

Results: Of the 851 eligible patients, 776 were interested, 774 consented, and 773 were included in the analysis (completed at least one knowledge question in full). Thirty-eight percent of patients reported receipt of the aflibercept patient booklet; 23% the aflibercept audio CD; and 35% the aflibercept patient information leaflet. Patients' knowledge of health conditions to discuss with a doctor before an aflibercept injection was high, from 85% (95% CI, 82%-87%) to 92% (95% CI, 90%-94%) on 8 of 9 items. Knowledge was lower, 52% (95% CI, 48%-55%), on the one item related to pregnancy and breastfeeding, likely because this condition is less salient in the aflibercept patient population given the patients' ages (99% of patients in the study were ≥ 46 years). Knowledge about possible side effects varied by item, with the highest correct response proportion (74% [95% CI, 70%-77%]) for "eye pain" and the lowest (42% [95% CI, 39%-46%]) for "detachment of the gel-like substance inside the eye from the retina." Most patients (78% [95% CI, 75%-81%]) knew they should speak to their health care provider immediately if they think they might be having a side effect from their aflibercept injection.

Conclusions: Levels of patient knowledge were as expected, with highest knowledge on less complex concepts (eg, conditions to discuss with the physician and easily identified side effects) and lower knowledge on more complex concepts and issues less salient to the patient population (eg, more complex side effects and issues pertaining to women of childbearing potential).

1142 | Risk management of medication errors in the EU

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Background: The EU-Risk minimization plan (EU-RMP) describes important identified risks, important potential risks, and missing information for

medicines and strategies to limit these risks. Medication errors (MEs) can be recognized pre-authorization as an important risk and included in the EU-RMP with routine or additional risk minimization measures (aRMM).

Objectives: This study aims to describe the risk management of MEs for centrally authorized products (CAPs) in the EU.

Methods: The online European Public Assessment Reports at the time of authorization for all originator CAPs authorized between 1 January 2010 and 31 December 2015 were reviewed. The following data were collected: ATC code, safety concerns, implementation of routine or aRMM, studies to evaluate the effectiveness of RMM. Safety concerns were converted into the most appropriate *preferred terms* using the Medical Dictionary for Regulatory Activities (MedDRA®) version 19.0. ME safety concerns were identified using the narrow Standard MedDRA query and classified by ATC code, year of authorization, type of ME, routine or aRMM, type of RMM, and population targeted by aRMM.

Results: During the study period 231 CAPs were approved in the EEA, of which 60 had at least one ME safety concern. The proportion of CAPs with ME safety concerns increased from 21.1% in 2010 to 32.7% in 2015. In total 67 ME safety concerns were identified, of which 23 with aRMM. All aRMM consisted of educational material targeted at health care professionals (87.0%), patients (47.8%), or both (34.9%). ME safety concerns were most frequently categorized as important potential risks (74.6%) with more aRMM imposed when categorized as important identified risk (66.7% vs 28.0%). Anti-infectives for systemic use had most ME safety concerns (16.4%) but never aRMM. Cardiovascular medications had the highest proportion of additional RMM (4/5). The type of medication errors was highly variable: *medication error* (41), followed by *drug administration error* (5) and *accidental exposure to product* (5). For 83.6% of the aRMM for ME, effectiveness studies were requested.

Conclusions: The increased proportion of CAPs with ME safety concerns may be an indicator of increased awareness of the risk of medication errors, or increasingly complicated therapies and medicines. Further research is needed to evaluate the effectiveness and continuing need for aRMM for ME.