Good Pallet Practice – Product Recalls Highlight Need for Clearer Guidance

Many countries have legislation that requires pharmaceutical and medical device companies to follow Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) guidelines to ensure the proper production and distribution of medicinal products for human use. In Europe, the EU GDP guidelines (94/C 63/03) offer companies guidance on personnel, documentation, premises and equipment, deliveries to customers, returns and self-inspections. Guidelines fail, however, to address one key element in the distribution process: the use of pallets.

Pallets play a vitally important role in the pharmaceutical supply chain, transporting virtually all medicinal products from manufacturers to wholesalers and pharmacies. The majority of drug companies still use wooden pallets; some remain loyal to the humble wooden pallet through tradition, others due to the cost of switching to an alternative. This trend could be set to change, however: A series of incidents where pharmaceutical manufacturers have been forced to recall contaminated products has put a big question mark over the safety of using wooden pallets to distribute medicinal goods.

According to the US Food and Drug Administration (FDA) website,1 wood pallets were first identified as a likely cause of product contamination in January 2010, when Johnson & Johnson recalled certain lots of over-the-counter (OTC) drugs, including all Tylenol Arthritis Pain Caplet 100 count bottles in the USA, UAE and Fiji, and a further 26 product lots of OTC tablets, including Benadryl and Motrin, in June and July the same year. The recalls stem from an investigation of consumer reports of an unusual mouldy odour which caused gastrointestinal illness including nausea, vomiting and diarrhoea.

Also in June 2010, speciality pharmaceutical company Depomed recalled 52 lots of its diabetes drug Glumetza2 following similar customer complaints. Pfizer then became the third drug company to follow suit when it recalled a total of 360,000 bottles of its cholesterol-lowering drug Lipitor3 in August, October and December. Subsequent recalls by Johnson & Johnson, including three incidents in 2011, are thought to have cost the company approximately $900 million in one year alone.

The UK has not escaped the contamination issues. In May 2011, Johnson & Johnson’s manufacturing quality lapsed again, when it recalled at least 11,700 bottles of HIV/AIDS drug Prezista4 in several countries including the UK, Ireland, Germany, Austria and Canada, following consumer reports of a musty odour.

Wood Pallet Contamination
According to scientific tests, the cause of contamination was a chemical called ‘2,4,6-tribromoanisole’ or TBA, which is caused by the breakdown of another chemical, ‘tribromophenol’ or TBP, which is used in some countries by wooden pallet manufacturers both as a wood preservative and flame retardant.

Insufficiently dried wooden pallets exposed to high levels of humidity are susceptible to fungal growth which can result in the biomethylation of TBP to TBA. To avoid fungal growth, the moisture content in wooden pallets must not exceed 13 per cent; otherwise they become the perfect breeding ground for potentially harmful bacteria. Storing wooden pallets outside in wet or humid conditions and poor ventilation in warehouses can both contribute to fungal growth.

TBA is a highly volatile chemical and is most commonly detected by a mouldy, musty odour. Traces of TBA were found on the product packaging in each of the recall incidents highlighted, suggesting that the wooden pallets the products were transported and stored on were to blame for the contamination.

The National Wooden Pallet and Container Association (NWPCA) maintains that wooden pallets are a safe method for transporting pharmaceutical goods, but these three recent incidents suggest otherwise.

Next Steps for Manufacturers
Product recalls can have a significant financial impact – as a consequence of the withdrawn product and potential legal implications – and can seriously damage a company’s reputation.

What happens next is down to the pharmaceutical companies. One solution could be demanding that wooden pallet manufacturers provide certification to validate that the wood is not tainted with TBA. With new pallets this is simple, as the pallet supplier needs only to request certification from the sawmill. But if the pallet is recycled or resold, it is much more difficult, as there is no way of knowing whether the wood used in its production was treated by the chemical TBP.

What is certain is that drug manufacturers will need to take action if they want to prevent such recall incidents occurring in the future. Pfizer has reportedly promised to switch from wooden to moulded plastic pallets to solve the contamination issue.5 Over the next year, it will be interesting to see whether other drugmakers will do the same.

Call for Clearer Guidance
In the pharmaceutical industry, manufacturers take great care packaging products to ensure product safety and avoid external influence. However, it appears that less importance is given to choosing the type of pallets the products are distributed on.

