



Department of
**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

From The Chief Pharmaceutical Officer
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For Action: Assistant Director Integrated Care, Pharmacy and Medicines
Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of
HSC Trusts
Regulation Quality Improvement Authority


D R U G S A F E T Y I N F O R M A T I O N

For immediate dissemination during working hours

Dear Healthcare Professional

Merck Serono, Germany
Vigantoletten (1000 IU Colecalciferol) Tablets

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.

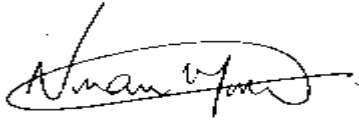
Although importers are advised that the prescriber must be made aware that Vigantoletten tablets contain soya oil, and are contraindicated for patients with allergies to this ingredient, it has come to the attention of the MHRA that not all users may be aware of these safety issues. This is of particular concern because packs and leaflets are in the German language. Although there is currently no legal requirement for imported unlicensed 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.

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.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:

CMO
CNO
CDO
CSSO
SMO
Director, Health Estates
Public Health Branch
Extended Nurse Prescribers
NICPLD

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPQAS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist