Primary and Community Care Directorate
Pharmacy Division

T: 0131-244 2518 F: 0131-244 2375
E: bill.scott@scotland.gsi.gov.uk
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The Scottish Government

1. Medical Directors NHS Boards
2. Directors of Public Health
3. Directors of Pharmacy
4. NHS 24

RIMONABANT: SUSPENSION OF MARKETING AUTHORISATIONS AS RISKS OUTWEIGH BENEFITS

Please see for urgent transmission a copy of a message from the Medicines and Healthcare products Regulatory Agency (MHRA) about the suspension of marketing authorisations for Rimonabant.

1. Please could Medical Directors in NHS Boards forward the message to :-
   - All general practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.
   - Deputising Services
   - Accident & Emergency Departments

2. Please could Directors of Public Health forward the message to:-
   - Chief Executives NHS Boards

3. Please could Directors of Pharmacy forward the message to :-
   - Community Pharmacists.4

Thank you for your co-operation.

Yours sincerely

Bill Scott

BILL SCOTT
Chief Pharmaceutical Officer

INVESTOR IN PEOPLE
POSITIVE ABOUT DISABLED PEOPLE

Rimonabant: suspension of marketing authorisation as risks outweigh benefits

Dear Healthcare Professional,

We are writing to inform you that the European Medicines Agency has completed a review of rimonabant (Acomplia) after concerns about its psychiatric safety. The review has found that the benefits of rimonabant do not outweigh the risks of psychiatric reactions in clinical use. The marketing authorisation for this medicine will be suspended across the European Union.

Advice for healthcare professionals and patients

- Prescribers should not issue any prescriptions for rimonabant, and should review the treatment of those who are currently taking this medicine
- Patients who are currently taking rimonabant should consult their doctor or pharmacist at a convenient time to discuss their treatment. If patients wish to stop taking rimonabant, it is safe to do so at any time
- Patients who are currently enrolled in clinical trials of rimonabant may wish to contact the trial investigator (the doctor who is treating them), who will be able to give more information. Trial investigators are being notified of this suspension of the marketing authorisation

Background

Rimonabant is an adjunct to diet and exercise for the treatment of obese adults (BMI ≥30 kg/m^2) or overweight (>27 kg/m^2) adults who have associated risk factors (eg, type 2 diabetes, dyslipidaemia).

At the time of rimonabant's approval in June 2006, psychiatric side-effects (particularly depression) were identified as the most important safety issue. Since approval, continued monitoring of the safety of rimonabant has led to updates to the product information and further advice for healthcare professionals to minimise the risk of this type of reaction (see *Drug Safety Update* May 2008, p 2–5; www.mhra.gov.uk/mhra/drugsafetyupdate).

Further assessment shows risks outweigh benefits

Further European assessment of rimonabant has concluded that the risks of treatment outweigh the benefits in clinical use. Therefore, the European Committee for Medicinal Products for Human Use has recommended that the marketing authorisation for this medicine should be suspended across the European Union.

This assessment looked at the available data for the benefits and risks associated with rimonabant, including studies that have been completed since its approval. The analyses showed that there was approximately a doubling of the risk of psychiatric disorders in patients taking rimonabant compared with patients taking placebo.

New data from ongoing studies and from spontaneous reports of adverse effects from rimonabant suggest that serious psychiatric disorders (including depression, sleep disturbances, anxiety, and aggression) might be more common in clinical use than in clinical trials completed before licensing.

Evidence for a clinically important benefit with rimonabant is limited because in practice the duration of treatment is considerably shorter than it has been in clinical studies, and because patients may not maintain weight loss after stopping treatment. There is no evidence that rimonabant reduces the morbidity or mortality associated with obesity.

The measures and clinical advice implemented to date to try to reduce the frequency of psychiatric reactions (particularly depression) with rimonabant have not adequately controlled this risk. The European review highlighted concern that some patients who were taking antidepressants were continuing to be prescribed rimonabant, despite the introduction of a contraindication in 2007.

Patients who may be at highest risk of psychiatric reactions cannot be identified reliably. Therefore, further restrictions on the use of this medicine would be unlikely to reduce the risk to an acceptable level.

Further information is available at www.mhra.gov.uk and www.emea.europa.eu.