#### **PGEU**

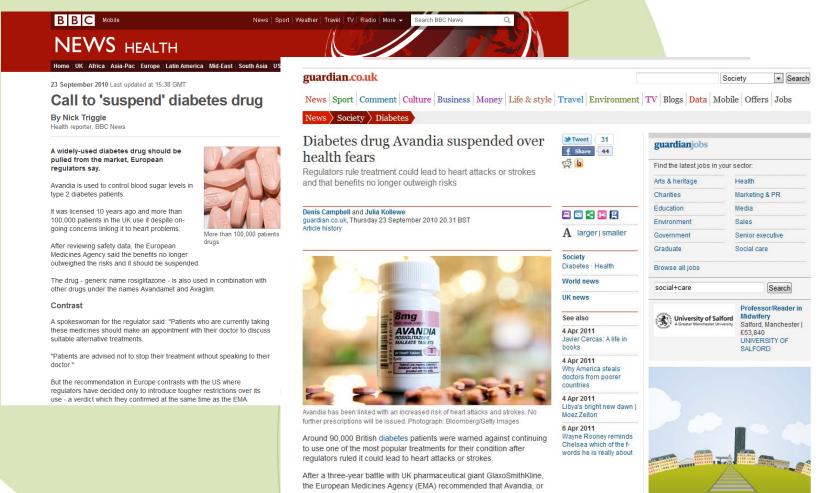
# **Eudra Vigilance:** Expectations of pharmacists

Jurate Svarcaite, PGEU
Pharmacovigilance Meeting EMA
17 June, 2011



### Most Recent Case: Avandia







## Eudra Vigilance validation study

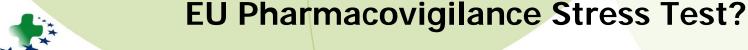
**PGEU** 

Direct evidence that more than 54% of serious safety issues can be detected earlier if Eudravigilance is used in addition to other pharmacovigilance resources.

- Why
  - Analysis of pooled data
  - Use of statistical tools
- Detection of rare ADRs
- ADRs detected earlier as absolute numbers are greater



Reference: Drug Safety, 33(6), pp. 475-487





## **PGEU**

## **Expectations of Pharmacists**

- Cases like Mediator to be detected earlier using Eudravigilance!
- 'Dear doctor' letter 'Dear health professional' letter.
- To be consulted in the future eventual revision on the PIL and SMPC content.
- Instant overview of medicines safety issues when using public interface of Eudravigilance.
- Feed back→ Individual follow up of reports + safety info feed
   into pharmacy ICT support tools.