الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Child Resistant Packaging requirements

Version 1.0

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Drug Sector

For Inquiries SDR.drug@sfda.gov.sa

For Comments Drug.Comments@sfda.gov.sa

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

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Implementation Notice

This document shall come into effect after a period of 18 months for new medicinal products that are seeking initial marketing authorization as well as for registered medicinal products. However, companies are encouraged to submit variation applications for registered products as early as possible to incorporate the necessary requirements.

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1. INTRODUCTION

1.1.Background

child-resistant packaging (CRP) has an important role in reducing the incidence of accidental poisoning in children, it is intended to provide a delay in the time taken by a child to open a package, thereby increasing the probability of adult intervention before the contents are fully accessible and can be ingested.

It should be noted that "child-resistant" should not be equated with "child-proof," because CRP is not designed to completely eliminate the possibility of an accidental pediatric ingestion. Therefore, SFDA recommends that all drugs, irrespective of the type of packaging, be stored safely out of reach and sight of children to further the overall public health efforts to address this safety issue.

1.1.Objective

The objective of this document is to set particular requirements for the reclosable packaging of medicinal products that may cause a significant risk of toxicity to children if accidentally ingested and to define the list of medicines that require a child-resistant packaging.

1.2.Scope

This document applies to medicinal products that is:

1. Intended to be administrated orally.
2. Supplied in a reclosable package.
3. Contains a substance, or a salt, ester, or other derivatives of a substance, that is specified in the list of products in section 3.

This guidance does not apply to a medicine that is:

- Used by, or administered to, a patient for treatment in hospital settings.
- In a container intended only as a bulk medicine pack.

1.3. Definitions

Child-resistant packaging means a package that is designed to be difficult for young children to open (or gain access to the contents), but which is not difficult for adults to use properly.

Reclosable package means a form of a container with a closure cap which, after it has been initially opened, is capable of being reclosed with a similar degree of security and is capable of being used a sufficient number of times to dispense the total contents without loss of security.

Container means a vessel of glass, plastic or a combination of materials designed to provide appropriate packaging for a product and have a neck finish suitable for the proper attachment of a closure.

Closure cap means the part of reclosable packages that is designed to fit an appropriate container providing a secure seal against environmental challenges.

2. REQUIREMENTS

A. General:

- The closure cap must:
    - Remain fit for its purpose until the expiry date of the medicine.
    - Retain its child-resistant properties for the expected number of openings and closings necessary to fully use the contents.
    - Compose of plastic material only.
- Adequate directions for opening and effectively reclosing the package must be written or clearly demonstrated in graphics.
- Performance of the child-resistant feature must not be adversely affected by the contents of the package.

B. Submission:

- Applicant must answer the questions related to CPR in the application form through SDR system.
- For new drug submission, detailed information on CRP should describe according to the *GCC Data requirements for Human Drugs Submission,* the Container / Closure system (section 3.2.P.7).
- For Registered products and in case of changes in the qualitative and quantitative composition of proposed packaging, the variation request should include detailed information on the Container / Closure system (section 3.2.P.7) and the request should be in accordance with *the Guidelines for Variation Requirements.*

3. LIST OF PRODUCTS

3.1 Classes of substance

Classes shown include any substance included under the given Anatomical Therapeutic Chemical (ATC) classification.

Item	Class
1	ACE INHIBITORS
2	ALPHA AND BETA BLOCKING AGENTS
3	ALPHA-ADRENORECEPTOR ANTAGONISTS including phenoxybenzamine
4	ANESTHETICS, LOCAL
5	ANGIOTENSIN II ANTAGONISTS
6	ANTIARRHYTHMICS
7	ANTICHOLINERGICS
8	ANTI-DEMENTIA DRUGS
9	ANTIDEPRESSANTS
10	ANTIEMETICS AND ANTINAUSEANTS
11	ANTIEPILEPTICS
12	ANTIHISTAMINES

13	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS
14	ANTIMALARIALS, except doxycycline
15	ANTINEOPLASTIC AGENTS
16	ANTI-PARKINSON DRUGS
17	ANTIPSYCHOTICS
18	ANTITHROMBOTIC AGENTS
19	BENZODIAZEPINE DERIVATIVES and BENZODIAZEPINE RELATED DRUGS
20	BETA BLOCKING AGENTS
21	CALCIUM CHANNEL BLOCKERS
22	CARDIAC GLYCOSIDES
23	CENTRALLY ACTING SYMPATHOMIMETICS
24	DIURETICS
25	ERGOT ALKALOIDS
26	MONOAMINE OXIDASE INHIBITORS
27	OPIOIDS
28	ORAL BLOOD GLUCOSE LOWERING DRUGS
29	ANTIBIOTICS

3.2 Individual substances

ALISKIREN.

AMBRISENTAN.

ANISE OIL, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of anise oil, or a combination of anise oil and any other essential oil named in this Part.

ASPIRIN.

