

Medicines in Schedule 1 to the Medicines Regulations 1984 that reference the manufacturer's original pack

1. Name of medicine	Alclometasone
Classification	Prescription; except when specified elsewhere in this schedule Restricted; for dermal use in medicines containing 0.05% or less and in packs containing not more than 30 grams that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack
MCC deliberations	<p>Item 8.1.1 of the 33rd meeting on 9 June 2005</p> <p>The NDPSC had requested that the MCC reconsider the current prescription medicine status of 0.05% dermal preparations. These had now been available in Australia as restricted medicines for some years. During that period there did not appear to have been any problems with their use as over-the-counter medicines. A similar result had become evident from reclassification in the UK. It was noted that these medicines were not widely used and evidence of misuse had not become apparent in either country. Nor did the products appear to be used in place of hydrocortisone as earlier feared by the Committee.</p> <p>Some members were still concerned with the difficulties of diagnosing skin problems and the ability of pharmacists to undertake this diagnosis. It was noted that dermatologists would be involved in pharmacist training.</p> <p>Although some Committee members were doubtful about the reclassification it was agreed that New Zealand should adopt the harmonised position provided pack warnings were included against use:</p> <ul style="list-style-type: none"> • on the face • for children • for psoriasis. <p>In order for these warnings to be enforceable the products would need to be sold only in packs approved specifically for sale as restricted medicines. Required warnings would be included in Part I of The New Zealand Regulatory Guidelines for Medicines. The Guidelines would also specify a maximum pack size of 30 grams.</p> <p>It was noted that the policy statement made by the Committee in November 2000 should now be revoked. This statement stated that topical corticosteroids which were more potent than 1% hydrocortisone or which had a wider range of indications than 1% hydrocortisone should be considered unsuitable for over-the-counter sale.</p> <p>Recommendation</p> <p>That skin preparations containing 0.05% of alclometasone or clobetasone should be reclassified as restricted medicines when sold in pack sizes of 30 grams or less and in the manufacturer's original pack which has received the consent of the Minister or the Director General to its sale as a restricted medicine</p>

	<p>That Medsafe should be asked to include the required warning statements against use on the face, for psoriasis or for children in the New Zealand Regulatory Guidelines for Medicines.</p> <p>That the Committee policy statement of November 2000 relating to topical steroids for over-the-counter sale should be revoked.</p>
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2. Name of medicine	Brompheniramine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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 brompheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012.</p> <p>When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the</p>

	medicine. However, there were a number of medicines (including brompheniramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.
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3. Name of medicine	Cetirizine
Classification	<p>Prescription; except for oral use Pharmacy-only; for oral use except in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply General sale; in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply</p>
Committee deliberations	<p>Item 6.1 of the 46th meeting on 15 November 2011 The Committee considered the reclassification of cetirizine hydrochloride 10 mg tablets and loratadine 10 mg tablets together. The safety, efficacy and abuse potential of both cetirizine hydrochloride and loratadine were similar to fexofenadine. Fexofenadine had been recommended for reclassification as a general sale medicine at the 42nd meeting on 3 November 2009. At the 42nd meeting the Committee accepted that seasonal allergic rhinitis was self-diagnosable. The Committee discussed the proposed labelling as there was a subtle difference between the proposed labelling for the two products. The cetirizine hydrochloride pack stated, Histaclear Once-a-Day Non-Drowsy Allergy Relief. Whereas the loratadine pack stated, Loraclear Once-a-Day Hayfever Relief - Non-drowsy antihistamine for rapid hayfever relief. It was agreed that the label for cetirizine hydrochloride pack should reflect the wording on the loratadine pack and decrease the prominence of the non-drowsy statement so that it is not in association with the product name. The pack could carry the statement 'Non-drowsy antihistamine...' in the same manner as that of loratadine. The Committee concluded that both cetirizine hydrochloride and loratadine should be reclassified from pharmacy-only medicine to general sale medicine when in packs containing sufficient tablets for only five days' supply and when used for Seasonal Allergic Rhinitis.</p> <p>Recommendation That cetirizine hydrochloride should be reclassified from pharmacy-only medicine to general sale medicine when in packs containing sufficient tablets for only five days' supply and when used for Seasonal Allergic Rhinitis. That Medsafe should review the labelling to ensure that the cetirizine hydrochloride pack was brought into line with the loratadine pack.</p>

4. Name of medicine	Chlorpheniramine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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 chlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including chlorpheniramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

5. Name of medicine	Cimetidine
Classification	Prescription; except when specified elsewhere in this schedule Restricted; 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
Committee deliberations	<p>Item 4ix of the 12th meeting on 25 November 1993</p> <p>Dr Martindale summarised the situation to date. She explained that the Ministry had felt it was appropriate to ask MCC to engage in a further round of consultation before proceeding with a recommendation. Given that various queries had been raised, it had seemed reasonable to prolong the consultation process. Dr Martindale said that the Ministry had supported in principle the reclassification of these medicines to over-the-counter status with certain conditions attached. It was now necessary for the Committee to provide the Ministry with principles which it would use when evaluating an application to approve an over-the-counter pack. She said that a changed medicine notification would be necessary to gain approval for an over-the-counter pack. She suggested that members first consider the comments arising from the consultation process and determine whether or not they had changed their earlier position on the proposed reclassification. Dr Martindale added that all companies involved with these medicines now appeared to be in favour of having an over-the-counter presentation of their product. She stressed the importance of there being an over-the-counter pack containing all the appropriate patient information in plain language, rather than having prescription packs broken down to suitable size by a pharmacist. She also pointed out that at the previous meeting it had not been possible to establish precise indications or dosages for specific products as the relevant material had not been available. Reporting on events in Australia, Dr Martindale said that the Australians intended to reclassify these medicines and were about to publish their intention to do so. Because of their 2-year rule they would be able to consider cimetidine, famotidine and ranitidine but not nizatidine. The DPSSC had accepted the material from the June meeting of MCC and intended to use similar pack warnings. They also intended to include warnings for cimetidine concerning interactions with warfarin, phenytoin, and theophylline. Dr Martindale added that the Australian scheduling Committee did not concern itself with indications when reclassifying medicines.</p> <p>Dr Martindale also pointed out that the British indications, dosages and treatment periods were now available and should be considered. She suggested it might be sensible for NZ to adopt the 2-week limit of treatment accepted in Britain rather than the 10-day period suggested at the previous meeting. She added that Australia intended to do the same.</p> <p>The Committee considered and discussed the information presented by the companies and professional bodies and agreed it was in favour of proceeding with the proposed reclassification provided the medicines could be presented in approved over-the-counter packs. It was agreed that rather than establish precise dosages, indications and warning statements, a set of principles should be agreed to and that these would be used by Therapeutics evaluators when assessing changed medicine notifications for over-the-counter presentations.</p> <p>The following framework was decided on and it was agreed that relevant details for each medicine would be finalised by evaluators in the Therapeutics Section at the time a changed medicine notification for an over-the-counter pack was</p>

	<p>evaluated. Evaluators would work within the framework established by MCC. Some latitude would be allowed within the framework depending on the evidence supplied for each individual medicine. The medicines schedule would be worded in such a way as to allow these medicines to be sold over-the-counter only when presented in approved over-the-counter packs.</p> <p>Recommendation</p> <p>That cimetidine, famotidine, nizatidine and ranitidine become restricted medicines when they are sold in over-the-counter-specific packs appropriately labelled. It is recommended that the medicines be used only for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity or on the recommendation of a doctor. The over-the-counter pack must contain not more than 14 days' supply.</p> <p>That recommended dose limits be established for each medicine by Therapeutics Section evaluators as being suitable for the over-the-counter indications specified and that these are supported by clinical data.</p> <p>That comprehensive consumer information be provided in plain language. The consumer information must contain warnings and precautions worded in a manner considered appropriate by the Therapeutics Section of the Ministry of Health for each individual medicine. The warnings and precautions must cover the following:</p> <ul style="list-style-type: none"> i a warning not to use the medicine for any purpose other than that specified on the pack unless under the supervision of a doctor ii the need to consult a doctor if symptoms persist iii the need to consult a doctor if symptoms recur iv the need to consult a doctor if symptoms become worse v the need to consult a doctor if new or additional related symptoms occur vi a warning against use with non-steroidal anti-inflammatory medicines unless under the supervision of a doctor vii a warning to use with caution if over 40 years of age viii a warning not to use without medical supervision if warfarin, phenytoin or theophylline are being taken (for cimetidine only).
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6. Name of medicine	Clobetasone
Classification	Prescription; except when specified elsewhere in this schedule Restricted; for dermal use in medicines containing 0.05% or less and in packs containing not more than 30 grams that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack
Committee deliberations	Item 8.1.1 of the 33rd meeting on 9 June 2005 The NDPSC had requested that the MCC reconsider the current prescription medicine status of 0.05% dermal preparations.

	<p>These had now been available in Australia as restricted medicines for some years. During that period there did not appear to have been any problems with their use as over-the-counter medicines. A similar result had become evident from reclassification in the UK. It was noted that these medicines were not widely used and evidence of misuse had not become apparent in either country. Nor did the products appear to be used in place of hydrocortisone as earlier feared by the Committee.</p> <p>Some members were still concerned with the difficulties of diagnosing skin problems and the ability of pharmacists to undertake this diagnosis. It was noted that dermatologists would be involved in pharmacist training.</p> <p>Although some Committee members were doubtful about the reclassification it was agreed that New Zealand should adopt the harmonised position provided pack warnings were included against use:</p> <ul style="list-style-type: none"> • on the face • for children • for psoriasis. <p>In order for these warnings to be enforceable the products would need to be sold only in packs approved specifically for sale as restricted medicines. Required warnings would be included in Part I of The New Zealand Regulatory Guidelines for Medicines. The guidelines would also specify a maximum pack size of 30 grams.</p> <p>It was noted that the policy statement made by the Committee in November 2000 should now be revoked. This statement stated that topical corticosteroids which were more potent than 1% hydrocortisone or which had a wider range of indications than 1% hydrocortisone should be considered unsuitable for over-the-counter sale.</p> <p>Recommendation</p> <p>That skin preparations containing 0.05% of alclometasone or clobetasone should be reclassified as restricted medicines when sold in pack sizes of 30 grams or less and in the manufacturer's original pack which has received the consent of the Minister or the Director General to its sale as a restricted medicine</p> <p>That Medsafe should be asked to include the required warning statements against use on the face, for psoriasis or for children in the New Zealand Regulatory Guidelines for Medicines.</p> <p>That the Committee policy statement of November 2000 relating to topical steroids for over-the-counter sale should be revoked.</p>
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7. Name of medicine	Cocaine
Classification	Prescription; except when specified elsewhere in this schedule Pharmacy-only; in medicines for oral use, containing not more than 0.1% of cocaine, 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, and when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine

Committee deliberations	N/A
Medsafe comment	Added by means of an update to the Medicines Regulations 1984, the Medicines Amendment Regulations 2011. Medsafe went through the Schedules to the Misuse of Drugs Act 1975 to identify substances that had a therapeutic purpose. Those substances were then included in Schedule 1. This was done because if a medicine is also a controlled drug, then the Medicines Act 1981 and Misuse of Drugs Act 1975 both apply. Where there is any inconsistency between the two sets of legislation, the Misuse of Drugs legislation takes precedence over the Medicines legislation. For substances scheduled only in Misuse of Drugs Act 1975, some of the Medicines Act 1981 controls (with respect to labelling or advertising) that should apply to a prescription medicine would not.

8. Name of medicine	Codeine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; in medicines for oral use containing not more than 15 milligrams of codeine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of codeine, 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, for use as an analgesic and when sold in a pack of not more than 5 days' supply, approved by the Minister or the Director-General for distribution as a restricted medicine</p> <p>Pharmacy-only; in medicines for oral use, containing not more than 15 milligrams of codeine per solid dosage unit or per dose of liquid with a maximum daily dose not exceeding 100 milligrams of codeine, 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, for the treatment of the symptoms of cough and cold and when sold in a pack of not more than 6 days' supply, approved by the Minister or the Director-General for distribution as a pharmacy-only medicine</p>
Committee deliberations	<p>Item 5.2 of the 42nd meeting on 3 November 2009</p> <p>The Committee's deliberations centred around three main questions, whether:</p> <ol style="list-style-type: none"> a dose unit should contain not more than either 15 mg or 12 mg codeine base the pack size should contain five days or seven days as the maximum the reclassification should include codeine-containing cough and cold preparations (such medicines have not been considered separately to date). <p>The Chair emphasised to the Committee that, with respect to the NDPSC recommendation, the agreed approach for harmonisation was that the countries should harmonise at the lowest schedule unless there were public health reasons not to. The recent decision in the United Kingdom reported by the Medicines and Healthcare products Regulatory Agency could be considered pivotal to the Committee's consideration.</p>

The Committee discussed at length the classification proposal, the risks and benefits of codeine containing products, and what was appropriate risk management to limit the risk of addiction. The pharmacist member noted that in the wide range of pharmacies in which she had worked, medicines that are abused such as cyclizine and stimulant laxatives are usually handled very well, including by pharmacy staff. It was noted that there were instances she was aware of in which the pharmacist discussed the codeine addiction with the consumer and appropriate advice was sought. However, the awareness of this issue in pharmacy, including who is abusing, needed improvement. This pharmacist member suggested, rather than a restricted medicine classification, reducing the pack size and having products classified as pharmacy-only, alongside asking industry and pharmacy organisations to support placing these products out of reach of consumers (behind the counter), would be sufficient to manage the risk of addiction. This member also suggested codeine containing products could, when advertised, include a warning statement that prolonged use could lead to addiction. It was noted that making these products restricted medicines would mean the vast majority of people who were using these medicines without abusing them would have to wait for a pharmacist and have their name and address recorded for each occasion of purchase.

Concerns were expressed about the common medical practice software default to 720 paracetamol and codeine tablets, if prescribed.

