

Keeping our children safe

An estimated 100,000 accidental child poisonings, primarily from pharmaceutical products, occur in Germany every year. And small children up to three years old are the most likely to be affected. Dr Rolf Abelmann, managing director of ivm Childsafe, outlines the role child-resistant packaging must play in rectifying this problem

Child-resistant packaging, representing the last barrier, as it were, between the infant and the packaged content, has an important part to play in solving the problem. Although the industry's awareness of this type of safety packaging has increased, knowledge about differences and subtleties is often lacking.

Independent of the child-resistant packaging's system and material, a review of the safety function is necessary to ensure that it works correctly before being put to use. A standardised certification procedure can bring about clarity; it can vouchsafe the packaging's quality and product safety at that time. There is not just one type of child-resistant packaging.

Legal framework

In Europe, such packaging certification of pharmaceutical products is done in compliance with the ISO 8317 for reclosable and EN 14375 for non-reclosable packages. Tests are conducted with the two target groups in question – small children between 42-51 months, and senior citizen between 50-70 years – and serve as a basis for this certification. In international comparison, the US was the first country to create standards that made child-resistant packaging mandatory for the vast majority of drugs more than 35 years ago.

Today, comparable requirements and standards are in place in Germany as well as internationally. The company bringing the product to market bears the responsibility of compliance with these norms and standards. There is a sound reasoning behind this, because it's always the entire product that is being certified, not the individual components.

In the development of child-resistant packaging, it is important to create hurdles that are difficult for children to overcome, but easy enough for senior citizens to solve and operate. To get this balance right, appropriate packaging concepts are based on the following skills: motor, fine motor skills, logic, experience, patience and intuition. A basic distinction is made between reclosable and non-reclosable child-resistant packaging.

Reclosable child resistant packaging can be closed again in a child-resistant way after opening and removing part of the contents. Many systems are based on an opening trick that is not known to toddlers and also very challenging for their level of motor co-ordination. The most well-known examples are types of packaging with a screw-on cap, which can be opened only by pushing down and turning simultaneously.

With non-reclosable child-resistant packaging, the units are individually packaged and removed. Their best-known forms are pharmaceutical blisters with individually wrapped pills or tablets.

Testing the function

Child-resistant packaging's functionality must be tested in order to be described as child-resistant. For example, a safety mechanism based on the "push and turn" principle is no evidence that the opening and the removal of the contents by small children is really prevented.

It often happens that safety mechanisms are designed to be technically complex and include the interaction of different factors to prevent opening by small children, but still fail in practical use.



Dr Rolf Abelmann

There are international standards and test procedures to check the function and to assess whether a package can rightly be called child-resistant.

In testing on pharmaceutical packaging in Europe, where it is conducted in compliance with standards ISO 8317 and EN 14375, in order to test child-resistance, up to 200 infants aged 42-51 months will be asked twice to open the package for a five minute period. Prior to the second test period there is a single demonstration of the opening procedure without further explanation. The packs are filled with neutral and non-hazardous substances, like for example water or placebos.

The certification requirements are fulfilled if, within the first five minutes, no more than 15% of the children manage to open the package and no more than 20% access the contents of the package throughout the entire 10min period.

The prescribed age of the infants is significantly higher than the highest risk group for poisoning accidents, namely children under the age of 36 months, thereby providing additional risk reduction.

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