PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

29 January 2016

MCC Secretary
Medsafe
PO Box 5013
Wellington 6145

via email: committees@moh.govt.nz

Dear Sir/Madam,

**Proposal to change the classification statement wording for various Restricted and Pharmacy-Only Medicines**

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 pharmacists from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

The over-the-counter provision of medicines is a key healthcare service provided by pharmacies to their communities. The greater restrictions placed on these medicines compared to general sale medicines reflect the degree of professional involvement and/or oversight to ensure their appropriate use. In assessing patients and treating them with medicines from a pharmacy, pharmacists must comply with all professional, ethical and regulatory requirements that pertain to that medicine and/or classification of medicine.

The wording of the classification statement of a Restricted or Pharmacy-Only medicine effectively sets additional regulatory criteria by which that medicine may be supplied, in addition to the legislated requirements in the Medicines Act and Regulations of each medicine classification, as well as professional and ethical obligations.

Regulation 23 of the Medicines Regulations 1984 provides certain exemptions to the detailed labelling requirements of proprietary medicines if the medicine is being ***"packed, supplied, or sold by an authorised prescriber or a pharmacist with reference to the needs of a particular patient or (as the case may be) a particular customer"***. After assessing the appropriateness of treatment with a Restricted or Pharmacist-Only medicine, pharmacists may utilise this permission to supply particular patients with smaller or cheaper pack sizes, compared to the proprietary product available.

In accordance with legislation, such repackaged medicines are not permitted to be advertised or stocked for patient self-selection. Regulation 23 also requires the inclusion of specific labelling information - comparable to if the medicine were being dispensed pursuant to a prescription. Furthermore, in utilising this mechanism for supplying medicines, pharmacists must also meet their obligations under the Code of Health and Disability Services Consumers' Rights particularly ensuring consumers are fully informed of potential benefits and risks.

There can be a number of reasons why a pharmacist may wish to supply a repackaged/packed-down medicine instead of a proprietary product. Some of these reasons include:

- Allows pharmacists to easily supply a medicine if a specifically approved proprietary pack is unavailable or out of stock
- Only one brand has an approved over the counter pack available, while other brands are available for dispensing pursuant to a prescription
- The pharmacy does not usually keep the over the counter pack, but does keep a larger stock pack/bottle that is used for dispensing prescriptions. This can provide stock control advantages for some pharmacies.
- The patient wishes to purchase a smaller quantity that is available in the approved pack, either due to cost perceived need
- The pharmacist wishes to provide a smaller quantity that is available in the approved pack – which may be excessive to a patients' needs, there is concern about potential misuse, or the pharmacist and patient wish to trial a medicine for whatever reason. Approved packs often provide the maximum quantity permitted, therefore an opportunity to supply a smaller quantity can be beneficial
- Supplying a packed-down/repackaged medicine is usually cheaper for the patient, which can be an important barrier for a number of people a pharmacist's community

The classification wording of some Restricted and Pharmacy-Only medicines includes a statement that only approved or manufacturer's original packs may be supplied. For these medicines, the benefits described above that the function in Regulation 23 provides for, cannot be utilised. We note that many Restricted and Pharmacy-Only medicines have no specific requirement for only supplying approved or manufacturer's original packs.

Working in collaboration with the Pharmacy Guild of New Zealand, who will make a submission supporting this proposal, we seek to change the classification wording for the medicines listed below, to remove the reference that only approved or manufacturer's original packs may be supplied.

Removing the original or approved pack requirement does not negate such packs from being available or supplied to patients, just that pharmacists would have the opportunity to supply a packed-down version for a particular patient if this would be beneficial. These medicines have already been deemed to be appropriate for supply from a pharmacist or pharmacy. Not having to rely on the availability of, or conform to the presentation of a specific pack, will mean for some patients a safer or more affordable form of medicine may be provided.

We note that the following proposal makes no change to the requirements of supply of that medicine, other than the reference to only providing an approved or manufacturer's original pack. That is, any indication, age restriction, maximum dose size, daily dose size, or quantity will still apply.

