Background The implementation of intensive monitoring programmes allows the identification of early occurrence of adverse drug reactions (ADR), in a comprehensive and exhaustive way. Afatinib was included in this pharmacovigilance programme (PP), which involves patient follow-up, carried out by pharmacists, to monitor the safety use of new drugs.

Purpose Analyse the results of afatinib in a PP.

Material and methods A retrospective study was carried out to analyse the follow-ups of a patient treated with afatinib. Data were collected by consulting the patient’s clinical file and monitoring records of the pharmaceutical department.

Results Female patient, 88 years’ old, caucasian with non-small cell lung cancer, with pleural metastasis and EGFR+. Started first-line treatment in December 2016 with oral vinorelbine, suspended in April 2017 due to gastrointestinal intolerance. Started afatinib 40 mg in April 2017 and was included in the PP. First follow-up performed by the pharmacist in May, patient showed erythematous/ acneiform skin reaction dispersed in limbs and trunk, intense pruritus, nausea and ocular complaints. Pharmacist advised the oncologist and it was decided to oversight. Eye complaints continued in the second follow-up in June. The oncologist was called again, evaluated and referred the patient to ophthalmology. The patient was observed in July and diagnosed with keratitis with ulceration in the left eye, which led to the suspension of treatment in August. The patient resumed treatment with dose reduction (afatinib 30 mg) in November, with improvement of complaints. In the March 2018 follow-up, the patient referred to the pharmacist numbness, rash and face oedema. The oncologist was called and decided to maintain therapy and oversight. In the next follow-up the patient maintained the complaints and treatment was suspended. Both suspected ADR were reported to the national pharmacovigilance unit. An imaging control of the disease was programmed to further decisions concerning treatment. In July, there was evidence of biochemical progression, and the oncologist discontinued therapy.

Conclusion The early approval of drugs that covers therapeutic gaps reveals the necessity to implement effective and systematic methodologies that allow the surveillance of their use. Monitoring by the pharmacist promotes and contributes to safety and adherence in the use of medicines.

References
http://www.ema.europa.eu
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