

CRITICAL SURVEY ON THE GUIDELINES UNDER RECOMMENDATION OF CHILD RESISTANT PACKAGING FOR PHARMACEUTICAL PRODUCTS

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REVIEW ARTICLE

Singh Sangeeta*, Gupta Manish

School of Pharmacy, Lloyd Institute of Management and Technology
Greater Noida (Delhi/NCR), India.

*Corresponding Author's E-mail: sangeetasingh29@gmail.com

ABSTRACT

Child resistant packaging is an integral part of packaging industry. In order to reduce the risk of poisoning in children due to accidental ingestion of hazardous chemicals like over - the - counter (OTC) medications, household items, pesticides & automobile chemicals, led the US Congress to pass the Poison Prevention Packaging Act of 1970 under the authorship of US Senator Frank E. Moss (Politician).(1)

The introduction of child resistant packaging resulted in considerable drop in the rate of poisoning. Guidelines of various countries helps in preventing forty to eighty percent of childhood poisoning. The World Health Organization & UNICEF states that Child Resistant Packaging is one of the best documented success in preventing poisoning in children.

Keywords: Child resistant packaging, Reclosable, Poison Prevention Packaging Act, BS EN, ISO.

INTRODUCTION

Dr. Henri Breault (1967) invented the safety cap "that couldn't just be opened using anything with thumbs and half a developed brain".(2) Dr. Henri Breault's concept of safety cap was successfully supported by Peter Hedgewick with design "Palm N Turn". The child resistant packaging, thus helps in keeping out little hands of the products like medicines, cleaning products, gardening goods & other household chemicals which could harm them. It also makes sure that adults can still be able to close and open it easily.(3)

According to Poison Prevention Packaging Act (PPPA), the child resistant packaging should be designed or constructed so as to be significantly difficult for children under five years of age to open within a reasonable time, so as to get a toxic effect of substance contained and also not difficult for normal adults to use properly.(4)

The age group for the human performance test is 42 to 51 months, during these tests, 200 children aged 42 to 51 months, had to try and open the package, if 80% are unable to open the package

is considered child resistant. Also adults aged between 50-70 years chosen as 100 volunteers, if 90% of the adults open the package and close it within reasonable time, the package passes the test.(5,6)

Literature

Child resistant packaging was introduced in USA in the year 1970. Due to various types of accidental poisoning after ingestion of automotive, gardening, house hold products as well as medicinal products & other harmful substances, legislation came into existence in the form of poison prevention packaging act which reduces the frequency of accidental poisoning in children.

In order to measure the functional reliability an adult used performance, tests were performed on 200 children in the age group of 42 to 51 months, the package were given to pair of children and given five minutes to try to open the package. If they do not open the package within five minutes, then another five minutes were given to every single child, if not more that 20% of 200 children could open the package, the

package is considered child resistant. To check the product whether they are senior friendly a group of 100 adults aged 50-70 tested individually, they are given five minutes to open and close the package, if 90% of 100 adults could open and close the pack within five minutes, it passes as child resistant pack. (7)

Products Which Require Child Resistant Packaging:

The PPPA allows the Commission to set rules requiring child-resistant packaging for specific types of products customarily used in or around the household if it determines:

- That those products present a risk of serious injury or serious illness to children under five who are able to open the packages of the products and drink, eat, or handle the contents, and
- That technology exists or can be developed to produce child-resistant packaging for such products, that the packaging can be used with modern mass production and assembly techniques, and that the packaging will adequately protect the integrity of the product and not interfere with its intended storage or use.

To date, the Commission has issued rules that require child-resistant packaging for the following types of household products:

1) Chemical and Cosmetic products

- a. The following products that contain 10% or more by weight of petroleum distillates: furniture polish, and kindling and illuminating products such as lighter fluid and lamp oil,
- b. Paint solvents that contain 10% or more by weight of benzene, toluene, xylene, or petroleum distillates;
- c. Dry products such as granules, flakes or powders that contain 10% or more by weight of sodium or potassium hydroxide, and all other products containing 2% or more of these chemicals;
- d. Liquid products containing 4% or more by weight of methyl alcohol;
- e. Liquid products containing 10% or more by weight of turpentine;
- f. Products containing 10% or more by weight

- of sulfuric acid;
- g. Liquid products containing 10% or more by weight of ethylene glycol;
- h. Liquid home permanent wave neutralizers that contain more than 600 mg of sodium bromate or more than 50 mg of potassium bromate;
- i. Liquid glue removers containing more than 500 mg of acetonitrile;
- j. Liquid products containing more than 5% methacrylic acid on a weight to volume basis;
- k. Products containing more than 50 mg of elemental fluoride in a concentration that is more than 0.5% on a weight-to-volume basis for liquids and a weight-to-weight basis for solid products.