1. US Food and Drug Administration (FDA) website
2. Depomed
3. Pfizer
4. Johnson & Johnson
5. Pfizer
The Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03) provide only vague advice on the topic of delivering medicinal products to wholesalers. Under the heading ‘Deliveries to customer’, section 20 states: “Medicinal products should be transported in such a way that: they do not contaminate, and are not contaminated by, other products or materials.”

When selecting which type of pallet to use, there are a number of factors that should be considered and prioritised: material; size; load capacity; strength; handling; application; and frequency of use.

Offering drug manufacturers clearer guidance on the distribution of medicinal products, in particular on the selection and use of pallets, will allow them to make an informed decision and could prevent future product recalls associated with pallet-related contamination.

More than a Drug Problem
New data from scientific tests suggests that it’s not just the pharmaceutical industry that needs to be cautious of the hidden dangers of wooden pallets. In the United States, the safety of wooden pallets for transporting food was recently questioned by consumer advocate The National Consumers League (NCL) following an examination in which wooden pallets tested positive for food-borne pathogens, including E. coli, Salmonella and Listeria. In May 2010, the NCL examined 140 wooden and plastic pallets stored behind grocery stores. Approximately 33 per cent of the wooden pallets showed signs of unsanitary conditions where bacteria could easily grow, and 10 per cent tested positive for E. coli, which can cause food poisoning. Even more alarming is that 2.9 per cent tested positive for the potentially deadly bug Listeria, which causes 2500 illnesses and 500 deaths annually in the United States.

So does this spell the extinction of the humble wooden pallet, and what alternatives are there? Switch to Plastic
The invention of the pallet is a relatively recent innovation, made in the shipping industry, the first one appearing in the United States in the early 20th century. The earliest referenced patent is Howard T. Hallowell’s 1924 ‘Lift Truck Platform’, a simple skid that consisted only of stringers fastened to a top deck. During World War II, the development of the pallet really took off with the increasing need to ship goods and arms. Palletised loads could handle more goods with fewer people, freeing up men for military service. The introduction of the wooden pallet spelled a new era for the shipping industry and it wasn’t long before a standard pallet size was adopted.

Today in Europe, there are approximately half a billion pallets in circulation every year, with 70 million of those in circulation in the UK. The wooden pallet remains dominant, accounting for about 90 per cent of these pallets. Plastic pallets currently make up the other 10 per cent, but with the threat of wooden pallet contamination, plastic pallets could become the saviour of the pharmaceutical supply chain. Hygiene First
My advice to drug companies is simple – put hygiene first and go plastic. If you are using wooden pallets out of habit, perhaps now is the time to re-evaluate your distribution process and consider a safer and more hygienic alternative, like hygienic plastic pallets.

Of course, all plastic pallets are ‘hygienic’ when compared to traditional wooden pallets, but for transporting medicines and other pharmaceutical products, there are many advantages to using the IPS Hygienic pallet. The pallet is made from the highest quality food-grade virgin or recycled materials and complies with EU safety legislation. It has totally smooth, sealed surfaces, unlike wooden pallets, which are susceptible to cross-contamination issues caused by mould and dust. It can be easily cleaned manually or with an automated system, as it doesn’t absorb moisture - even under the most adverse conditions - and is tolerant of weak acids and alkalis. There are no nails, sharp edges or splinters and no risk of loose component parts breaking free under manual lifting conditions.
If concerns over cost have been stopping you from switching from wooden pallets to plastic, it might surprise you to learn that in a normal handling and loading scenario, plastic pallets have a lifespan often exceeding ten years – up to 10 times longer than a wooden pallet. Although the initial investment in plastic pallets is higher, taking into account the extended working life of plastic pallets they are an excellent investment for the future.

Conclusion
The safe delivery of medicinal products from the manufacturer to the wholesaler is something pharmacists, doctors and patients all rely on. Although EU Good Distribution Practice guidance offers basic guidance on the distribution of medicinal products for human use, in its current form it is vague and fails to address the important topic of pallets.

Product contamination issues caused by certain types of pallets could be prevented by offering pharmaceutical manufacturers clearer guidance on the selection and use of pallets in the distribution process. To achieve this, however, manufacturers must be prepared to re-evaluate the use of pallets in the supply chain and put hygiene at the top of their agenda.

References
6. The Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)
7. National Consumers League website: NCL calls on FDA to regulate industry after tests reveal hidden pathogens on pallets used to transport food, 26 May 2010. www.nclnet.org

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