The Committee discussed these suggestions and finally agreed, by majority vote, to reclassify codeine in combination products as a restricted medicine when:

- each dose unit contains not more than 15 mg of codeine base
- the maximum daily dose is limited to 100 mg of codeine base
- the pack size is not more than five days' supply
- sold in packs approved by the Minister or the Director-General for distribution as a restricted medicine.

The Committee also concluded that cough and cold preparations containing codeine could be classified as pharmacy-only medicines when:

- each dose unit contains not more than 15 mg of codeine base
- the maximum daily dose is limited to 100 mg of codeine base
- the pack size is not more than six days' supply
- sold in packs approved by the Minister or the Director-General for distribution as a pharmacy-only medicine.

The Committee noted these recommendations could create the situation where those addicted to codeine may try to seek alternative sources of codeine from cough and cold medicines.

Following discussion the Committee agreed that the decision to allow cough and cold preparations containing codeine to continue to be available at the pharmacy-only level should be reviewed in 12-18 months' time. In the interim the Committee recommended that Medsafe should write to the Pharmaceutical Society and the Pharmacy Guild explaining that, following the reclassification of codeine in combination analgesic products as restricted medicines, the risk of patients addicted to codeine transferring from analgesics to the cough and cold preparations containing codeine could increase. The letter should request the Pharmacy sector to treat codeine containing cough and cold medicines as potentially addictive

	<p>medicines and, in keeping with the Pharmacy Council Code of Ethics, require these products be moved behind the counter and not be available for self-selection. The letter would also ask pharmacists to warn patients about the risk of addiction to cough and cold preparations. The Committee finally suggested that Medsafe should publish an article on the reclassification of codeine for General Practitioners and pharmacists in Prescriber Update. The article should also advise prescribers and pharmacists to warn patients about the risks of addiction to codeine.</p> <p>The Committee also discussed the United Kingdom's decision to label codeine containing products with warning statements regarding addiction. The Committee supported the United Kingdom's approach and felt it would further discourage long term use of these products. Medsafe should insert these requirements into the New Zealand Regulatory Guidelines for Medicines.</p> <p>Recommendation</p> <p>That codeine in combination products should be reclassified as a restricted medicine when:</p> <ul style="list-style-type: none"> • each dose unit contains not more than 15 mg of codeine base • the maximum daily dose is limited to 100 mg of codeine base • the pack size is not more than five days' supply • sold in packs approved by the Minister or the Director-General for distribution as a restricted medicine. <p>That the decision to allow cough and cold preparations containing codeine to continue to be available at the pharmacy-only level would be reviewed in 12-18 months-time.</p> <p>That Medsafe should write to the Pharmaceutical Society and the Pharmacy Guild regarding the reclassification of codeine in combination products and the recommended reclassification of cough and cold preparations.</p> <p>That Medsafe should be requested to write an article on the reclassification of codeine for General Practitioners in Prescriber Update.</p> <p>That Medsafe require codeine containing products to be labelled with warning statements similar to those required in the United Kingdom – 'Do not use for more than 3 days' and 'Codeine is an addictive substance'.</p> <p>That the requirements for codeine in combination products to be reclassified as a restricted medicine should be inserted into the New Zealand Regulatory Guidelines for Medicines by Medsafe.</p>
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9. Name of medicine	Cyclizine
Classification	Prescription; except when specified elsewhere in this schedule Restricted; for oral use other than in medicines used for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 6 dosage units; for oral use in medicines used for the treatment of anxiety or insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units
Committee deliberations	Item 8.2.1d of the 54th meeting on 24 November 2015

	<p>In February 2015, the ACMS recommended that the Schedule 3 (pharmacist only medicine) entry for cyclizine be amended to specify divided preparations with a pack size limit of six dosage units, with an implementation date of 1 June 2015. The ACMS recommended an implementation date of 1 June 2015.</p> <p>The reasons for the recommendation comprised the following:</p> <ul style="list-style-type: none"> • A maximum pack size of six dosage units is proposed for cyclizine in Schedule 3, due to the potential for abuse (and the recommended dosage and short-term duration of use). A six tablet pack is sufficient for the agreed dose for cyclizine HCl 50 mg tablets and the short term treatment of motion sickness. Inclusion of a pack size limit is consistent with requirements for pack size limits in the SUSMP for other over-the-counter antihistamines for use for motion sickness, and in ARGOM for other over-the-counter antihistamine products with abuse potential (Schedule 3 antihistamines indicated for use in insomnia). All these products are intended for short term use only. • There are currently no registered Schedule 3 cyclizine preparations. The only cyclizine product currently on the ARTG is a Schedule 4 injection (for prevention of nausea and vomiting, post-operatively). • Potential for adverse effects as a result of accumulation of cyclizine on repeated dosing (due to long half-life). • Cyclizine in oral preparations is currently Schedule 3 (rather than Schedule 2, as for other antihistamines with antiemetic indications) due to its abuse potential. No history of abuse is noted in Australia (no oral cyclizine products are registered), but there have been reports of abuse of over-the-counter cyclizine products by opiate users in New Zealand (tablets are dissolved in water and injected, usually with methadone), and reports of abuse of cyclizine by methadone users in the UK. • The Schedule 3 entry should specify divided dose cyclizine preparations (for oral use). This would result in oral liquids being rescheduled to Schedule 4 – this is appropriate, as liquid cyclizine preparations present a greater risk of abuse than solid dose preparations, it would not affect any current products, and TGA has not considered any oral cyclizine product for use in children under 12 years. <p>The Committee considered harmonising with the above classification.</p> <p>Recommendation</p> <p>That the restricted medicine entry of cyclizine should be amended to specify divided preparations sold in the manufacturer's original pack containing not more than with a pack size limit of six dosage units for oral use other than in medicines used for the treatment of anxiety or insomnia; for oral use for the treatment of anxiety or insomnia.</p>
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10. Name of medicine	Desogestrel
Classification	Prescription; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their

	distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme
Committee deliberations	<p>Item 6.4 of the 57th meeting on 1 November 2016</p> <p>It was noted that the revised submission included a World Health Organisation document which reviewed the medical eligibility criteria for contraception. It was also noted that the submitters' had addressed all material concerns raised at previous meetings.</p> <p>The Committee focused on the following areas of concern:</p> <ol style="list-style-type: none"> 1. the set of circumstances under which women would be eligible to receive SOCs from a pharmacist 2. the duration a pharmacist would be able to provide this service from the date of an original medical practitioner's prescription 3. confirmation that the submitters will work with the Council and the PSNZ in finalising the training programme and an evaluation. <p>The Committee assessed and discussed the set of circumstances under which women may be eligible to receive SOCs from a pharmacist. The five scenarios discussed are provided below:</p> <ol style="list-style-type: none"> a. New Zealand woman who has run out of her SOCs b. overseas woman who has run out of her SOCs c. woman collecting ECP, and is a previous SOC user d. woman wanting to restart contraception, and is a previous SOC user e. woman wanting postpartum contraception, and is a previous SOC user. <p>The Committee discussed the switching of formulations and when this was appropriate against the proposed five scenarios. The Committee noted that a switch in SOCs would only be appropriate in two situations:</p> <ol style="list-style-type: none"> 1. when a woman from overseas had run out of her SOCs, and 2. when a woman who was a previous SOC user wanted postpartum contraception. <p>The Committee considered that a switch in formulation was not appropriate in the other circumstances. In the circumstance where a woman had come from overseas, the Committee did not have any concerns for a switch from a formulation that was not available in New Zealand but considered that a switch should be made to a formulation that is the most similar to the originally prescribed oral contraceptive.</p> <p>The Committee discussed the circumstances of a woman wanting postpartum contraception who was a previous SOC user, and had either breastfed her baby or had chosen not to breastfeed her baby.</p> <p>The Committee considered an extra provision should be added to women wanting SOCs postpartum who were a previous SOC user should require a medical consultation. The Committee considered that a comprehensive medical consultation should be required as there are a number of options that would not be able to be provided by pharmacists and should be discussed. Thus, for a woman wanting SOCs postpartum who was a previous SOC user and had not breastfed her baby could be supplied with the same SOC. Whereas women wanting SOCs postpartum who were a previous SOC user but had</p>

breastfed her child could be supplied with selected POPs to give them enough time to have a consultation with a medical practitioner and decide which contraception is best.

The representatives confirmed that they understood the Committee's concerns regarding the switching of SOC's for women who were previous SOC users and wanted postpartum contraception after breastfeeding their baby and confirmed that referrals to their medical practitioner would take place in this situation or if the women indicated they were considering other contraception options.

The Committee also noted the final recommendation made by the Australian Delegate at the Advisory Committee on Medicine Scheduling meeting in March 2015, which was no change to the reclassification of SOC's as the use of a checklist as proposed is not an adequate alternative to a comprehensive medical evaluations. However, the Committee considered that the revised submission had the potential to address all previous and present concerns.

The Chair reminded the Committee of the recommendation made at the 54th meeting, that it had recommended the supply of SOC's for three years from the date of an original medical practitioner's prescription, and that consideration of another length of period should only be considered on the grounds of new evidence.

The Committee noted the study included in the comment provided by the RNZCGP. The results of the survey, of 141 general practitioners did not highlight any new evidence with regards to the safety of SOC's. The Committee also noted that the training tool had, to an extent, accounted for any previous concerns regarding awareness and detection of sexually transmitted infections.

The Committee considered the length of period against the five scenarios and established that a:

- a. one year period would be too short as it is no different from current practice
- b. two year period would be insufficient when taking into account the realistic timelines of a woman wanting postpartum oral contraception
- c. five year period would be too long as the Committee considered there was a higher possibility of changes in the woman's health potentially affecting her risk.

The Committee reviewed the training tools and the two checklists provided for the combined SOC's and selected POP's. The Committee noted that these documents were still under development with the Council and the PSNZ.

The Committee requested that the programme be monitored and an evaluation be provided to the Committee as it would be interested to see the effect of the reclassification.

Recommendation

That the prescription medicine entry for selected oral contraceptives (SOC) (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) should be amended to prescription medicines except when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme that is accredited by the Pharmacy Council and the Pharmaceutical Society of New Zealand, when indicated for oral contraception in women who have previously been prescribed a SOC within the last three years from the date of an original medical practitioner's prescription and meet one of the following five scenarios with the conditions that there is no

	<p>switching between selected combined oral contraceptive pill formulations, except where the formulation is not available in New Zealand as the woman has come from overseas:</p> <ol style="list-style-type: none"> NZ woman who has run out of her SOC overseas woman who has run out of her SOC woman collecting the emergency contraceptive pill who is a previous SOC user woman wanting to restart contraception who is a previous SOC user woman wanting postpartum contraception who is a previous SOC user. <p>In the case where women are previous SOC users who have been breastfeeding and are wanting postpartum contraception, they can be supplied with selected progesterone only pills and are to be referred to their medical practitioner. That Green Cross Healthcare Limited and Natalie Gauld Ltd should update Medsafe of the changes required to the training and monitoring procedures to reflect the Committee's recommendations.</p> <p>That market sales should be collected and analysed to monitor the success of the scheme in improving access to oral contraceptive pills. The Committee is interested in being updated on the outcomes of this recommendation.</p>
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11. Name of medicine	Dexchlorpheniramine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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 dexchlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p>

	<p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including dexchlorpheniramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

12. Name of medicine	Diphenhydramine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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 diphenhydramine 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</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p>

	<p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including diphenhydramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

13. Name of medicine	Doxylamine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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 doxylamine or when at least 1 of the other active ingredients is a sympathomimetic decongestant</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p>

	<p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including doxylamine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

14. Name of medicine	Esomeprazole
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>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 gastro-oesophageal reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than 7 dosage units</p>
Committee deliberations	<p>Item 8.2.1a of the 55th meeting on 3 May 2016</p> <p>The ACMS recommended that esomeprazole in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than seven days' supply, be down-scheduled from restricted (Schedule 3) medicine to pharmacy-only (Schedule 2) medicine.</p> <p>The ACMS also recommended to the delegate that consideration be given to down-scheduling the other over-the-counter proton pump inhibitors (PPIs) (lansoprazole, omeprazole and rabeprazole) from restricted (Schedule 3) medicine to pharmacy-only (Schedule 2) medicine in packs containing not more than seven day' supply.</p> <p>The ACMS had based its recommendations on the following:</p> <ol style="list-style-type: none"> esomeprazole is a safe and effective first-line treatment for consumers with frequent symptoms of gastro-oesophageal reflux disease heartburn and other symptoms of gastro-oesophageal reflux disease are common esomeprazole has very low toxicity with short-term use

	<p>d. the proposed pharmacy-only (Schedule 2) pack size (seven days' supply), labelling (including Required Advisory Statements for Medicine Labels (RASML) warning statements) and provision of consumer medicine information will help ensure appropriate use of esomeprazole as a pharmacy-only (Schedule 2) medicine</p> <p>e. the current RASML label warnings for all over-the-counter PPIs would apply to esomeprazole as a pharmacy-only (Schedule 2) medicine or as a restricted (Schedule 3) medicine</p> <p>f. esomeprazole may be more effective in the treatment of gastro oesophageal reflux disease than ranitidine which is currently available as an unscheduled medicine (seven days' supply) and as a pharmacy-only (Schedule 2) medicine (14 days' supply).</p> <p>The Committee considered harmonising with the above classification, and recommended that esomeprazole should be classified in the same manner as omeprazole.</p> <p>Recommendation</p> <p>That esomeprazole in divided solid dosage forms for oral use containing 20 mg or less with a maximum daily dose of 20 mg for the short-term symptomatic relief of gastro-oesophageal reflux-like symptoms in sufferers aged 18 years and over when sold in the manufacturer's original pack containing not more than seven dosage units should be a pharmacy-only medicine. That the label statement on the manufacturer's original pack should include the following warnings:</p> <ul style="list-style-type: none"> • Do not use if you are experiencing weight loss, persistent regurgitation of food or vomiting, difficulty swallowing or symptoms of gastro-intestinal bleeding, except on medical advice. • This product is for temporary use only. [or] For short term use only. • Do not use this medicine for any purpose other than that specified on the pack, except on doctor's advice. • Do not use if you are pregnant except on the advice of a healthcare professional. • Consult a doctor if symptoms/condition persist(s), worsens or recur. • Consult a doctor if new or additional symptoms occur.
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15. Name of medicine	Ethinylloestradiol
Classification	Prescription; except when supplied at a strength of 35 micrograms or less in combination with either levonorgestrel or norethisterone for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme
Committee deliberations	Item 6.4 of the 57th meeting on 1 November 2016

It was noted that the revised submission included a World Health Organisation document which reviewed the medical eligibility criteria for contraception. It was also noted that the submitters' had addressed all material concerns raised at previous meetings.