Please note that drugs and dietary supplements that meet these specifications also require child resistant packaging;

2) Mouthwash products containing 3 grams or more of ethanol. Please note that mouthwashes that are drugs and that have 3 grams or more ethanol also require child-resistant packaging.

3) Drugs and dietary supplements

- a. The following products for human use that are intended to be taken orally: aspirin; prescription and controlled drugs; products containing more than 1 gram of acetaminophen, products containing 1 gram or more of ibuprofen; products containing more than the equivalent of 66 mg of diphenhydramine base; and products containing more than 0.045 mg of loperamide;
- b. Liquid products containing more than 5% methyl salicylate;
- c. Products containing 250 mg. or more of elemental iron in a concentration of 0.025% or more on a weight-to-volume basis for liquids and 0.05% on a weight-to-weight basis for non-liquids;
- d. Products containing more than 5 mg of lidocaine or 0.5 mg of dibucaine;
- e. Products for human use containing 250 mg or more of naproxen, or more than 50 mg of ketoprofen;
- f. Products containing fluoride and mouthwash containing ethanol. (See the description above.);

g. Products for human use containing more than 14 mg minoxidil.(8)

The packaging instructions should also have tips like “hazardous chemical like medicine, pesticides, house hold cleaning items, paint, automobile chemical in their original packaging, beyond reach of child. Regarding medicine they should be kept into their packaging containers with safety cap on.

International Standards

International Standards are applicable to both reclosable & non-reclosable packaging and marketing; authorization holders are required to demonstrate compliance with these standards.

Reclosable packaging consists of container-closure system which when the closure is removed allow access to more than one dosage unit and which can be reassemble to form a child resistant pack. The performance of these containers must comply with BS EN ISO 8317.

Non-reclosable containers are container-closure system which when opened cannot be reassemble to form a child resistant package. Blister packs come into this category. Such non-reclosable packs must be tested to demonstrate compliance with BS EN 14735.

The British Standard Institute produced a consumer guide to child resistant packaging and the standards which commands the development and overview of the standards for the child resistant packaging.(9)

Guidelines of various countries on Child Resistant Packaging:

Child resistant packaging is regulated by most of the government in the world, although each country has their own regulations, there is different view on child resistant packaging among the countries but the aim of all regulation is quite similar. The essence behind the different regulations and the guidelines is that a child resistant package must pass test of:

- a) a child test
- b) a senior adult test.

Child Resistant Packaging in Countries:

India

The Indian Standard for child resistant packaging is IS 14233 (1995) is similar to BS 7236:1989, and applicable to strip and blister packaging. The test is performed mechanically. The children are not subjected to test for packaging.(10)

Japan

There is no guideline as far as child resistant packaging is concerned. The pharma company packs the pharmaceutical products in protective way to make it safe for children.(11)

Australia

For the reclosable packages, the performance guidelines are based on compliance with the type testing requirements of at least one of the following standards:

- ISO 8317:2003, entitled child resistant packaging requirement and testing procedure for reclosable packages (as amended by technical corrigendum issued in January 2005:ISO 8317:2003 /Cor1.2005, child resistant packaging - requirement and testing procedure for reclosable packages technical corrigendum;
- The British Standards Institution, Standard BS EN ISO 8317:2004, entitled child resistant packaging, requirement and testing procedure of for reclosable packages.
- The Canadian Standards Association CSA – Z76.1 – 99. Entitled reclosable child resistant packages;
- The Unites States Code of Federal Regulations, title 16, part 1700, section [(1700)]15 entitled poison prevention packaging standard and title 16, part 1700, section [1700.]20, entitled testing procedure for special packaging.
- The Australian Standard AS 1928 – 2007, entitled child resistant packaging - requirement and testing procedures for reclosable packages (ISO_8317:2003MOD). (12)

Although there is minute difference between the standards from the different organizations, the parameters like child group test, age of children, passing the test limit & adult test, like ages of the adult and passing the test limit are consistent.

Therefore compliance of any of the above said standards provide equal assurance that a package, when test for type according to any standard meets required level of child acceptance and ease of use for the grownups.(13)

New-Zealand

The New-Zealand standard for child resistant packages refers to numbers of other standards as being equivalent for compliance purpose “provided the child resistant packaging conforms with the test regimes of any standard recognized as being equivalent by NZS 5825:1991, it will be acceptable as a means of compliance for the purpose of these code”.