AZADIRACHTA INDICA (NEEM), in a preparation for human dermal use containing more than 1 per cent of cold pressed neem seed oil.

BASIL OIL, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation or oil containing 5 per cent or less of methyl chavicol.

BAY OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of bay oil, or a combination of bay oil and any other essential oil named in this Part.

BOSENTAN.

BROMHEXINE.

CAJUPUT OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of cajuput oil, or a combination of cajuput oil and any other essential oil named in this Part.

CAMPHORATED OIL.

CAMPHOR, except:

(a) in a liquid preparation containing 2.5 per cent or less of camphor;

(b) in an essential oil containing 10 per cent or less of camphor, packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert;

(c) in an essential oil packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(d) in rosemary oil, sage oil (Spanish), or lavandin oil as such.

CARAPICHEA IPECACUANHA (IPECACUANHA).

CASSIA OIL, except in a preparation containing 2 per cent or less of cassia oil.

CHLORAL HYDRATE.

CILOSTAZOL.

CINEOLE, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert;

(b) in a preparation or oil containing 25 per cent or less of cineole; or

(c) in rosemary oil or camphor oil (white).

CINNAMON BARK OIL, except in a preparation containing 2 per cent or less of cinnamon bark oil.

CINNAMON LEAF OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of cinnamon leaf oil, or a combination of cinnamon leaf oil and any other essential oil named in this Part.

CLONIDINE.

CLOVE OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of clove oil, or a combination of clove oil and any other essential oil named in this Part.

COLCHICINE.

DEFERASIROX.

DEXTROMETHORPHAN.

ETHANOL, in any medication or mouthwash preparation containing more than 3 grams of ethanol in a single pack.

EUCALYPTUS OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of eucalyptus oil, or a combination of eucalyptus oil and any other essential oil named in this Part.

FLUORIDE SALTS, in a pack containing the equivalent of more than 50 milligrams of elemental fluorine.

GUAIFENESIN.

IRON COMPOUNDS, in a pack containing a total of more than 250 milligrams of elemental iron, except for divided preparations in which:

(a) the iron is compounded with one or more other active ingredients; and

(b) the amount of elemental iron per dosage unit is 5 milligrams or less.

However iron oxides that are present as an excipient, in either a divided preparation containing 10 milligrams or less of total iron oxides per dosage unit or an undivided preparation containing 1 per cent or less of total iron oxides, may be excluded from the calculation of elemental iron content.

IVABRADINE.

LANTHANUM.

LENALIDOMIDE.

MARJORAM OIL, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert, or

(b) in a preparation containing 50 per cent or less of marjoram oil, or a combination of marjoram oil and any other essential oil named in this Part.

MELALEUCA OIL, except:

(a) when packed in a container having a nominal capacity of 15 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 25 per cent or less of melaleuca oil, or a combination of melaleuca oil and any other essential oil named in this Part.

METHYL SALICYLATE, in a liquid preparation containing 5 per cent or more of methyl salicylate.

MINOXIDIL, in a liquid preparation or a preparation for oral administration.

MOUTHWASH preparations — *see* ETHANOL.

NICOTINE.

NUTMEG OIL, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of nutmeg oil, or a combination of nutmeg oil and any other essential oil named in this Part.

PARACETAMOL - all solid dosage forms and liquid preparations.

PENNYROYAL OIL, except in a preparation containing 4 per cent or less of d-pulegone.

PENTOXYVERINE.

PHENYLEPHRINE.

PHOLCODINE.

PODOPHYLLUM/PODOPHYLLOTOXIN.

POLYGALA SENEGA (SENEGA).

POTASSIUM SALTS, in a pack containing a total of more than 4000 milligrams of elemental potassium, except:

(a) in a divided preparation in which the amount of elemental potassium per dosage unit is 40 milligrams to less; or

(b) when the potassium is present in the form of glucosamine sulfate potassium chloride complex.

PSEUDOEPHEDRINE.

RILUZOLE.

SAGE OIL DALMATIAN, except in a preparation containing 4 per cent or less of thujone.

SALBUTAMOL.

SASSAFRAS OIL, except in a preparation containing 1 per cent or less of safrole.

STAR ANISE OIL, except:

(a) when packed in a container having a nominal capacity of 50 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of star anise oil, or a combination of star anise oil and any other essential oil named in this Part.

THEOPHYLLINE.

THYME OIL, except:

(a) when packed in a container having a nominal capacity of 25 millilitres or less and fitted with a restricted flow insert; or

(b) in a preparation containing 50 per cent or less of thyme oil, or a combination of thyme oil and any other essential oil named in this Part.

THYROXINE.

VARENICLINE.

WINTERGREEN OIL — *see* METHYL SALICYLATE.

4. REFERENCES

- TGA Child-resistant packaging requirements for medicines, 2018
- Consumer Product Safety commission, Poison Prevention Packaging Act of 1970 Regulations-Part 1700, 2012