Child Resistant Packaging (CRP) for Pharmaceutical Products

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Every year toddlers and young children are hospitalised or die through the ingestion of pharmaceutical products. The packaging is the last defence against this and so must be as well designed as possible. So what happens when a package is designed and then manufactured? Well, it must then be tested in accordance with the child safety legislation in existence.

The international standards for child resistant packaging lay down the features and tests it has to pass through in order to be deemed child resistant. Packaging manufacturers and manufacturers of pharmaceutical products should prove their packaging is in accordance with these standards and that it fulfils the existing provisions by a testing and certification process. But note only an institute which has been accredited as a certification body according to EN 45011 has permission to issue these certificates. Only accredited certification bodies (www.ivm-childsafe.com) are allowed to conduct the necessary tests and certify packages that meet the standards and can thus provide reliable certification and legal protection assistance.

THE CURRENT SITIUATION

Unfortunately there are still many dangerous pharmaceutical substances that are packaged in non-child resistant packaging and are far too easy for a small curious child to gain access to. Or are packaged in child resistant packaging that has not been put to the test and certified. There is also the situation that in some countries there are toxic substances that are beyond the scope of the legislation created by the law makers but to a learned medical professional would make absolute common sense to be in child resistant packaging.

There is the reliable push and turn design mechanism, which it cannot be argued, has prevented the injury and death of many children since its inception. But now we see many differing delivery methods and how do we know the effectiveness of these when considering child resistance. We now see transdermal patches, self-injection sticks, single doesage pouches/sachets, ampules, vials and inhalers. In the last decade one unit dose packaging has become increasingly popular with manufactures as it helps to reduce dispensing errors and consumption over dosages.

There are different kinds of child resistance features for pharmaceuticals. A child resistant package either is made of a difficult-to-open material or a trick is needed to open the package. The ideal solution for the design and construction of child resistant packaging is to be based around mental abilities, not only physical ones. The focus should be on having two actions required for opening but are too complicated for children to work out by accident. But not only re-closable containers such as bottles can be equipped with a child safety device, here then comes the difficulty for non-re-closable packs such as blister stripes. Their level of child resistance can be increased, for example by using very strong, but at the same time flexible foils or by attaching self-adhesive covers to the foils which have to be peeled off in order to get the pill, commonly known as peel and push.

STANDARDS

The mere existence of a child resistant opening mechanism on a bottle, blister, etc. does not mean that it is automatically child resistant. International standards for CRP have been legislated defining the requirements a packaging has to fulfil in order to prove the proper functioning of the child safety device. In the European Union two main standards apply: ISO 8317 (2003) for reclosable child resistant packaging and EN 14375 (2003) for non-reclosable child resistant packaging for pharmaceutical products. These standards mark quality standards for child resistant packaging and, at the same time, represent the only commonly accepted possibility to prove child safety of packaging. It is therefore desirable for the whole pharmaceutical industry, be it bottlers and packaging manufacturers or pharmaceutical producers, to have harmonised standards.

For blister packs, it is important to define when the package is to be considered as opened. EN 14375 lays down that a blister pack is to be considered opened during tests with children when they were able to remove more than eight units (provided that the blister has more than eight cavities, if not, at least 10 units will be provided for the test). Clearly it is highly dangerous however to define a package as opened if the testing person could remove more than eight units, because there are obviously many drugs that are very dangerous to infants even if they swallow far less than eight units.

US requirements according to US 16 CFR § 1700.20 say that the definition of "opened" (that is the number of units removed) depends on the degree of dangerousness of the active ingredient (degree of toxicity). The described testing procedures are in accordance with the standards for child resistant packaging and are conducted by certification bodies which have been accredited as such according to EN 45011 and which thus have permission to certify the conformity of the pack in question with the existing standards.

It is important to appeal to pharmaceutical producers as well as to packaging manufacturers to treat the subject of child resistant packaging with the necessary sense of responsibility, because the children's safety is in their hands.

The use of certified child resistant packaging can provide reliable safety and assistance in legal protection against possible indemnity claims in case of accidents. Despite the legal differences concerning the type of medicine and the ingredients that require child resistant packaging, the standards for child resistant packaging for pharmaceuticals, ISO 8317 and EN 14375 are widely accepted, acknowledged and appreciated in most countries. When getting a package certified, it is important not to forget about the American standards, it might turn out handy and far less expensive to get a package certified according to both provisions. For questions about the certification of CRP and the acceptance in Europe and the United States, ivm Childsafe can provide impartial and informative information.

NEXT STEPS

For creative and intelligent approaches to re-closable, as well as non-reclosable child resistant packaging, the chances of becoming a success, if put into practice in good time are good. It is therefore highly advisable to look into the subject of certified child resistant packaging from the very beginning, especially in the early steps of product development. The ivm Childsafe has been accredited according to EN 45011 as a certification body. Certified CRP by an accredited certification body, child resistance is not only an indispensable safeguard for drugs and medicines; it is also a key argument in modern packaging marketing strategies.

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