The standards followed by NZS 5825:1991 are:

- ISO 8317:1989 (International)
- AS 1928:1989 (Australia)
- BS EN 28317:1993 (UK)
- CAN/CSA-Z76.1-M89 (CANADA)
- DIN 55 559:1980 (Germany)
- US [Poison Prevention Packaging Act of 1970 regulations part 1700 (USA)]

Performance test in general is performed on 200 children aged from 42 to 51 months, and 100 adults between the ages 50 to 70 (including people with disabilities), at least 85 percent of the children must be unable to open the container within five minutes and at least 80 percent of the children must not open the container with in five minute following a non verbal demonstration of how to open a container. For adults, at least 90 percent must be able to open the containers (standard New Zealand 1991).(14)

United Kingdom

Child resistant reclosable packs were first introduced in to the UK in mid 1970s. In the UK, non-reclosable child resistant packs were slow to emerge being standardized only in 2001. To be child resistant, a pack must comply with one of the following standards:

- BS EN ISO 8317.2004, an International Standard, which covers reclosable packaging for any content.

- BS EN 14375:2003, European Standard which covers non-reclosable packaging for medicines.
- BS EN 862:2005 European Standard, which covers non-reclosable packaging for non-medicines.
- 16 CFR 1700.20, an American Regulation, which covers both reclosable and non-reclosable packaging for both medicines and non-medicines. This regulation is mandatory in United States and has been adopted by a number of other countries.(15)

Unites States

Child resistant packaging came about in 1970, when the US enacted the Poison Prevention Packaging Act (PPPA). Originally developed to prevent children from ingesting any hazardous household products, lawmakers first applied the PPPA to drugs in 1972. Originally applied to aspirin, the law has since expanded to include other drugs as well. Child poisoning decreased significantly after the law become active.

According to PPPA, “the term “special packaging” means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or to obtain a toxic or harmful amount of substances contained therein within a reasonable time and not difficult for normal adult to use properly, but does not mean packaging which all such children cannot open or obtain toxic or harmful amount within a reasonable time”.

American Regulation published under US 16 CFR II 1700.20 and many other countries follow similar established standards.

- EN ISO 8317 : 2004:It is the international standard for reclosable child resistant packaging and it applies to pharmaceutical as well as to chemical products.(16)
- EN 862 (2005): It is equivalent to DIN EN 862 (2006) – is the international standard for non-reclosable child resistant packaging for non-pharmaceutical products. Non – reclosable means that the whole content is used all at once; the child safety mechanism cannot be reconstructed.(17)
- EN 14375 (2003): It is equivalent to DIN EN 14375 (2004) – is the European Standard for non – reclosable packages for the

pharmaceutical products. This standard is specially relevant for blister packs, stick packs & granule bags.(18)

Briefing

The selection of exact child resistant packaging depends entirely on the sponsor, if reclosable Child Resistant Packaging is used, it must comply with at least one of the national or international standards and the sponsors must satisfy themselves and must hold all the record that establishes this. If non-reclosable packaging such as blister or foil strips are used they must also comply with requirements of any national or international guideline of any country.

General Guideline for Safety Regarding Accidental Poisoning

- Always store chemicals in their original container,
- Dispose of unwanted medicines and chemicals safely,
- Whereas possible always by product in child resistant container,
- Keep medicines and chemicals out of reach of children,
- Always keep medicines and chemicals in lock cupboards.

SUMMARY

Standards play a very important role in the regulatory process and regulation is a powerful tool to reduce the toll of child accident. Enforcement of regulation relies on market surveillance by the national authorities therefore; co-operation has to be coordinated between the regulation commission and the enforcement officials. Even though all the solution provided by child resistant packaging, CRP is last measure of whole range of protective measures but they do not assume the responsibility of parents and the guardians, it is still their duty to store pharmaceuticals out of reach of the children.

CONCLUSION

- CRP doesn't offer a complete protection, it is only one of a number of strategies aimed at preventing children from poisoning themselves, its purpose is primarily to slow down but not to necessarily stop, full access

by a child to a toxic substance.

- The tests of child resistant packaging are not scientifically based therefore mechanical tests methods are to be introduced.
- Although child resistant packaging reduced accidental ingestion of hazardous chemicals but it is proven to present difficulty to the elderly.
- Children Protection is important for medicinal products but accessibility by elderly people is equally important.
- Consumer groups have responsibility to the Younger's as well as the elders.

Recommendations

Child resistant standard is not scientifically based, therefore; more studies required on mechanical test methods.

Difficulties to the elderly while handling child resistant packaging is to be considered specially for the adults with disabilities.

A single harmonized system for all the regulatory guidelines should be established and followed by each and every country.

ACKNOWLEDGEMENT

I express my gratitude to my guide Dr. Manish Kumar Gupta for helping me in writing this manuscript.

CONFLICTS OF INTEREST

Author declares that there are no conflict of interest in this work.

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