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Rather (child) safe than sorry

Numerous child poisonings are caused by pharmaceuticals. But safety is so easy.

By Dr Rolf Abelmann and Adriana Calabrese

Child resistant packaging (CRP) is used to restrict access of small children to the hazardous content. During the years CRP has been used to package medicine the number of children who have died from poisonings has declined significantly in countries where comprehensive regulations about the use of CRP for pharmaceuticals have been introduced. But internationally, the legal instructions differ a lot in the kind of medicines that must be packed this way. International standards for CRP describe requirements and test procedures to ensure the package is child resistant, also in the eyes of the law. Therefore, a certificate has to be issued by an institute which has been accredited according to EN 45011 to be able to provide legal protection.

Design options and construction

A child resistant package is usually made of a difficult-to-open material or a trick is needed to open the package. The best solution for the design and construction of child proof packaging is to be based around mental abilities. A good approach is having two different actions which are physically undemanding but too complicated for children to work out by accident. Non-reclosable packs such as blister stripes can be made child resistant for example by using very strong but flexible foils or by attaching self-adhesive covers to the foils which have to be peeled off.

In the European Union two standards apply: ISO 8317 (2003) for reclosable child resistant packaging and EN 14375 (2003) for nonreclosable child resistant packaging for pharmaceutical products. In course of the certification procedure, standardized tests for child safe

packaging are conducted with children as well as with senior citizens in order to guarantee their functional reliability and their user friendliness. In South Africa, these standards apply, as well as EN 862 (2005).

Compulsory use of CRP for pharmaceuticals

In the UK, the Medicines (Child Safety) Regulations 2003 requires the use CRP for drugs and medical devices containing aspirin, paracetamol or more than 24mg of elemental iron. It is doubtful whether these instructions are sufficient to ensure child safety, because there are highly dangerous drugs such as blood pressure medication or antibiotics. In Germany (according to section 28 of the German Medicine Act), the Federal Institute for Drugs and Medical Devices has compiled a list of several hundred active agents of drugs that absolutely require child resistant packaging that has been certified according to ISO 8317 or EN 14375 (www.childresistant.org). The legal requirements in the United States published under US 16 CFR § 1700 are even more far-ranging. This law governs the use of child resistant packaging for almost all drugs available on prescription. Evidently, internationally operating companies are confronted with a multitude of country-specific regulations. Thus it is highly recommendable to play safe and use high-quality certified child resistant packaging in order to be sure to fulfil the legal requirements of all countries.

Potential problems

Especially with blister packs, manufacturers are under the misconception of thinking that a specific type of laminated cover foil for blister packs could be certified and that all blisters equipped with this foil are child resistant according to the standards. But there are many aspects that influence child safety of blister packaging: material and size of the cover or formable foil and even different designs of the cavities or tablets inside may affect child resistance of the packaging. Hence, only a complete package can be tested and certified child resistant according to EN 14375. Therefore a new certification is required for every individual new blister design. The same applies to reclosable packaging such as bottles. A specific closure alone is not child resistant and cannot be certified, only a complete package. If a closure for reclosable CRP is used on different container sizes, ISO 8317 permits the certification of a series of closures to reduce the number of test to be conducted. Unfortunately, there are also packages equipped with a closure that may render the risk of a container being opened by a child smaller, but cannot prevent it. Such packages are not child resistant in the legal sense and have not been certified by an authorised body.

It is highly advisable to look into the subject of certified child resistant packaging from the very beginning. Only the use of certified child resistant packaging can provide reliable safety and legal protection against possible indemnity claims. □

Dr Rolf Abelmann is from IVM (Institut VerpackungsMarktforschung) in Brunswick, Germany. The company has more than 30 years of experience in the field of testing and certifying child resistant packaging and is accredited according to EN 45011 as a certification body.

Surviving patent losses

Which strategies can big pharmaceutical companies use to manage the impact of patent protection loss?

Exclusivity is everything in the pharmaceutical brand business. Without it, power over pricing disappears and sales evaporate, leaving drug makers helpless – but can this fate be avoided, asks a new report by GlobalData.

The report considers the looming challenge faced by pharmaceutical giants, namely patent protection losses. Big companies in this arena must either prepare to submit to revenue losses, or adopt methods of managing the impact of brand patent expiry. Strengthening of drug development pipelines, opportune product launches and cost saving initiatives may hold the key to surviving patent losses.

While the birth of a blockbuster drug brings new income and energy to a company, the drug's patent loss causes revenue to drop, leaving the company's financial situation to suffer. Over the next five years, the global pharmaceutical industry will face a $140 billion invasion of generic drugs due to patent protection losses, as in 2011 and 2012 alone, the US is due to see major brands worth $40 billion lose patent protection.

A sizeable portion of a pharmaceutical company's revenue evaporates when a product loses patent protection, as cheap generic copies flood the market. Within a few weeks there is an approximate 70 to 75 per cent switch from branded product to generic equivalent, motivated by an 80 to 85 per cent reduction in price. This results in disaster for the jilted brand, and therefore strategies to offset these losses are essential.

Over time, the pharmaceutical industry has adopted strategies to generate the "evergreen" concept, in which a brand can continue its market performance indefinitely. In reality, no brand can provide revenue forever, but GlobalData has analysed the strategies most usually adopted by the industry which pave a way for revenue to be extended.

These strategies include the development of formulation improvements, which allow a basic drug formula to be remarketed as a unique product. The 'chiral switch' is one strategy that pharmaceutical companies adopt, inventing 'chiral compounds' which are mirror images of existing drugs, exhibiting similar chemical properties, but performing significantly different biological activities.

Existing medications can also be improved upon by developing once-daily, or extended-release formulations. Alternatively, product extensions can use the drug to treat different indications. Lastly, moving a drug within the consumer marketplace from prescription (Rx) to Over-the-Counter (OTC) status allows companies to direct products going off-patent to more accessible use, spurring sales.

Such methods of brand promotion must be used and perfected in order for pharmaceutical giants to survive the incoming influx of generic medications, as the loss of patent protection forces the industry to step up the competition. □