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TO: Wholesale Dealers  
Responsible Persons

### **RE. VIOLATION OF THE MEDICINES ACT AND ENFORCEMENT ACTIONS**

As you are aware the Medicines Act 2003 has now been fully in force since 1<sup>st</sup> December 2003. In addition various subsidiary legislation has since been published as legal notices, with the last amendments and publications being effected in the last two months of 2005.

The role of the Medicines Authority during the transition period and the first few months following the enactment of new legislation has been focused on the educational aspect and the explanation and guidance in respect of the new requirements. This approach should have given enough time for stakeholders operating in the pharmaceutical field to get in line and improve the standards in accordance with the stipulated requirements.

Various reports and complaints have been received by the Medicines Authority during 2005 with respect to wholesale dealing activities and breaches of the Medicines Act. From the investigations carried out it resulted that the absolute majority of these reports were justified and enforcement actions were indeed taken. Again the approach taken by the Medicines Authority was directed at educating and introducing the regulatory culture rather than seeking prosecution in court in the first instance.

The time has now come for more compliance to be achieved in respect of pharmaceutical activities. In this respect wholesale dealers are reminded of their obligations as stipulated in local legislation and EU Directives. In this context you are being informed that a stricter approach will be taken during the coming months in order to ensure and achieve compliance. Cases, especially those associated with repetitive non-compliance and those involving second time offenders will be acted upon according to the provisions of the law. This may include suspension or revocation of licences and prosecution in court. Cases involving the pharmacy profession will be referred to the Pharmacy Council.

The achievement of compliance will not only result in a smooth and transparent system but will also ensure that public health is safeguarded in the interest of patients.

This information is being relayed for your necessary actions and compliance.

Regards

R. Busuttill  
Director General, Health