



From: The Chief Pharmaceutical Officer
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For Action:

Heads of Pharmacy and Medicines Management, HSC Trusts
Assistant Director of Pharmacy and Medicines Management,
HSC Board
All Community Pharmacies
All GP Practices

For Information:

Medical Directors, HSC Trusts
Nursing Directors, HSC Trusts
Regional Medicines Information Centre
Regional Pharmaceutical Procurement Service

Date: 18 February 2011

Dear Colleague

UPDATED GUIDANCE ON REPORTING DEFECTIVE MEDICINES

This letter advises on the process which should be followed to report defective medicines and replaces all previous guidance and advice issued on this subject.

In all cases, suspected defects in medicines should be reported direct to the MHRA Defective Medicines Report Centre (DMRC) by using the online form available at: <http://www.mhra.gov.uk/Onlineservices/Medicines/Reportingsuspecteddefects/inmedicines/Suspecteddefectform/index.htm>.

The DMRC receives and assesses complaints and reports of actual or suspected defects in medicinal products for human use and co-ordinates the necessary actions. They provide an assessment and communication system between suppliers (manufacturers and distributors), users of medicines and other regulatory authorities. DMRC can be contacted by e mail or telephone and the contact details are listed below.

DMRC contact details

Telephone: 020 3080 6574 during office hours Monday to Friday 9:00 -17:00
Telephone: 020 7210 3000 for urgent calls outside of normal working hours, at weekends or on public holidays, ask for the MHRA Duty Officer.
Email: dmrc@mhra.gsi.gov.uk

In addition, the Pharmacy Advice and Services Branch at DHSSPS should be notified with details of the medicine, nature of the defect and the action taken. They should also be informed of the subsequent response by DMRC. Initial contact with DHSSPS should be made by telephone followed by a brief report via e mail, the contact details are listed below.

DHSSPS contact details

mark.timoney@dhsspsni.gov.uk telephone 028 9052 0050
cathy.harrison@dhsspsni.gov.uk telephone 028 9052 3236

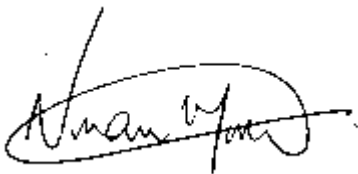
In response to the wide range of enquiries the DMRC receives on suspected defective medicinal products they have produced 'A Guide to Defective Medicinal Products' which can be accessed via:

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspecteddefectsinmedicines/index.htm>

The guide is a useful reference for anyone dealing with a defective medicine and sets out what should be done by healthcare professionals before any contact is made with the MHRA or the Licence Holder. Professionals may also contact MHRA or Licence Holders to seek information or advice. This guidance does not replace local procedures.

This notice should be brought to the attention of all healthcare professionals who may be involved with reporting defective medicines.

Yours sincerely



Chief Pharmaceutical Officer

cc CMO
Dr P Woods
Dr J Livingstone
Dr M Timoney
Mrs C Harrison