The Committee focused on the following areas of concern:

4. the set of circumstances under which women would be eligible to receive SOCs from a pharmacist
5. the duration a pharmacist would be able to provide this service from the date of an original medical practitioner's prescription
6. confirmation that the submitters will work with the Council and the PSNZ in finalising the training programme and an evaluation.

The Committee assessed and discussed the set of circumstances under which women may be eligible to receive SOCs from a pharmacist. The five scenarios discussed are provided below:

- f. New Zealand woman who has run out of her SOCs
- g. overseas woman who has run out of her SOCs
- h. woman collecting ECP, and is a previous SOC user
- i. woman wanting to restart contraception, and is a previous SOC user
- j. woman wanting postpartum contraception, and is a previous SOC user.

The Committee discussed the switching of formulations and when this was appropriate against the proposed five scenarios.

The Committee noted that a switch in SOCs would only be appropriate in two situations:

3. when a woman from overseas had run out of her SOCs, and
4. when a woman who was a previous SOC user wanted postpartum contraception.

The Committee considered that a switch in formulation was not appropriate in the other circumstances. In the circumstance where a woman had come from overseas, the Committee did not have any concerns for a switch from a formulation that was not available in New Zealand but considered that a switch should be made to a formulation that is the most similar to the originally prescribed oral contraceptive.

The Committee discussed the circumstances of a woman wanting postpartum contraception who was a previous SOC user, and had either breastfed her baby or had chosen not to breastfeed her baby.

The Committee considered an extra provision should be added to women wanting SOCs postpartum who were a previous SOC user should require a medical consultation. The Committee considered that a comprehensive medical consultation should be required as there are a number of options that would not be able to be provided by pharmacists and should be discussed. Thus, for a woman wanting SOCs postpartum who was a previous SOC user and had not breastfed her baby could be supplied with the same SOC. Whereas women wanting SOCs postpartum who were a previous SOC user but had breastfed her child could be supplied with selected POPs to give them enough time to have a consultation with a medical practitioner and decide which contraception is best.

The representatives confirmed that they understood the Committee's concerns regarding the switching of SOCs for women who were previous SOC users and wanted postpartum contraception after breastfeeding their baby and confirmed that

referrals to their medical practitioner would take place in this situation or if the women indicated they were considering other contraception options.

The Committee also noted the final recommendation made by the Australian Delegate at the Advisory Committee on Medicine Scheduling meeting in March 2015, which was no change to the reclassification of SOC as the use of a checklist as proposed is not an adequate alternative to a comprehensive medical evaluations. However, the Committee considered that the revised submission had the potential to address all previous and present concerns.

The Chair reminded the Committee of the recommendation made at the 54th meeting, that it had recommended the supply of SOC for three years from the date of an original medical practitioner's prescription, and that consideration of another length of period should only be considered on the grounds of new evidence.

The Committee noted the study included in the comment provided by the RNZCGP. The results of the survey, of 141 general practitioners did not highlight any new evidence with regards to the safety of SOC. The Committee also noted that the training tool had, to an extent, accounted for any previous concerns regarding awareness and detection of sexually transmitted infections.

The Committee considered the length of period against the five scenarios and established that a:

- d. one year period would be too short as it is no different from current practice
- e. two year period would be insufficient when taking into account the realistic timelines of a woman wanting postpartum oral contraception
- f. five year period would be too long as the Committee considered there was a higher possibility of changes in the woman's health potentially affecting her risk.

The Committee reviewed the training tools and the two checklists provided for the combined SOC and selected POP. The Committee noted that these documents were still under development with the Council and the PSNZ.

The Committee requested that the programme be monitored and an evaluation be provided to the Committee as it would be interested to see the effect of the reclassification.

Recommendation

That the prescription medicine entry for selected oral contraceptives (SOC) (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) should be amended to prescription medicines except when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme that is accredited by the Pharmacy Council and the Pharmaceutical Society of New Zealand, when indicated for oral contraception in women who have previously been prescribed a SOC within the last three years from the date of an original medical practitioner's prescription and meet one of the following five scenarios with the conditions that there is no switching between selected combined oral contraceptive pill formulations, except where the formulation is not available in New Zealand as the woman has come from overseas:

- f. NZ woman who has run out of her SOC
- g. overseas woman who has run out of her SOC
- h. woman collecting the emergency contraceptive pill who is a previous SOC user

	<p>i. woman wanting to restart contraception who is a previous SOC user</p> <p>j. woman wanting postpartum contraception who is a previous SOC user.</p> <p>In the case where women are previous SOC users who have been breastfeeding and are wanting postpartum contraception, they can be supplied with selected progesterone only pills and are to be referred to their medical practitioner. That Green Cross Healthcare Limited and Natalie Gauld Ltd should update Medsafe of the changes required to the training and monitoring procedures to reflect the Committee's recommendations.</p> <p>That market sales should be collected and analysed to monitor the success of the scheme in improving access to oral contraceptive pills. The Committee is interested in being updated on the outcomes of this recommendation.</p>
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16. Name of medicine	Famciclovir
Classification	Prescription; except when specified elsewhere in this schedule Restricted; in divided solid dosage forms for oral use containing 500 milligrams or less for the treatment of recurrent herpes labialis when sold in the manufacturer's original pack containing up to 3 dosage units
Committee deliberations	<p>Item 5.3 of the 42nd meeting on 3 November 2009</p> <p>At the 41st meeting on 14 May 2009 the Committee considered a submission for the reclassification of famciclovir 500 mg tablets from prescription medicine to restricted medicine when sold in packs of three tablets for the treatment of recurrent Herpes labialis (cold sores). The Committee recommended that there should be no change to the current prescription medicine classification. However, the Committee agreed to review the submission if further information was provided. Such information should include warnings and precautions relating to age and to use in patients with diabetes as well as any other training material that would aid in identifying patients who may have impaired renal function or may be immunocompromised. Patient advice should also include information not to repeat treatment within the course of an illness. The reclassification was reconsidered because the sponsor company had provided additional information in support of the classification change. A treatment algorithm had been developed which was designed to help pharmacists identify patients who might benefit from the appropriate cold sore therapy and to screen out patients who were unsuitable for over-the-counter treatment, for example patients who may have impaired renal function or may be immunocompromised. In addition the company had proposed that the following warning statements be added to the pack:</p> <ol style="list-style-type: none"> a. caution: If you have kidney disease check with your doctor or pharmacist before commencing treatment b. not recommended for patients under 18 years of age. <p>The revised submission also proposed three other changes:</p> <ol style="list-style-type: none"> a. to market the product as Famvir ONCE which would help reinforce the single dose concept b. to supply every pharmacy with a 'Famvir ONCE Training Kit' c. to develop patient education material aimed at making patients aware of the optimal time to treat cold sores and to speak to their pharmacist about all treatment options.

