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As physicians become more reliant on prescribing medications to treat illness instead of advocating preventive measures, the risks associated with accidental medication poisonings is increasing. In the UK, approximately 50%¹ of our population take prescription medicine whilst in the US the figure is over 60%². These figures are not quoted to in any way reflect on cases genuinely requiring prescription medication, they do however provide an insight into the volume of medicines in circulation and with this, the scale of potential risk to children. Poison centres in the US treat between 60,000 and 70,000 children each year for accidental ingestion.

Advancements in [packaging technology](#) such as soluble packs, films etc are undoubtedly to be viewed as a progression, it is questionable however whether there is a parallel effort in creating the child resistant packaging necessary to ensure these products are safe for the environments they occupy. Whilst Mercola³ reports that pain medications are the single most frequent cause of fatalities from accidental medication poisonings in children, household products still present an alarming number of ingestion cases. In medicine terms the category of substances with the largest number of deaths across all ages (including intentional use of opioids in teens), are medications containing acetaminophen, sedatives, sleeping medications, stimulants, and cardiovascular drugs. In terms of household products the most common issue is becoming the soluble-packed alkaline detergents.

There is an abundance of information and even some creative solutions available to the **packaging industry**, with the ease of access to online information manufacturers are able to appraise themselves in consumer and regulatory concerns and safety is no exception. There is however possibly a lack of understanding what truly constitutes child-resistant packaging and also a preparedness to await regulatory obligation before introducing protection.



One question we hear raised from time to time is whether the effectiveness of some of the conventional child resistant packaging of today is to be assumed appropriate for today's world. Some of the established institutions will feel strongly that it is, however it is arguable whether the combined impact of freedom of information, intelligence of today's children, and the tragic increase in cases of diminished responsibility are effectively measured.

Non-medicine packaging

Whilst Origin's work of over 50 years has revolved largely around medicine packaging and drug delivery devices, there is perhaps a sharper increase in casualties from the non-medicine product categories.

The advance in soluble packaging is an example of a welcomed and convenient technological

development, in our opinion it has been delivered upon with an apparent disregard of the potential harm to children. Soluble dishwasher tablets for example contain aggressive and corrosive alkaline salts. Ingestion of these products is becoming a common occurrence yet apart from warnings printed on the box, there is no physical barrier provided in the packaging to protect children. These often-colourful capsules are attractive to young children as is evidenced in the ingestion cases. How many of us in reality have these accessible to children in our homes? and how many of us have located and read the product information?

Unlike medicines, there are virtually no defined regulations to control the packaging of such products, guidance notes on **packaging** enforce only our impact on the environment but stop short of enforcing child safety values. If this situation continues little is likely to change on commercial scales to develop packaging to reduce these risks, yet without apportioning the burden unfairly, should we really wait for regulations to be imposed to meet the need? Regulation supports good practice and no doubt it will be pronounced on one day, in the meantime we wonder if our moral and ethical obligations are being fairly considered?

Child Resistant is Not Child Proof

An important consideration is the terminology used in matters pertaining to child safety, rarely if ever is packaging child proof. The balance between child resistance and senior accessibility restricts just how far we can restrain children and the senior friendly challenge is something of an interminable debate. Accommodating both aspects in design is a significant challenge, regulating such a conflicting scope is probably harder still.

Child resistance should, according to the ISO8404 Standard (non re-closable) be considered the last line of defence, not the first line. Whatever packaging is developed to meet the fine balance of abilities between children and seniors it should be always remembered that "child resistant" is never "child proof" and therefore the practise of keeping medicines out of sight and reach of children should be mandatory.

There will no doubt exist some interesting papers on child psychology that will substantiate this comment, but the fact is that for all our experience we still tend to underestimate the innocent, inquisitive nature of children. An article by VWA entitled "children see things differently"⁴ gives a simplistic message of how things appear to young children and provides thought-provoking questions about what consideration should be made when designing safety into these packages. Even the bright colours used as a means of retail marketing or shelf impact attract young children in an entirely different way to how they are intended.