We therefore propose changes to the classification statement wording for the following medicines:

(References to approved/original pack requirements are highlighted with underline)

**Restricted Medicines**

***Lansoprazole***

Current classification:

> Restricted Medicine: in divided solid dosage forms for oral use containing 15 milligrams or less with a maximum daily dose of 15 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over or the relief of heartburn when sold in the manufacturer's original pack containing not more than 14 dosage units

Classification sought:

> Restricted Medicine: in divided solid dosage forms for oral use containing 15 milligrams or less with a maximum daily dose of 15 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over or the relief of heartburn when sold in a pack containing not more than 14 dosage units

Comment:

Professional guidelines were made available to pharmacists following the reclassification of omeprazole to Restricted Medicine (it has since been down-scheduled to Pharmacy-Only). We do not have an estimate of the perceived demand or extent of the use of lansoprazole as a Restricted Medicine, however this change would provide for an opportunity to trial comparison of lansoprazole over another proton pump inhibitor if a smaller quantity could be made available.

***Promethazine***

Current classification:

> Restricted Medicine: for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units

Classification sought:

> for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia when sold in a pack containing not more than 10 dosage units

Comment:

We note that the Pharmacy-Only classification for promethazine does not include any requirement to be sold in approved or manufacturer's original packs. Pharmacists may therefore supply repackaged promethazine as a pharmacy-only medicine when complying with the requirements of that classification.

(Pharmacy-Only classification: for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing promethazine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft)

***Sumatriptan***

Current classification:

> Restricted Medicine: for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 50 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets that has received the consent of the Minister or the Director-General to its sale as a restricted medicine

Classification sought:

> Restricted Medicine: for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 50 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets

Comment:

Not all brands have an approved over the counter pack available. Repackaged product could be more affordable for some.

**Pharmacy-Only Classified Medicines**

***Ibuprofen***

Current classification:

> Pharmacy-Only: for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in the manufacturer's original pack containing not more than 8 grams; for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in the manufacturer's original pack containing not more than 100 dose units; except in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units

Classification sought:

> Pharmacy-Only: for oral use in liquid form with a recommended daily dose of not more than 1.2 grams for the relief of pain and reduction of fever or inflammation when sold in a pack containing not more than 8 grams; for oral use in solid dose form containing not more than 200 milligrams per dose form and with a recommended daily dose of not more than 1.2 grams when sold in a pack containing not more than 100 dose units; except in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in a pack containing not more than 25 dose units

(General sale: for external use; in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack)

Comment:

The proposed wording change would provide an opportunity to supply smaller quantities of ibuprofen liquid or tablets when required. This could assist reducing cost barriers for some communities. We restate our note above that pharmacists must ensure patients are fully

informed when using medicines – we would expect clear and specific dosing information to be noted on the label of a repackaged product.

***Omeprazole***

Current classification:

> Pharmacy-Only: in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 28 dosage units

Classification sought:

> Pharmacy-Only: in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in a pack containing not more than 28 dosage units

***and***

***Pantoprazole***

Current classification:

> Pharmacy-Only: in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 28 dosage units

Classification sought:

> Pharmacy-Only: in divided solid dosage forms for oral use containing 20 milligrams or less with a maximum daily dose of 20 milligrams for the short-term symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over when sold in a pack containing not more than 28 dosage units

Comment:

Both omeprazole and pantoprazole are classified as Pharmacy-Only medicines. Not all brands have an approved over-the-counter product available. As referred to under lansoprazole above, being able to supply a repackaged product could provide an opportunity to trial smaller quantities to test / compare tolerability or efficacy between proton pump inhibitors. This is in addition to the other potential reasons for supplying a repackaged medicine, as described earlier.

***Opium***

Current classification:

> Pharmacy-Only: *in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine*

Classification sought:

> Pharmacy-Only: *in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health*

Comment:

Commonly available as the cough suppressant 'Gees Linctus' (camphorated opium + oxymel squill + tolu syrup). Gees Linctus is currently available in 200mL or 2L bottle sizes. Pharmacists often pack down smaller quantities from the 2L stock bottle to supply to an individual over the counter for affordability (anecdotally, Gees Linctus is frequently requested by older people). Many pharmacists also seek to supply smaller quantities than the 200mL product for affordability purposes, but also where they have concerns about the legitimacy of the request or potential for misuse. It is already common practice for many pharmacists to repack this medicine into smaller quantities, therefore we seek to have this regulatory amendment made to reflect what the Society would consider acceptable and professional practice.

**Pholcodine**

Current classification:

> Pharmacy-Only: in medicines for oral use containing not more than 15 milligrams of pholcodine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of pholcodine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

Classification sought:

> Pharmacy-Only: in medicines for oral use containing not more than 15 milligrams of pholcodine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of pholcodine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means, or in a yield that would constitute a risk to health

Comment:

Similar to the comments made above under Opium, in suitable cases, pharmacists seek to supply smaller quantities for affordability, or where the potential for misuse might be a concern, rather than only being able to sell the quantities made available in the approved packs.