	<p>The sponsor company also provided information which had also been submitted to the NDPSC for consideration at the October 2009 meeting.</p> <p>One pre-meeting comment had been received during the consultation period and this was in support of the reclassification of famciclovir 500 mg tablets from prescription medicine to restricted medicine.</p> <p>The Committee felt that some issues were still outstanding. The treatment algorithm needed elaboration, especially how to check whether a patient was immunocompromised. Extensive use of famciclovir in immunocompromised patients could theoretically lead to the development of resistance.</p> <p>It was noted that, while pharmacists could not always know if a person had renal impairment as the person may not know themselves, as a single dose given immediately there would not be an accumulation from this drug if there was renal impairment present. Other medicines available without prescription used in multiple doses also have a caution for renal impairment.</p> <p>The Committee concluded that famciclovir 500 mg tablets could be reclassified from prescription medicine to restricted medicine when sold in packs of three tablets for the treatment of recurrent Herpes labialis (cold sores) provided Medsafe is satisfied that:</p> <ul style="list-style-type: none"> • the sponsor company has approached the Pharmaceutical Society requesting their input on the treatment algorithm and implemented any suggested changes required • a warning that treatment should not be repeated within seven days is included on the label. <p>Medsafe should insert these requirements into the New Zealand Regulatory Guidelines for Medicines.</p> <p>Recommendation</p> <p>That tablets containing 500 mg or less of famciclovir should be reclassified as a restricted medicine when sold in packs approved by the Minister or the Director-General for distribution as a restricted medicine.</p> <p>That the requirements famciclovir to be reclassified as a restricted medicine should be inserted into the New Zealand Regulatory Guidelines for Medicines by Medsafe.</p> <p>That Medsafe should be satisfied:</p> <ul style="list-style-type: none"> • the sponsor company has approached the Pharmaceutical Society requesting their input on the treatment algorithm and implemented any suggested changes required • a warning that treatment should not be repeated within seven days is included.
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17. Name of medicine	Famotidine
Classification	Prescription; except when specified elsewhere in this schedule Pharmacy-only; 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

<p>Committee deliberations</p>	<p><u>Item 4ix of the 12th meeting on 25 November 1993</u></p> <p>Dr Martindale summarised the situation to date. She explained that the Ministry had felt it was appropriate to ask MCC to engage in a further round of consultation before proceeding with a recommendation. Given that various queries had been raised, it had seemed reasonable to prolong the consultation process. Dr Martindale said that the Ministry had supported in principle the reclassification of these medicines to over-the-counter status with certain conditions attached. It was now necessary for the Committee to provide the Ministry with principles which it would use when evaluating an application to approve an over-the-counter pack. She said that a changed medicine notification would be necessary to gain approval for an over-the-counter pack. She suggested that members first consider the comments arising from the consultation process and determine whether or not they had changed their earlier position on the proposed reclassification. Dr Martindale added that all companies involved with these medicines now appeared to be in favour of having an over-the-counter presentation of their product. She stressed the importance of there being an over-the-counter pack containing all the appropriate patient information in plain language, rather than having prescription packs broken down to suitable size by a pharmacist. She also pointed out that at the previous meeting it had not been possible to establish precise indications or dosages for specific products as the relevant material had not been available. Reporting on events in Australia, Dr Martindale said that the Australians intended to reclassify these medicines and were about to publish their intention to do so. Because of their 2-year rule they would be able to consider cimetidine, famotidine and ranitidine but not nizatidine. The DPSSC had accepted the material from the June meeting of MCC and intended to use similar pack warnings. They also intended to include warnings for cimetidine concerning interactions with warfarin, phenytoin, and theophylline. Dr Martindale added that the Australian scheduling Committee did not concern itself with indications when reclassifying medicines.</p> <p>Dr Martindale also pointed out that the British indications, dosages and treatment periods were now available and should be considered. She suggested it might be sensible for NZ to adopt the 2-week limit of treatment accepted in Britain rather than the 10-day period suggested at the previous meeting. She added that Australia intended to do the same.</p> <p>The Committee considered and discussed the information presented by the companies and professional bodies and agreed it was in favour of proceeding with the proposed reclassification provided the medicines could be presented in approved over-the-counter packs. It was agreed that rather than establish precise dosages, indications and warning statements, a set of principles should be agreed to and that these would be used by Therapeutics evaluators when assessing changed medicine notifications for over-the-counter presentations.</p> <p>The following framework was decided on and it was agreed that relevant details for each medicine would be finalised by evaluators in the Therapeutics Section at the time a changed medicine notification for an over-the-counter pack was evaluated. Evaluators would work within the framework established by MCC. Some latitude would be allowed within the framework depending on the evidence supplied for each individual medicine. The medicines schedule would be worded in such a way as to allow these medicines to be sold over-the-counter only when presented in approved over-the-counter packs.</p> <p>Recommendation</p>
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	<p>That cimetidine, famotidine, nizatidine and ranitidine become restricted medicines when they are sold in over-the-counter-specific packs appropriately labelled. It is recommended that the medicines be used only for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity or on the recommendation of a doctor. The over-the-counter pack must contain not more than 14 days' supply.</p> <p>That recommended dose limits be established for each medicine by Therapeutics Section evaluators as being suitable for the over-the-counter indications specified and that these are supported by clinical data.</p> <p>That comprehensive consumer information be provided in plain language. The consumer information must contain warnings and precautions worded in a manner considered appropriate by the Therapeutics Section of the Ministry of Health for each individual medicine. The warnings and precautions must cover the following:</p> <ul style="list-style-type: none"> i a warning not to use the medicine for any purpose other than that specified on the pack unless under the supervision of a doctor ii the need to consult a doctor if symptoms persist iii the need to consult a doctor if symptoms recur iv the need to consult a doctor if symptoms become worse v the need to consult a doctor if new or additional related symptoms occur vi a warning against use with non-steroidal anti-inflammatory medicines unless under the supervision of a doctor vii a warning to use with caution if over 40 years of age viii a warning not to use without medical supervision if warfarin, phenytoin or theophylline are being taken (for cimetidine only).
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18. Name of medicine	Fexofenadine
Classification	<p>Prescription; except for oral use</p> <p>Pharmacy-only; for oral use except for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply</p> <p>General sale; for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply</p>
Committee deliberations	<p>Item 6.2 of the 42nd meeting on 3 November 2009</p> <p>This was a company submission for the reclassification of fexofenadine hydrochloride 60 mg capsules, 120 mg film coated tablets and 60 mg film coated tablets from pharmacy-only medicine to general sales medicine for the treatment of Seasonal</p>

Allergic Rhinitis. Specifically the application sought to facilitate the supply of a small (maximum 10 dosage units) oral presentation of fexofenadine, when used only for short term treatment (maximum five days of therapy) in adults and children 12 years and over with a maximum daily dose of 120 mg.

