

New Standards and Regulations for Child Resistant Packaging of Pharmaceutical Products

Outline of Presentation

- Definition
- History of CR Pharmaceutical Packaging
- Countries with Standards and Legislation for CR Pharmaceutical Packaging
- Experience with CR Packaging
- Some HASS data

Outline (continued)

- Reclosable and Non Reclosable CR Packaging
- The actual Situation in the UK
- The Test Method
- Type Testing
- Mechanical Testing
- Conclusions

Definition

- „Packaging designed and constructed to be difficult for young children to open within a reasonable time and that is not difficult for adults to use properly“.

Source: Guidance on Compliance with the Medicines (Child Safety), Regulation 2003, MHRA; John Trepper, VP Perrit Labs „Blister Packaging and Harmonisation“ May 2000

The History

The Idea of Child Resistant Packaging started in the USA:

⇒ Code of Federal Regulations Part 1700 to 1750
Subchapter E - **POISON PREVENTION**

PACKAGING ACT

1970 Regulations

⇒ Introduces the **Concept of Child Panel Testing**

Adult Test Panel

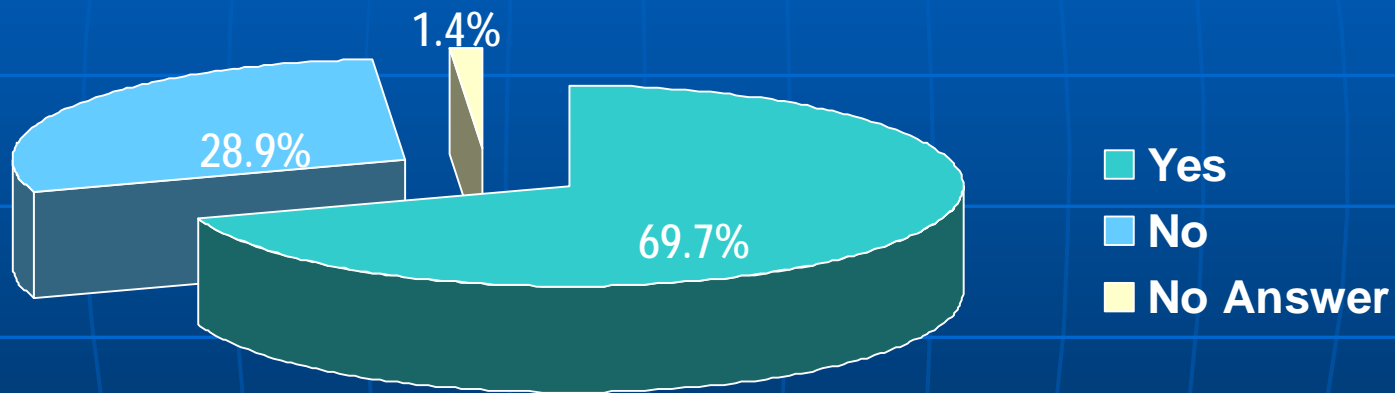
⇒ **Liability driven**

Countries with Standards and Legislation for Pharmaceutical CR Packaging

- United States of America 1970
- United Kingdom, BS 7236 CoP 1975
- Canada 1979
- Germany, DIN 55559 1979
- Italy (Regulation only, no Std) 1984
- Australia 1985
- Netherlands, following DIN 1985
- UK, BS 8404 2003

Experience with CR Packaging

Do you, yourself have trouble opening child-resistant packages?



Almost 70% have trouble opening child-resistant packages.
Source: „Packaging“ USA, June 1990

Experience with CR Packaging (Continued)

Difficulty in opening:

- Young Parent 51.5%
- Middle aged parent 68.0%
- Working older Couple 78.3%
- Retired older Couple 82.2%

Resulted in older adult test panel (50 to 70 years old) initially 18 to 45 years old, changed in the late 80ies

Source: „Packaging“ USA, June 1990

Some HASS Data 1

1995 total suspected accidental poisonings of children less than 5 years of age, in total 1776:

■ Pharmaceuticals involved	988	55.6%
■ Original or disp. Pack inv.	963	54.2%
■ Number involving solids	534	30.0%
■ Number involv. liquids	429	24.2%

Some HASS Data 2

Solids

- Recloseables

CR	33	1.9%
non CR	8	0.45%
CR ?	65	3.7%
Σ	106	6 %

- Non-Recloseable

CR	0	
non CR	1	0.06%
CR ?	78	4.4%
Σ	79	4.4%

Solids with no pack data

329 18.5%

HASS Data (Continued)

■ Liquids in Reclosables	CR	173	9.7%
	non CR	12	0.7%
	CR ?	244	13.7%

HASS Data (continued)

PAGB (Pharmaceutical Association of Great Britain) has monitored HASS data for many years and found:

Suspected child poisonings declined consistently from 1982 – 1998

- By 33% for all children
- By > 50% for those under 5 years of age,
- While over this period the percentage of non reclosable pharmaceutical packs increased significantly.

