

Shortages of pharmaceuticals

Background

Since the onset of the economic recession, there have been shortages of pharmaceuticals in the UK.

These shortages result from wholesalers' exporting pharmaceuticals rather than retaining them for the home market. Whilst the value of the £ sterling is low vis-à-vis the EURO, this is profitable. (When the £ sterling was strong, UK wholesalers imported from abroad.)

The practice is called parallel trading, is legal and in line with the EU's principle of free trade. Pharmaceutical manufacturers have challenged parallel trading in the European Court of Justice but without success.

Parallel trading reduces the profits of the manufacturers because they charge different countries different prices for drugs depending on their economic status. E.g. they sell cheaply to Greece and at a higher rate to France.

In order to curb parallel trading, manufacturers imposed supply quotas per country – based on previous years' sales. In the case of the UK, these quotas were too low because the manufacturers did not know the percentage of drugs previously obtained by parallel trading/importing.

So, low volumes of supply coupled with opportunistic exporting result in shortages of pharmaceuticals. Community pharmacists have difficulty in obtaining regular supplies. Patients and their carers go from place to place to get their repeat prescriptions. A great deal of time and nervous energy is expended. Health and perhaps lives are threatened. Shortages of cancer and anti-epileptic drugs have caused particular concern not only in York but throughout the country.

To try and find a solution, York LINK has contacted the public through its membership, Minster Radio and the Evening Press; York's community pharmacists and the Chief Pharmacist at York Teaching Hospital; the Department of Health; the former and current Under Secretary of State for Health; and the World Health Organization Regional Office for Europe (WHO); as well as the Royal Pharmaceutical Society; an expert on parallel trading in the London School of Economics; and local MPs.

The way forward

York LINK's subgroup on pharmacies and pharmaceuticals is determined to pursue this issue.

The authorities confirm that wholesalers, as qualified pharmacists, have a moral responsibility to ensure adequate supplies for the UK.

WHO has pointed out that a solution would be to include in the licence obligations for wholesalers a requirement to provide, within 24 hours, drugs requested by community pharmacists - thus obliging them to maintain adequate stocks for retail in the UK.

The Medicines and Health Regulatory Agency (MHRA) which is the body issuing wholesaler dealers' licences has confirmed (see note for the file dated 23 August 2011) that conditions for licensing contain no such requirement.

UK follows the European Directive 2001/83/EC and European Guidance on Good Distribution Practice 94/C63/03 – copy attached. The Guidance is concerned almost entirely with maintenance of quality. The only reference to delivery time comes in the first section entitled “**Principle**” and reads “... **the quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period**”. Under the heading “**Deliveries to customers**” paragraph 19 states “**In case of emergency, wholesalers should be in a position to supply immediately the medicinal products that they regularly supply to the persons entitled to supply the products to the public**”.

Recommendations

1. York LINK recommends the MHRA strengthen, with immediate effect, the obligations of the wholesale dealers in the UK by interpreting – in writing – “a satisfactory time period” as **within 24 hours**.
2. York LINK recommends that representatives of the UK within the appropriate bodies of the EU propose an amendment to the European Guidance on Good Distribution Practice 94/C63/03 **to specify that wholesalers should ensure supply to their regular retailers within 24 hours when so required**.