At their 56th meeting in June 2009, the NDPSC considered the scheduling of fexofenadine, including a proposal to exempt fexofenadine in preparations for oral use for the short term treatment of Seasonal Allergic Rhinitis. The NDPSC agreed to defer consideration until their October 2009 meeting so that data presented after the application could be evaluated.

Two pre-meeting comments had been received during the consultation period. One interested body supported the reclassification because it understood a significant number of New Zealanders were not adequately addressing their allergy problems. The other interested body did not support the reclassification. Despite an indication for Seasonal Allergic Rhinitis, it was suggested the public would see it as an antihistamine available from the supermarket for all sorts of other conditions. No questions would be asked by, or answers given by, supermarket checkout operators.

The main issue that the Committee's discussions surrounded were whether a patient could self-diagnose Seasonal Allergic Rhinitis and whether it would be appropriate to have such a product for sale in the supermarket. Concerns were raised around pregnancy and whether patients would use the product for other indications.

The Committee concluded that these issues could be addressed by appropriate labels and so fexofenadine hydrochloride 60 mg capsules, 120 mg film coated tablets and 60 mg film coated tablets should be reclassified from pharmacy-only medicine to general sales medicine for the treatment of Seasonal Allergic Rhinitis.

The Committee recommended that a warning statement should be included on the pack to the effect of 'do not use with other anti-histamines; this product should not be used when pregnant or when breast feeding except when advised by your Doctor or Pharmacist'. Medsafe should insert these requirements into the appropriate section of the New Zealand Regulatory Guidelines for Medicines.

Recommendation

That capsules containing 60 mg or less and tablets containing 120 mg or less of fexofenadine hydrochloride should be classified as general sales medicines when:

- used only for short term treatment (maximum five days of therapy) of Seasonal Allergic Rhinitis
- used in adults and children 12 years and over
- used in small (maximum 10 dosage units) oral presentations with a maximum daily dose of 120 mg
- sold in packs approved by the Minister or the Director-General for distribution as a general sales medicine.

That the requirements for fexofenadine hydrochloride to be classified as a general sales medicine should be inserted into the New Zealand Regulatory Guidelines for Medicines by Medsafe.

That Medsafe should be satisfied with the proposed warning labels of any product containing fexofenadine hydrochloride seeking consent for distribution as a general sale medicine.

19. Name of medicine	Fluconazole
Classification	Prescription; except when specified elsewhere in this schedule Restricted; for oral use in medicines that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack containing 150 milligrams or less as a single dose for the treatment of vaginal candidiasis
Committee deliberations	<p>Item 5.1 of the 31st meeting on 21 May 2004</p> <p>The recommendation from the NDPSC to reclassify from prescription medicine to restricted medicine had been deferred from the 30th meeting pending further information.</p> <p>The Committee noted that since the previous meeting, the company had made a submission and was no longer seeking use of the medicine as a second-line treatment. At the previous meeting the Committee had agreed that second-line treatment would be almost impossible to implement for such a product at an over-the-counter level of access.</p> <p>Members agreed that there would be consumer convenience associated with the single dose oral product over topical products.</p> <p>The compliance advantage of a single dose product was also recognised. Consumers using topical products requiring several days' application might be tempted to discontinue use of the product before completion of the recommended course because the condition had been alleviated. Such non-compliance would not be possible with a single dose.</p> <p>Some concern was expressed about the lost window of opportunity for consultation on wider issues and for taking of smears if the product were to no longer require medical consultation. However, it was noted that vaginal antifungals were already available over the counter and that this product would merely add another option of treatment to those already available as over-the-counter medicines.</p> <p>The Committee considered the safety of the medicine for use in pregnancy and concluded that the risks associated with a single 150 milligram dose would be minimal. Any problems which had been reported had resulted from repeated long-term doses. The submission noted a decrease in bioavailability of ethinyloestradiol with concomitant fluconazole. Two studies from late 1990s/early 2000s indicated an increase in levels from co-administration of fluconazole. One paper suggested potential for clinically significant interaction, the other noted no threat of contraceptive failure. Members agreed that clinically significant interaction with oral contraceptives would have manifested itself over the intervening years with extensive over-the-counter fluconazole use in the UK.</p> <p>Some members were concerned that the convenience of the product would mean a move away from the use of topical preparations. Because oral doses had a longer half-life than topical dose forms, there was some concern that there would be greater potential for interactions with other medicines and complementary products. However, it was agreed that, in most cases, the potential for interactions was not likely to be significant at the intended dose and that the matter could be addressed through label warnings.</p> <p>Possible resistance was also considered. As the product was subsidised only with specialist recommendation it was not widely prescribed so little was known about any local development of resistance. Research showed that while there were</p>

thought to be some problems, there was very little evidence to support the development of resistance to fluconazole when used for vaginal thrush. Information had been provided to show that the mechanism by which resistance could occur was quite different from that for bacterial resistance as there was no evidence of plasmid transfer of resistance occurring in fungi. The concerns about resistance therefore, appeared to be still at a mainly theoretical stage. It was agreed that any signs of the development of resistance would be likely to show up very quickly in other regulatory bodies. The matter could be readily addressed if this were to occur.

Members also considered the possibility of incorrect diagnosis. They agreed that there were issues surrounding use of the product in the presence of a bacterial infection. It also agreed that thrush problems often arose from other issues which could not be solved by either topical or oral antifungals. For this reason members thought it was important that consumers should recognise the symptoms of both thrush and of bacterial infections and that, ideally, they should have already had a previous diagnosis before using the product. They agreed that the symptoms for thrush should be specified on the product information as being an itchy, white, odourless discharge and that consumers should be instructed to consult a doctor if they had not previously been diagnosed with vaginal thrush or if they experienced discharge with colour or odour. Consumers should also be urged to consult a doctor if the condition had not resolved within three days or was recurrent in that it had recurred more than once in the past six months.

While they concluded that accreditation of pharmacists was not necessary for sale of the product, members agreed that they would like to see more detail in the pharmacy training programme. The company should therefore be asked to focus on its pharmacist training programme. The pharmacy education programme should include details on how to:

- identify whether there had been previous diagnosis and refer to a doctor if there had not been
- assist the consumer to recognise the classic symptoms of itchy, white, odourless discharge
- assist the consumer to recognise symptoms of other types of infection manifested by coloured discharge and/or odour and to advise seeking medical advice if these were present
- advise on questioning the consumer for signs of systemic illness such as diabetes and to refer to a doctor when such signs were present
- advise the consumer to seek medical advice if no improvement was observed after 3 days (for consistency with CMI)
- advise the consumer to seek medical advice if the condition occurred more than twice in 6 months
- advise the consumer on the remainder of the warnings consistent with those in the CMI.

