



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Consultation Paper

DESCRIPTION OF THE PROPOSED GROUPING ORDER

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Background

The purpose of the Grouping Order is to specify the circumstances in which two or more products may be grouped under a single product licence.

Section 3.10 of the draft Medicine Rules sets out the criteria which make medicines separate and distinct. The objective of grouping is to provide a legislative mechanism whereby, provided certain conditions are met, some changes to a medicine that would technically make it “separate and distinct” can be made without creating a the need for a separate product licence.

Grouping facilitates transition from one product to another. In certain situations it can reduce the number of product licences required to be held (and thus reduce the annual charges payable by the licence holder). Grouping can also enable retention of the product licence number (which may avoid the need for the product licence holder to print a new label).

Types of Grouping

There are two types of grouping – “Replacement Grouping” where the changed product replaces the previous one, and “Concurrent Grouping” where the two products co-exist.

“Replacement Grouping” may apply when a minor change is made to an existing product, and the new version is to the replace that product. In this case, the product licence holder is expected to cease supply of the existing product before introducing the replacement product to the market. Removing the existing product from the market is required because the product licence number is a unique identifier used to facilitate product recalls and reporting of adverse events. It is, therefore, unacceptable for two “different” products to be in the marketplace with the same product licence number.

“Concurrent Grouping” may apply to export medicines and some allergen products and medical gases. It may apply, for example, where an export version of a licensed product differs from the version marketed domestically in respect of its labelling or the use of a flavouring or colouring.

Proposed Content of the Grouping Order

NB. In all instances of Grouping, the product licence authorising the supply of the “new” and “existing” medicines must be held by the same licence holder.

Definitions

"**existing medicine**" means a medicine that is authorised to be supplied or exported under a product licence which is in force.

"**new medicine**" means a medicine that is required to be supplied or exported under the authority of a product licence.

"**restricted ingredient**" has the meaning given by subsection 3.10(2) of the Medicines Rule

"**product name**" has the meaning given by subsection 3.10(8) of the Medicines Rule.

A. *Replacement Groupings*

(Where the new medicine is to replace the existing medicine in use.)

Grouping a new Class 1 medicine to an existing Class 1 medicine

Different Name

- The difference between the new product and the existing product is a change to the product name.

Different indications

- The difference between the new product and the existing product is a change to the indications.

Different Directions for Use

- Where the medicine includes a restricted ingredient based on single or daily dose, the difference between the new product and the existing product is a change of directions for use.

Different quantity of excipient which is a restricted ingredient

- Where the medicine contains a restricted ingredient that is not an active ingredient, the difference between the new product and the existing product is a change to the quantity or concentration of that restricted ingredient.

Removal or addition of an excipient

- The difference between the new product and the existing product is the removal or addition of an excipient(s).

Grouping a new Class 2 medicine to an existing Class 2 medicine

Different Name

- The difference between the new product and the existing product is a change to the product name.

Different quantity of excipient

- The difference between the new product and the existing product is a change to the formulation of the product which only involves increasing or decreasing the amount of an excipient (ie not adding or deleting the excipient).

Removal or addition of a fragrance, flavour, printing ink or colour

- The difference between the new product and the existing product is the removal or addition of an ingredient that is only used for the purpose of fragrance or flavouring or as a printing ink or colouring agent.

Different indications

- The difference between the new product and the existing product is a change to the indications.

Different Directions for Use

- The difference between the new product and the existing product is a change to the directions for use.

B. Concurrent Groupings

(Where the new medicine can be concurrently supplied or exported with the existing medicine to which the new medicine is grouped.)

Grouping a new Export-only (Class 1) medicine to an existing Export-only (Class 1) medicine

Different Name

- The only difference between the new medicine and the existing medicine is the product name.

Different indications for use and/ or directions for use

- The difference between the new medicines and the existing medicine is different indications for use; or different directions for use; or both different indications for use and different directions for use.

Export-only (Class 2) medicine to an existing Export-only (Class 2) medicine

Different Name

- The only difference between the new medicine and the existing medicine is the product name.

Different indications for use and/ or directions for use

- The difference between the new medicines and the existing medicine is different indications for use; or different directions for use; or both different indications for use and different directions for use.

Grouping an Export-only (Class 1) medicine to an existing Class 1 medicine

(Note: for grouping to apply the new medicine must continue to comply with any standards for labelling)

Different Name

- The only difference between the new medicine and the existing medicine is the product name.

Different indications

- The difference between the new medicine and the existing medicine is a change to the indications, provided that the indications for the new medicine do not include any reference, whether direct or implied, to a serious disease, condition or disorder.

Removal or addition of a fragrance, flavour, printing ink or colour

- The difference between the new product and the existing product is the removal or addition of an ingredient that is only used for the purpose of fragrance or flavouring or as a printing ink or colouring agent.

Grouping an Export-only (Class 2) medicine to an existing Class 2 medicine

Different Name

- The only difference between the new product and the existing product is the trade or brand name.

Grouping an existing allergen product to a new allergen product

Different strength, container type or indications for use

- Where the new medicine and the existing medicine are both allergen extracts which are made from the same components, the extracts differ from each other only in one or more of the following: strength, container type or indications for use.

Grouping an existing medical gas product to a new medical gas product (being medical gas products which require a product licence to be supplied in Aust/NZ)

Different proportions of each element / compound

- Where the new medicine and the existing medicine are medical gases which are mixtures of chemical elements or chemical compounds and they contain the same chemical elements or chemical compounds, the medical gases differ only in the proportions of each element or compound in the mixture.