

Finger pointed at Asian outsourcing as factor in product recalls

By Kirsty Barnes

22/02/2007 - The number of product recalls in the UK jumped by 8 per cent in the last year, with the problem compounded by the trend towards outsourcing to developing countries such as those in Asia, says law firm Reynolds Porter Chamberlain (RPC).

In a report recently released by the London-based firm, the UK saw 179 product recalls, across all industries including pharmaceuticals, up from 165 the previous year.

In addition, the number of notifications made by the UK's Department of Trade and Industry (DTI) to the European Commission, under the Rapid Alert System for Non-Food Products System (RAPEX), increased to 58 for products manufactured in China, compared to just 16 notifications for products originating from countries in Europe.

This trend has continued in 2007, with three of the four RAPEX notifications to date relating to products manufactured in China, said the law firm.

"With more manufacturing being outsourced to China and other developing countries, it is harder to maintain quality control," said Mark Kendall, partner at RPC.

"It can be much more difficult to identify issues in production that is carried out overseas."

Indeed, this very issue is high on the radar of the two trade associations of the world's two largest pharma economies – Europe and the US – who have taken the unusual step of banding together to condemn their regulatory authorities for poor regulation of foreign active pharmaceutical ingredient (API) manufacturers.

The Synthetic Organic Chemical Manufacturers Association (SOCMA) and the European Fine Chemicals Group (EFCG) are demanding that regulators increase their inspections of such foreign facilities.

Despite having strict rules in place to ensure that drug APIs meet current good manufacturing practices (cGMP), the US Food & Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMA) do not inspect all foreign facilities manufacturing APIs serving them, claim EFCG and SOCMA.

"As it stands today, all the credibility that these health authorities have been building up over the last 20 years is now being eroded," the organisations said in a statement last October.

"There is a very strong belief that if a medicine has been approved by the health authorities that it is "safe" – unfortunately this is not true."

EFCG and SOCMA claim that many foreign facilities have never been inspected even though 75-80 per cent of all APIs used by EU and US drug manufacturers are imported, mainly from India and China.

According to a 1999 FDA report, 242 manufacturers imported in the US without being inspected.

In the European Union, the situation is equally alarming. There, the EU is unable to account for the number of manufacturing facilities importing into the EU, without consideration to the number of inspections performed.

"Clearly the regulators are not looking where they should be," said Guy Villax, chairman of EFCG's Pharmaceuticals Business Committee, speaking at the 2006 CPhI trade show in Paris.

"This also means that there is no filter to separate the wheat from the chaf, because of course there are some very high quality foreign manufacturers."

Meanwhile, despite the increasing incidence of product recalls, many businesses are still without product recall cover, said Kendall.

This is despite the fact that there are some restrictions on when companies can claim losses back on recall insurance - some product recall insurers will not pay out if the recall is forced on its policyholder by a public body, such as the FDA, or if it does not consider the recall to be essential for health and safety reasons.

Furthermore, failing to act quickly can also create problems for a business when it tries to recoup the cost of a product recall from its insurer, not to mention the legal ramifications.

"The legal costs and compensation paid out can be colossal, so the need to recall quickly is vital and so is insurance cover," said Kendall.

"In addition, there is a fear that, if a company does not have product recall insurance in place, it will not launch a recall and consumers will be put at risk."