Health and Healthcare Improvement Directorate
Pharmacy and Medicines Division

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23 January 2012

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

Dear Healthcare Professional,

DRUG SAFETY INFORMATION Nos 3 and 4 - IMMEDIATE

Please see the attached drug safety information for onward transmission as below.
Please could all Directors of Pharmacy forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

1. Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

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DRUG SAFETY INFORMATION

For immediate dissemination during working hours

Date:23 January 2012 EL (12)A/04 Our Ref: MDR 40-01/12

Dear Healthcare Professional,

MHRA Safety Information for Vigantoletten (1000 IU Colecalciferol) Tablets

(Merck Serono, Germany)

The above unlicensed product is imported in significant quantities into the UK.

Importers of medicines that are unlicensed in the UK must notify the MHRA in accordance with The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005/2789. For further information, please see also Guidance Note 14, available on the MHRA Website (http://www.mhra.gov.uk).

Notifications for importation of unlicensed medicines are assessed by the MHRA and objections may be raised where there are prohibitive safety or quality concerns, or in the case of non-objections to import, advice issued where users need to be aware of safety or quality issues.

Although importers are advised that the prescriber must be made aware that Vigantoletten tablets contain soya oil, and are contraindicated for patients with allergies to this ingredient, it has come to the attention of the MHRA that not all users may be aware of these safety issues. This is of particular concern because packs and leaflets are in the German language. Although there is currently no legal requirement for imported medicines to be labelled in English, the expectation in the National Health Service is that suitable English language labelling will be provided as a matter of good practice. NHS guidance has been issued which reflects this.

Allergy to soya oil may lead to severe allergic reactions including anaphylaxis. Recipients are therefore asked to bring this information to the attention of relevant professionals.

Yours faithfully,

Graham Matthews

Senior Pharmaceutical Assessor, **Unlicensed Medicines**

MHRA Distribution (further recipients by cascade):
Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Care Quality Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)