Child-resistant Packaging Laws are becoming More Restrictive

Throughout the world, we are getting more and more used to the "push and turn" and "squeeze and turn" functions of many household products. It has been noticed that drug manufacturers and packagers in both Europe and in the US over time are met with far-reaching regulations with regard to ensuring that drugs are packed in a manner that effectively protects the welfare and safety of children.

Child-resistant (CR) packaging for many prescription drugs (PD) - for both solid dosages and liquid formulations - has been mandatory for many years; however during the last years there has also been a trend moving towards CR packaging for over-the-counter (OTC) products.

With the still increasing consumption of medicines, there is a growing market for OTC products. Today an ordinary household keeps many different drugs, and thereby the exposure towards children is increased significantly.

Industry has shown that reasons for using CR packaging for OTC products are not only regulative. The constant focus on children's safety and prevention of serious accidents seems to play a crucial role when choosing primary plastic pharmaceutical packaging. In general, statistics show that suicide attempts among children have decreased, but unfortunately it also shows that children overdose more on medication use, i.e. a product like vitamins is the cause of children dying of overdoses because they unintentionally eat too many vitamins. In addition to safer storage at home, the solution could be to use CR packaging for vitamins.

However regulations, recommendations, and common practice differ from country to country and from customer to customer.

It is difficult to ignore senior-friendliness when talking about child-resistance, as these do not go hand in hand. The difficulty has always been to balance proper protection and ease of use. Recognising that the older population will be high over the coming decades, and at the same time more and more comprehensive standards for drug packaging are formulated, I consider that the design of the CR function is a fit subject for discussion. In the future the well-known and well-incorporated "push/squeeze and turn" moves will, to a greater extent, be accompanied by other designs which allow seniors and people with limited dexterity to better open and close the packaging.

Opposite, or in addition to, children's safety organisations, the interests of the aging population are also represented. Associations promoting societies without age barriers and ageism are also very active when it comes to pharmaceutical packaging. They argue that there are more pensioners than teenagers, so their plea is to focus on pharmaceutical packaging with opening procedure properties which offer good patient adherence.

Different institutions, such as Swedish Apoteket, are recognising the development of innovative packaging solutions with the prize for "Best Drug Packaging". In 2002 the development of the innovative Duma® Multi-Grip Cap, which is designed for people with disabilities and influences the capability of administering self-medication in various ways, was honoured.

Drug manufacturers and packagers want patients to get best value from their products in terms of health outcomes and safe use. As the packaging design has a key

contribution to this we, as a supplier of pharmaceutical plastic packaging, want to establish a co-creating process with our customers with the aim of creating preference for their products.

Lately we have become aware of the recommendation from the United States Consumer Product Safety Commission (CPSC) to make it mandatory to use CR packaging for all OTC and PD products containing more than 0.08mg of imidazoline-group substances in a single package. Imidazolines (tetrahydrozoline, naphazoline, oxymetazoline and xylometazoline) are a family of drugs that are vasoconstrictors indicated for ophthalmic irritation and/or nasal congestion.

According to CPSC, imidazolines can cause serious adverse reactions, such as central nervous system (CNS) depression, decreased heart rate and depressed ventilation in children treated with these drugs, or who accidentally ingest them.

The notice of proposed rulemaking requiring CR packaging for imidazolines is dated January this year, and it has already resulted in a lot of activity at the Gerresheimer site, which is manufacturing dropper bottle systems, nebulisers and nasal sprays.

This action is taken under the Poison Prevention Packaging Act (PPPA) of 1970.

Assuming the CPSC's proposed rule is made final, shortly thereafter, drug manufacturers and packagers using more than 0.08mg of imidazolines are obliged to change their primary packaging. Although no decision has been made yet, some of our customers in the human and animal health industries have already decided to change to CR packaging. Regulations on this area are anticipated – "it is just a matter of time", they predict.

And time can become the big issue. CPSC proposes a one-year implementation period after the effective date of the final rule. On behalf of the pharmaceutical industry, the Consumer Healthcare Products Association (CHPA) requested an extension to child-resistant imidazolines product packaging. The CHPA argues that drug manufacturers and packers need at least two years to design, develop and test child-resistant packaging to ensure continued consumer access to eye drops, nasal decongestants and other products with imidazoline ingredients.

The marketplace for primary packaging is not well represented with standard child-resistant packaging solutions for this type of product, and therefore design development is most likely to be done. Few suppliers of ophthalmic primary plastic packaging have standard CR solutions or CR closures which can be adapted to the customers' existing bottles.

Despite the best case of adapting an existing standard CR closure to the bottles already used, our experience is that such a change still requires a relatively long implementation period. In this line of business, many aspects must be considered to meet the stringent market demands of today and tomorrow!

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