Senior Friendly Child Resistance

Accommodating both Senior Friendly and Child Resistant values in design is a significant challenge, whilst regulating such a conflicting scope is probably harder still. In many ways, the senior accessibility aspect is less definable than the child resistance. With children, we have fairly prescribed parameters of ability in the child safe testing age bracket of 42 to 51 months. The scope of abilities present in the adult test panel however of 50 to 70 year olds presents a hugely different picture.

The loss of dexterity and in some cases the ability also to coordinate is often diminished in our latter

years. The key principles required in achieving effective [child resistance](#) are by definition the same principles needed to enable the aging population. As our aging population is also increasing and advances in medicine is enabling us to retain our independence longer, questions could be raised as to whether 70 is still a relevant top end age for the testing protocol.

Storage of Harmful Substances

The storage of medicines and other potentially harmful substances therefore requires a responsible approach. As already stated, child resistance is the last line of defence. The most secure way without doubt to ensure children to not access these products is to ensure they never see them in the first place.

The deliberate misuse of opioid substitute has been the greatest cause of child ingestion of pharmacy-dispensed child medicine ingestions in the UK that have led to actual fatality. It is important to recognise that these tragic instances have rarely (never in our experience) proved to be the result of non-compliant packaging.

A report from Alder Hey hospital, Liverpool⁵ found that of 30 methadone ingestion cases; 22 involved re-closable screw cap bottles and only 2 of these were found to be original and child resistant. Such evidence sadly proves that even compliant packaging cannot be expected to provide the intended protection if medicine is transferred to non-child resistant packaging.

The cause of these breaches in security after police investigation have always proved to be the outcome of diminished responsibility on behalf of the adult. One simple measure that could be enforced easily in our opinion is to provide education to patients using such medication that the product must be stored in the container it was supplied in.

Regulations and Testing

We have effective and well recognised regulations for the safe containment of medicines and the necessity of a common test protocol has long been considered essential for these products. Re-closable packaging to BSEN ISO8317 and its American equivalent, 16CFR 1700.20 are still effective and the 2015 version of the ISO Standard has cleared up some areas of confusion.

To gain approval the complete pack must be tested – container and closure. Whilst many closures are produced to provide child resistance it is not possible to assume that because one pack combination passes another will pass also.

Testing in the UK is carried out at UKAS approved test centres in accordance with the relevant test protocol. Marginal differences apply between the European and US procedures but there is no meaningful difference in our opinion between the two with the exception of the re-securing aspect of the US test 16CFR1700.20

Some test centres provide an expedited 'pre-application' test service providing a smaller test panel for a lower cost (Origin can advise regarding this). The test conditions are as per the protocol and the results helpful in ascertaining whether there are any fundamental issues in the pack design. Successful pre-app tests can usually then be scheduled quickly to full protocol testing if there appear to be no issues. A further benefit from such preliminary testing is that we are able to 'weight' the

test panel to include more or less of certain age brackets to create robust test conditions.

The official test protocol requires 200 able-bodied children between 42 and 51 months and can be carried out either with the full 200 contingent or by a method of sequential testing. For the adult test a panel of 100 is required between the ages of 50 and 70 years.

Compliance – how do I know?

With over 50 years experience in child safe packaging we know there are an increasing number of packs in circulation that cannot be considered child resistant, as might be expected a number of these are imported. Research suggests to us that an assumption is often made that because a cap appears to have a push-and-turn mechanism it must be child resistant, however this is not a wise assumption.

We suggest a common practise should be to ask your supplier for a technical file and certificate of child resistance for the pack you are using. Remember that technically there is no such thing as a "[child resistant cap](#)" as for a pack to be child resistant you should have a certificate which specifies the container and cap.

If your product is sold within the UK and EU then the BSEN ISO8317 certificate is the correct document for your activities. If your product is to be sold in the US you will need the 16CFR1700.20 certificate to comply with the regulations currently in force in the US.

If you require support in design and supporting your packaging formation transition into child safe compliant packaging. Get in touch today with our design team: npd@originltd.com

Further Information

Origin Packaging Limited (originltd.com)
Child Safe Packaging Group (CSPG)
Child Accident Prevention Trust (CAPT)
British Standards Institute (BSI)