

Dealing with a product recall



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Let's face it, things rarely run smoothly all of the time – and that's even true in the pharmaceutical industry! Thanks to changes in technology, product developments and good old human error, problems crop up. And though it doesn't happen very often, one of the problems we sometimes need to deal with is product recall – where the manufacturer or a governing body, such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, asks for a particular batch or all of a certain product to be returned to the manufacturer because the safety, quality or efficacy of a distributed product may be compromised.

There are several reasons why a product can be recalled – possibly a patient has had an adverse reaction; it's been found that the formulation is incorrect; the product has poor stability or appearance; or maybe the packaging is wrong.

Rest assured that there were very few recalled products in the UK in 2004 – less than one a month. But however infrequent, it's still useful to know how you can play your part in ensuring the correct procedures are followed when it does happen.

Durbin PLC is a British company based in South Harrow, London. Established in 1963, the company specialises in supplying quality assured pharmaceuticals, medical equipment and consumable supplies to healthcare professionals and aid agencies in over 145 countries. As well as reacting rapidly to emergency situations, Durbin PLC responds to healthcare supply needs from local project level to national scale programmes.

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If you have bought your products from a reliable company, they will have excellent 'batch traceability' procedures. Their records will show exactly what they have supplied to whom. They can then contact each and every one of their customers who have received that batch of the recalled product.

In the UK, a product recall is categorised classes 1 to 4. A Class 1 recall is known as an 'urgent recall' where the situation involves potential risk to patients and it means your supplier must take immediate action regardless of the time of day or night – one recent example involved Durbin's Responsible Person calling overseas customers from 4am! A Class 2 recall means your supplier must respond within 48 hours. A Class 3 recall requires action to be taken within five days. A Class 4 recall simply means your supplier needs to inform you that the product has been categorised as 'caution in use' – for example, the packaging colour or font size of the wording on the blister pack may be slightly different.

A recall can also be 'restricted', which means that your supplier will only inform healthcare professionals, such as wholesalers, retail pharmacists, hospitals, clinics, dispensing doctors – in this case, the public, the media and the patients are not involved.

So, the first you're likely to hear about a product recall is when your supplier telephones with the details of the product or batch number. He or she will ask you to confirm how many packs are

in your possession and request that you hold on to this remaining stock. The next step is that you are sent written confirmation of the defective goods. You may then need to return the products, and your supplier will verify and record the quantity before transferring the product to his quarantine area. A Quality Incident report is prepared by the company's Responsible Person and the goods are returned to the manufacturer who dispose of the product under strict controls.

This may all sound like a lot of hassle, but at least if you buy from a reliable company credit notes are issued for the full amount lost so you are not liable for the cost. And at the end of the day, the patient's safety comes first. ■



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