Safety statement on metered dose inhalers

The Australian Commission on Safety and Quality in Health Care (the Commission) recommends established metered dose inhalers are prescribed and communicated by the metered dose, even if the product is labelled with additional information on the delivered dose.

The labelling and packaging of established metered dose inhalers and other metered dose products usually states the quantity of active ingredient per metered dose. This may be accompanied by additional information on the quantity of active ingredient in a delivered dose. It is recommended where both doses are described, these products are:

- Prescribed and communicated by the metered dose
- Labelled at point of dispense with metered dose. The delivered dose may also be displayed if clearly described, such as 'each inhalation contains a metered dose of (X micrograms) which is equivalent to a delivered dose of (Y micrograms)'.

More recent inhaled products are labelled only with the delivered dose. These will be prescribed, communicated and labelled with the delivered dose.

It is also recommended that:

- Consumers understand how to use their inhaler correctly to ensure a complete dose is delivered to the site of action
- Electronic medication management systems are configured to describe the doses consistently between systems for all purposes including prescribing, dispensing administration and reporting.

Rationale

The Commission has been made aware that revised labelling of some metered dose medicines has led to confusion for consumers, prescribers, nursing and pharmacy staff. These products include inhalers, dry powder inhalers and other metered dose products such as nasal sprays. In some health service organisations, this has led to omissions or delays in treatment contributing to exacerbations of respiratory disease.

Therapeutic Goods Order (TGO) 91[1] released by the Therapeutic Goods Administration (TGA) in 2016 requires the delivered dose to be used on labelling of these medicines unless the metered dose is established in clinical practice. Manufacturers may choose to label products with additional information on the delivered dose where previously only the metered dose was displayed.

Established products are predominantly prescribed by the metered dose. Confusion has arisen at the point of administration of products with revised labelling that has both sets of information. The prescribed dose may not directly relate to the dose displayed on the product label leading to concern over whether the medicine is the medicine prescribed and about what dose is to be administered.

For example, Symbicort Turbuhaler contains the active ingredient eformoterol fumarate dihydrate. This medicine name has changed according to the international harmonisation of medicine names[2] to formoterol (eformoterol) fumarate dihydrate. Symbicort Turbuhaler 400/12 labelling now includes the revised naming and the delivered dose (320/9) alongside the metered dose (400/12).

The label states *Symbicort Turbuhaler 400/12 (budesonide 400 micrograms / formoterol (eformoterol) fumarate dihydrate 12 micrograms delivers budesonide 320 micrograms / formoterol (eformoterol) fumarate dihydrate 9 micrograms).*

The manufacturer has written to pharmacists with this information[3].

Background

Therapeutic Goods Order (TGO) 91[1], introduced in 2016, requires the delivered dose to be included on labelling of these medicines unless the therapeutic dose was clinically established using the metered dose. Delivered dose is the more accurate measure of the amount of active ingredient reaching the patient and is used to describe the dose of new medicines or new presentations of medicines. However, the regulation allows flexibility for established medicines to continue to be described by the metered dose.

The international harmonisation of medicine ingredient names was introduced in 2016 to align Australia's medicine names with international systems, preferably using International Non-proprietary names (INNs) [2]. The timing of this activity coincides with introduction of TGO 91. This allows manufacturers to update their labels to comply with TGO 91 and accommodate active ingredient name changes at the same time.

Consultation

The Commission's Health Services Medication Safety Expert Advisory Group and the TGA support this safety statement.

References

1. Therapeutic Goods Administration. Therapeutic Goods Order No. 91 Standard for labels of prescription and related medicines www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92
2. Therapeutic Goods Administration. International harmonisation of medicine names www.tga.gov.au/book-page/executive-summary
3. Letter from AstraZeneca to Pharmacists. Packaging Change Symbicort (budesonide & formoterol (eformoterol) fumarate dihydrate) Turbuhaler