Dear Healthcare Professionals,

Stimulant laxatives (bisacodyl, senna and sennosides, sodium picosulfate) available over-the-counter: new measures to support safe use

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency’s (MHRA) announcement that it has introduced pack size restrictions, revised recommended ages for use, and new safety warnings for over-the-counter stimulant laxatives (orally and rectally administered) following a national safety review. Stimulant laxatives are used to treat constipation. Medicines available in the United Kingdom over-the-counter are bisacodyl, senna and sennosides, and sodium picosulfate.

The safety of stimulant laxatives has been under close review by the MHRA for many years following concerns relating to misuse and abuse. Previous measures have included the addition of warnings to some products to advise that laxatives do not aid weight loss and that long-term use may be harmful.

Following a national safety review, including advice from expert advisory groups and an Expert Working Group, the Commission on Human Medicines (CHM) has recommended the MHRA introduce a package of measures to support the safe use of over-the-counter stimulant laxatives in the United Kingdom. In their in-depth review of the benefits and risks of these medicines, CHM noted that stimulant laxatives have an acceptable safety profile, have been widely used for many years, and are generally used responsibly. However, CHM also considered evidence that stimulant laxatives are subject to misuse and overuse. Such cases mostly concern people with eating disorders, although misuse and overuse are likely to be under-reported. Occasional, serious reports of misuse and overdose have been received, including rare reports of fatalities. Furthermore, CHM noted that current clinical guidance recommends that stimulant laxatives should not be used first-line for short-term constipation. CHM concluded that stimulant laxatives could continue to be available to patients to purchase, subject to a range of proportionate measures to reduce the risk of misuse and support correct use.

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Changes to stimulant laxatives to support safety:

Pack size restrictions
- Smaller packs will continue to be available for general sale for the treatment of short-term, occasional constipation for use in adults only. Products available for general sale will be limited to a pack size of two short treatment courses (up to 20 standard-strength tablets, 10 maximum-strength tablets or 100ml solution/syrup). This limit is to reflect that these medicines should be used for only short-term, occasional constipation.

Revised recommended ages for use
- Stimulant laxatives on general sale (in shops and supermarkets) will be recommended for use only in people 18 years or older. Stimulant laxatives should no longer be used in children under 12 years without advice from a prescriber, while products for children aged 12 to 17 years can be supplied under the supervision of a pharmacist.

Harmonisation of indications and new safety warnings
- The indications for all stimulant laxative products available over-the-counter have been made consistent and any uses not appropriate for the self-care setting have been removed. Where stimulant laxatives are required regularly for longer-term use in chronic constipation or for indications not appropriate for the self-care setting, such as bowel clearance before surgery, they will be available as prescription-only products.
- Warnings in the patient information leaflets that accompany these medicines will be made consistent and advise patients that overuse of stimulant laxatives may be harmful due to the risk of fluid and electrolyte disturbances and potential disruption of intestinal function. Warnings are also being added to packaging to support awareness. The product information will also include the new age recommendations.

Advice for healthcare professionals:

Constipation treatment options
- For constipation, manage underlying causes and advise adult patients on appropriate first-line dietary and lifestyle measures, such as increasing dietary fibre, fluid intake, and activity levels.
- Stimulant laxatives should only be used if other laxatives (bulk-forming and osmotic) are ineffective (as clinical guidance).
- Children younger than 12 years should not use stimulant laxatives without advice from a prescriber and clinical guidance should be followed.

Changes to availability
- Large packs of stimulant laxatives will no longer be available from general sale outlets, such as newsagents and supermarkets; smaller packs will continue to be available in these outlets for short-

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term, occasional constipation in adults.

- Pharmacies will continue to hold larger packs of up to 100 tablets for use in adults and children aged 12 years or older, under the supervision of a pharmacist.

Advice to provide to patients
- Seek support from a doctor, nurse, or pharmacist for ongoing constipation, rather than self-medicating with laxatives in the long-term.
- If symptoms of constipation persist after dietary and lifestyle changes and short-term laxative treatment (under the advice of pharmacist), or in case of persistent abdominal pain or passing blood, consult a doctor.
- Parents and caregivers should seek medical advice about constipation in children – children younger than 12 years should not use stimulant laxatives unless told to do so by their prescriber.

Please refer to the following website in MHRA for details:

In Hong Kong, there are registered pharmaceutical products containing bisacodyl (39 products), senna and sennosides (18 products), and sodium picosulfate (4 products). All products are over-the-counter medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to bisacodyl, senna and sennosides, and sodium picosulfate. In light of the above MHRA’s announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Undesirable Medical Advertisements and Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR Reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office’s website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)

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