

16th November 2004

The Medicinal Product Defect Reporting Form

The Inspectorate and Enforcement Directorate (IED) within the Medicines Authority has been investigating Medicinal Product defect reports since August 2003.

The Medicinal Product Defect Reporting Form is now available on the Medicines Authority website (www.medicinesauthority.gov.mt).

Therefore defects arising locally should now be reported on this form and be sent by e-mail (karl.de-marco@gov.mt) or fax (23439161) to the IED of the Medicines Authority.

These defects are investigated by the IED and actions required are decided upon in conjunction with the interested parties. The IED has the overall responsibility of coordinating the defect reports.

In cases where the above-mentioned defect reports lead to recalls the IED can opt to issue Drug Alert letters where a defective product has been distributed widely and/or there is a serious risk to health from the defect. The issuing of Drug Alert letters must be regarded as being complimentary to, and not a substitute for, any action taken by the Marketing Authorisation Holder (MAH) or its local representative. In fact any actions required (eg recalling a batch of product, issue of recall letters) remain the responsibility of the MAH or its local representative.

Once Drug Alert letters are issued these are then distributed by using the Drug Alert Cascade System whereby the Drug Alert letters are distributed by the IED throughout the private and public health sectors, if required, thereby ensuring rapid communication of safety information.