Reclosables and Non - Reclosables

- Standard for Reclosables
BS EN 28317:1993
due for revision 2004
- Standard for Non Reclosables
BS 8404:2001
EN 14375:2003

Reclosable and Non Reclosable Packs for Pharmaceutical Products

- In Europe more than 80% of all Solids are packed in Non Reclosable Packages (Blisters)

Main Reasons:

- High level of protection of each individual unit – longer shelf life
- Patient Compliance
- Hygiene
- **Only one dose available at a time**

The actual Situation in the UK

Non Reclosables

- Compliance with BS 8404 required.
 - ⇒for all medicines containing Aspirine, Paracetamol, more than 24 mg of elemental Iron
 - ⇒for existing MA DIN compliant materials acceptable, Adult Test required to be carried out before April 2005 + Stab. + Licence Variation.
 - ⇒for new MA DIN compliant materials acceptable, Adult Test required before application for MA

The Actual Situation in the UK (Continued)

Reclosables

- BS 6652 obsolete
- Compliance with BS EN 28317 (2004) will be required by Oct.2005
- In the Interim compliance with ISO 8317 required

The Test Method

- Sequential: 200 children max. age 42 to 50 month
50% male, 50% female
Groups of two children
5 minutes with instruction only
5 minutes with demonstration

Test Panel	Cumulative number of children	Package Openings					
		First 5 Minutes			Full 10 Minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1...	50	0-3	4-10	11+	0-5	6-14	15+
2...	100	4-10	11-18	19+	6-15	16-24	25+
3...	150	11-18	19-25	26+	16-25	26-34	35+
4...	200	19-30	31+	26-40	41+

The Testmethod (continued)

Child Testing

- Packages used for test purposes have to be identical to those used for the real product.
- Have to be chosen by random selection.
- Must not contain real product.
- Children who lose interest are instructed to continue.
- If a child refuses to continue the result will be noted but not taken into account.

The Test Method (continued)

Adult Testing

- 100 persons max. 50 - 70 years of age.
- Persons who have experience with CR packaging are not admitted.
- It has to be made sure that all participants can read the opening instructions.
- People with physical deficiencies (for example Arthritis, Parkinsons D.) are not admitted.

The Test Method (continued)

Adult Testing

Years of Age	Male (No. of participants)	Female (No. of participants)	Total (No. of participants)
50 - 54	8 or 7	17 or 18	25
55 - 59	7 or 8	18 or 17	25
60 - 70	15	35	50
Total	30	70	100

The Test Method (continued)

Adult Testing

- Each participant has to do the test individually (no communication between participants)
- 5 minutes to study the instructions and mechanism and to open the pack.
- Those participants who have succeeded to open the pack within the first 5 minute period have to open another identical pack within one minute.

The Test Method (continued)

Adult Testing

- Participants who don't succeed to open the CR packs within the 5' period are subject to a test with conventional non CR screw top closures (2)
- Only if successful, the result of the CR test will be taken into account.

Test Assessment

A pack is to be considered as child resistant if:

- minimum 85% of all children who took part were unable to gain access to more than 8 units of the product within 5 minutes and without demonstration.
- minimum 80% of all children who took part were unable to gain access to more than 8 units within 10 minutes and with demonstration.
- the pack fails if $>10\%$ of the adults do not succeed to open it within the 5 minutes respectively 1 minute period.

Type Testing

Materials (Packs) once approved can be referred to for new MAs without further testing.

- German Regulations approve type tested materials (packs) with the aim to reduce the number of children involved in panel tests.

(Fortschreibelliste)

- BS 8404 resp. MLX 291 accepts DIN approved materials (packs)

Mechanical Testing

Objective:

- Avoid involvement of children in and teaching them how to open child resistant packs.
- Establish an objective and repeatable validated test method.

„Project Blista“

Sponsored by pharmaceutical manufacturers and EU funded.

Conclusion 1

CONSUMER PROTECTION AND COMPLIANCE – CONFLICTING REQUIREMENTS

Heuer, Heuer, Lennecke - Compliance in der Arzneimitteltherapie, Wissenschaftliche Verlagsgesellschaft mbH Stuttgart 1999:
Recommendations for the handling of pharmaceutical packaging: Amongst other problems difficulties with the packaging may hinder the adherence to the medicinal therapy....

Conclusion 1 (continued)

CONSUMER PROTECTION AND COMPLIANCE

...if the patient fails to open it (the bottle) a relative will in most cases assist and will leave it open for the duration of the medicinal therapy...

...child resistant closures for tablets: it should be proceeded as above. It may help to take the tablets out of the container and to store them in another receptacle that is easy to open.

Conclusion 2

The more difficult it is to open a pack the higher the likelihood that it will be left open.

The use of Child resistant packages is the last in the line of protective measures and cannot release the caregiver from his responsibility to store these products in such way that they cannot be reached by children.

Conclusion 3

**„Child resistant ≠ Child safe“
Jill Cawthorne, Burford Research Consultants**

THE CHILD RESISTANT PACK IS
ALWAYS A COMPROMISE BETWEEN
CONFLICTING REQUIREMENTS

Thank you for your attention

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