erythropoiesis Stimulating Agent (ESA), for the treatment of anaemia associated with chronic kidney disease (CKD).

This recommendation emphasised the need to monitor haemoglobin levels (Hb) and safety and efficacy parameters.

Purpose To evaluate variations of efficacy (Hb levels) and safety (immunological reaction) of a new treatment, in patients with CKD after switching from CERA to epoetin zeta (EPO zeta), as per international and national guidelines.

To keep the same Hb level obtained before the shift.

To compare the cost differences of the two ESAs.

Materials and Methods A preliminary observational study (April–September 2012) was carried on CKD patients in haemodialysis care at the Department of Nephrology. The patients enrolled were treated with some of the doses of CERA indicated in the Recommendation for at least ten months. We evaluated ESA dosage, Hb level and dosage/kg.

Results The study included 12 patients (7 men and 5 women) with mean age 56.64 years (range 40–75). All patients were treated with EPO zeta (average initial dose 6500 IU/Kg/week); after monthly monitoring of Hb levels, the initial dose of EPO zeta was increased by 7.69% (average dose 7000 IU/Kg/week) and three months later, the median Hb level observed was 11.38 g/dl.

Statistical analysis showed no significant difference between CERA and EPO zeta in terms of Hb level (P = 0.408).

No adverse events due to treatment were recorded; no variation in iron supplementation.

The use of EPO zeta resulted in savings of 250 euro per month/patient versus CERA treatment.

Conclusions After switching from CERA therapy, the use of EPO zeta appears effective and safe for CKD patient treatment. Data showed the need to increase the dose of EPO zeta to maintain a steady Hb level. Despite the increased consumption, the use of this biosimilar could contribute to containing pharmaceutical costs.

No conflict of interest.


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Background These novel treatments for hepatitis C have been recently approved in Spain. Several studies have confirmed their great efficiency in achieving good virological response.

Purpose To present the preliminary results of treatment with these drugs in a 600-bed hospital and find the adherence of patients to triple treatment: ribavirin, peginterferon and boceprevir or telaprevir.