

PLEASE REPLY TO:

To Whom It May Concern

EIPG have become extremely concerned with the recent outbreaks of counterfeit medicines entering the supply chain in the UK. In particular, during the last 3 months in the UK, there have been incidences of counterfeit Plavix and Zyprexa being detected and subject to product recalls and fears for patient safety (Pharmaceutical Journal Vol 278, P635, 2007).

The current practice of Parallel Importation within the European Union has in no doubt added to the complexity of establishing a secure supply chain for many medicinal products. The immediate response from a number of Pharmaceutical Manufacturers is to restrict the product supply to a select number of wholesalers and distributors, to the dismay of many Community Pharmacists.

The EIPG at their recent General Assembly meeting held in Prague in April 2007 noted the difference between the EU Directive 2001/83/EC which obliges holders of a distribution authorisation to have a 'qualified person designated as responsible' and Regulation 10(1) of the Medicines for Human Use Regulations 2005 which state the requirements for a distributor to have a Responsible Person (RP) within the UK.

The RP is responsible for safeguarding product users against potential hazards arising from poor distribution practices as a result, for example, of purchasing suspect products, poor storage or failure to establish the bona fides of purchasers. There is no statutory requirement for the RP to be a Pharmacist, although this is desirable.

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It is the recommendation of the EIPG that the Responsible Person in *all markets of the EU* where the presence of the Qualified Person is not enforced, should be at the very minimum, replaced with a **Responsible Pharmacist**. It is the belief of EIPG that a Responsible Pharmacist would have personal knowledge of:

- a) The relevant provisions of the Medicines Act 1968 as amended.
- b) Directive 2001/83/EC as amended on the wholesale distribution of medicinal products for human use.
- c) The conditions of the Wholesaler Licence for which the Responsible Pharmacist is nominated.
- d) The products traded under the licence and the conditions necessary for the safe storage and distribution.

In ensuring that a Responsible Pharmacist or Qualified Person is mandated for wholesale and distribution supply chains in *all* European Markets including the UK, the EIPG believe that the impact of Counterfeit Medicines can be substantially reduced.

Yours faithfully

Dr Luigi G Martini & Mrs Jane Nicholson

Cc Mrs Emer Cooke, EMEA