***Ranitidine***

Current classification:

> Pharmacy-Only: in medicines for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in the manufacturer's original pack containing not more than 14 days' supply; except in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

Classification sought:

> Pharmacy-Only: in medicines for the symptomatic relief of heartburn, dyspepsia and hyperacidity or to be used on the recommendation of a registered medical practitioner when sold in a pack containing not more than 14 days' supply; except in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply

(General sale classification: in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply)

Comment:

We note that the second part of this classification refers to an exemption to the pharmacy-only classification – which is when it may be sold as a general sale medicine. We would

preserve the requirement to supply any general sale medicine outside of a pharmacy in the manufacturer's original pack, therefore the wording of the second part of the statement remains the same.

As mentioned earlier, not all Restricted or Pharmacy-Only Medicines are required to *only* be sold in approved or manufacturer's original packs. For the Committee's benefit, below are examples of medicine classification wording of comparable and selected other Restricted and Pharmacy-Only Medicines that pharmacists may currently supply without a specific requirement to only approved or manufacturer's original packs:

Oseltamivir

Restricted Medicine: in solid dosage forms for oral use containing 75 milligrams in a pack size of up to 10 dosage units for the treatment or prophylaxis of influenza in adults and children aged 13 years and older who have been exposed to the influenza virus

Prochlorperazine

Restricted Medicine: in packs containing not more than 10 tablets or capsules for the treatment of nausea associated with migraine

Levonorgestrel

Restricted Medicine: in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health

Diclofenac

Restricted Medicine: in solid dose form in medicines containing 25 milligrams or less and more than 12.5 milligrams per dose form in packs containing not more than 30 tablets or capsules

Pharmacy Only: in solid dose form in medicines containing 12.5 milligrams or less per dose form in packs containing not more than 30 tablets or capsules and with a recommended daily dose of not more than 75 milligrams

Desloratadine

Pharmacy-Only: for oral use

Dextromethorphan

Pharmacy Only: in liquid form containing more than 0.25% or in solid dose form containing more than 15 milligrams per dose form when in packs containing not more than 600 milligrams and with a recommended daily dose of not more than 120 milligrams; in medicines for the treatment of the symptoms of cough and cold in children aged 6-12 years

Levocetirizine

Pharmacy-Only: for oral use

Mefenamic acid

Pharmacy-Only: in solid dose form in packs containing not more than 30 tablets or capsules for the treatment of dysmenorrhoea

Naproxen

Pharmacy-Only: in solid dose form containing 250 milligrams or less per dose form in packs of not more than 30 tablets or capsules

Paracetamol

Pharmacy-Only: in liquid form; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams; in slow-release forms containing 665 milligrams or less and more than 500 milligrams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack

Promethazine

Pharmacy-Only: for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing promethazine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft

In proposing the above modifications to the classification statement of selected medicines, The Society does not perceive a conflict with the safety requirements sought in Medsafe's Label Statements Database - which predominantly relate to warnings associated with patient self-selection (would not apply) and recommendations for/contraindications to use. Such information is considered part of a pharmacist's assessment and supply under the permissions granted to them in legislation. Should this submission be accepted, in notifying the profession we will remind pharmacists of their obligations to ensure such supply is done safely and appropriately and in accordance with and contraindications, precautions or other safety information that may related to a particular medicine.

We note that the proposed modifications to classification wording would not affect the current labelling requirements for manufacturers packs, just the permission for pharmacists to supply the medicine outside of these. Manufacturers proprietary packs would still be displayed and supplied over the counter.

We also reinforce that we are not seeking to change the wording of the classification statements associated with medicines that are also available as general sale. Supply of medicines at a general sale level outside of a pharmacy does not have the professional oversight of a pharmacist and must continue to be supplied in the manufacturer's original pack, with all associated labelling and safety information.

We acknowledge that while pharmacy staff are permitted to supply Pharmacy-Only medicines in a pharmacy, under a pharmacists' supervision, only a pharmacist themselves would be permitted to supply a Pharmacy-Only medicine that was repackaged and supplied for the needs of a particular person in accordance with the permissions in legislation. We note this to reassure the Committee that pharmacy staff could not supply a repackaged medicine over the counter, only the proprietary products.

Thank you for consideration of this submission. We would be happy to discuss any aspect of this proposal further, as required.

Yours sincerely,

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