

EudraVigilance: Expectations of pharmacists

Jurate Svarcaite, PGEU
Pharmacovigilance Meeting EMA
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Most Recent Case: Avandia

PGEU



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Call to 'suspend' diabetes drug

By Nick Trigg
Health reporter, BBC News

A widely-used diabetes drug should be pulled from the market, European regulators say.

Avandia is used to control blood sugar levels in type 2 diabetes patients.

It was licensed 10 years ago and more than 100,000 patients in the UK use it despite ongoing concerns linking it to heart problems.

After reviewing safety data, the European Medicines Agency said the benefits no longer outweighed the risks and it should be suspended.

The drug - generic name rosiglitazone - is also used in combination with other drugs under the names Avandamet and Avaglim.

Contrast

A spokeswoman for the regulator said: "Patients who are currently taking these medicines should make an appointment with their doctor to discuss suitable alternative treatments."

"Patients are advised not to stop their treatment without speaking to their doctor."

But the recommendation in Europe contrasts with the US where regulators have decided only to introduce tougher restrictions over its use - a verdict which they confirmed at the same time as the EMA



More than 100,000 patients drugs

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Diabetes drug Avandia suspended over health fears

Regulators rule treatment could lead to heart attacks or strokes and that benefits no longer outweigh risks

Denis Campbell and Julia Kollewe
guardian.co.uk, Thursday 23 September 2010 20:31 BST
Article history



Avandia has been linked with an increased risk of heart attacks and strokes. No further prescriptions will be issued. Photograph: Bloomberg/Getty Images

Around 90,000 British diabetes patients were warned against continuing to use one of the most popular treatments for their condition after regulators ruled it could lead to heart attacks or strokes.

After a three-year battle with UK pharmaceutical giant GlaxoSmithKline, the European Medicines Agency (EMA) recommended that Avandia, or rosiglitazone, which is used by 2 million people worldwide, should be

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EudraVigilance validation study

- 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

EU Pharmacovigilance Stress Test?



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.