Recommendation

That single-dose 150 milligram oral fluconazole for the treatment of vaginal candidiasis should be reclassified to restricted medicine.

That the company should be asked to focus on its pharmacist education programme with particular regard to the points made by the Committee.

20. Name of medicine	Fluorides
Classification	<p>Prescription; for internal use in medicines containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram; except in parenteral nutrition replacement preparations; for external use in medicines containing more than 5.5 grams per litre or per kilogram except when supplied to a dental professional registered with the Dental Council</p> <p>Restricted; for external use in liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as restricted medicines; for external use in non-liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram, except in medicines containing 1.5 grams or less and more than 1 gram per litre or per kilogram; except when supplied to a dental professional registered with the Dental Council</p> <p>Pharmacy-only; for internal use in medicines containing 0.5 milligrams or less per dose unit; except in parenteral nutrition replacement preparations; for external use in liquid form in medicines containing 1 gram or less per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as pharmacy-only medicines except in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride; except when supplied to any dental professional registered with the Dental Council; except in medicines containing 15 milligrams or less per litre or per kilogram</p> <p>General sale; for external use in liquid form in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride which have been approved by the Minister or the Director-General for distribution as general sale medicines; for external use in non-liquid form in medicines containing 1.5 grams or less per litre or per kilogram and, when containing more than 1 gram per litre or per kilogram, sold in packs approved by the Minister or the Director-General for distribution as general sale medicines; in medicines containing 15 milligrams or less per litre or per kilogram; in parenteral nutrition replacement preparations</p>
Committee deliberations	<p>Item 8.2.1 of the 40th meeting on 25 November 2008</p> <p>The MCC had withheld making a recommendation on the classification of fluorides in New Zealand until the NDPSC had finalised its review of the scheduling of fluorides. This had now been completed. The finalised classification for fluorides in Australia was as follows:</p> <p>S4/Prescription Medicine In preparations for human use except when included in or expressly excluded from Schedule 2 or 3.</p> <p>S3/Restricted Medicine For human topical use:</p> <ul style="list-style-type: none"> • in liquid preparations containing 5500 mg/kg or less of fluoride ion, in a container with a child-resistant closure except when included in or expressly excluded from Schedule 2; or • in non-liquid preparations containing 5500 mg/kg or less of fluoride ion except:

	<ul style="list-style-type: none"> ○ in preparations for therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, compliant with the requirements of the Required Advisory Statements for Medicine Labels; ○ in preparations for non-therapeutic use containing 1500 mg/kg or less of fluoride ion and, when containing more than 1000 mg/kg fluoride ion, labelled with warnings to the following effect: <ul style="list-style-type: none"> 1. Do not swallow; and 2. Do not use [this product/name of product in children six years of age or less; or ● in preparations supplied to registered dental professionals or by approval of an appropriate authority. <p>S2/Pharmacy-Only Medicine</p> <ul style="list-style-type: none"> ● in preparations for ingestion containing 0.5 mg or less of fluoride ion per dosage unit; or ● in liquid preparations for topical use containing 1000 mg/kg or less of fluoride ion, in a container with a child-resistant closure: <ul style="list-style-type: none"> ○ for therapeutic use when compliant with the requirements of the Required Advisory Statements for Medicine Labels except in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride when fitted with a child-resistant closure and compliant with the requirements of the Required Advisory Statements for Medicine Labels; or ○ for non-therapeutic use when labelled with warnings to the following effect: <ul style="list-style-type: none"> a. Do not swallow; and b. Do not use [this product/name of product] in children six years of age or less, ○ except in preparations containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 mg total fluoride, when fitted with a child-resistant closure and labelled with warnings to the following effect: <ul style="list-style-type: none"> a. Do not swallow; and b. Do not use [this product/name of product] in children six years of age or less, ○ except in preparations containing 15 mg/kg or less of fluoride ion or preparations supplied to registered dental professionals or by approval of an appropriate authority. <p>Members agreed that there should be harmonisation with Australia on the classification of fluorides. They agreed that the wording which had been adopted in Australia was more straightforward than that currently used in the New Zealand schedule and would have only a limited impact on products currently on the market. It was noted that labelling guidelines would need to be put in place in the New Zealand Regulatory Guidelines for Medicines in order to be able to enforce the required warning and advisory statements and the requirement for child-resistant closures. Medsafe should be asked to put these requirements into effect and to devise suitable wording for the Schedule. Consultation would be required with the Chief Dental Officer in the Ministry of Health in order to ensure that access to fluoride products was available to the appropriate dental professionals.</p> <p>Recommendation That New Zealand should harmonise with Australia on the classification of fluoride products.</p>
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21. Name of medicine	Guaiphenesin
Classification	<p>Prescription; for oral use in medicines containing more than 2% or 200 milligrams per dose form except when specified elsewhere in this schedule; except for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing not more than 10 days' supply</p> <p>Restricted; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing more than 10 days' supply but not more than 30 days' supply</p> <p>General sale; for oral use in medicines containing 2% or less or 200 milligrams or less per dose form; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing not more than 10 days' supply</p>
Committee deliberations	<p>Item 6.2 of the 41st meeting on 14 May 2009</p> <p>This is a company submission for the reclassification from prescription medicine to general sales medicine of 600 mg and 1200 mg modified release guaiphenesin tablets for use as an expectorant to help relieve chest congestion. Guaiphenesin is currently a general sale medicine when for oral use in medicines containing 2% or less or 200 mg or less per dose form. There appeared to be few safety issues associated with the use of guaiphenesin and the modified release dose form had been available over-the-counter in the United States for 6-7 years. Nevertheless, the Committee was aware of a potential clinical risk of developing kidney stones at higher doses and considered that a warning about this should be included. It was also noted that guaiphenesin was not appropriate for patients with porphyria, though the incidence of this is low in New Zealand and a warning on the label was not essential.</p> <p>The Committee discussed other warning statements and agreed that the sponsor's statement of 'seek medical advice if your cough worsens or does not go away after a few days' was too vague. They recommended seeking medical advice if symptoms persist 'after three days'.</p> <p>Additional label warning statements proposed by the sponsor, and supported by the Committee, included 'Do not give to children under 12 years of age' and 'Do not exceed the stated dose'.</p> <p>The submission had proposed pack sizes of up to 100 tablets. This quantity was deemed excessive for distribution as a general sale medicine. Anyone requiring that much medication to treat a cough should consult a doctor. Limiting the pack size to a 5 day supply was thought to be more appropriate. This would be in line with the pack sizes of immediate release medicines containing guaiphenesin that were already available for general sale. A limited pack size could also reduce the risk of self-medicating for off-label use, such as in those suffering from fibromyalgia.</p> <p>The issue of a modified release dose form being available as a general sale medicine for treating coughs and colds was discussed but, ultimately, was not deemed to pose an obstacle to the medication being classified at this level.</p> <p>Guaiphenesin's efficacy in a modified release dose form was also discussed. The Committee was assured by the Chairman that the sponsor would need to provide Medsafe with satisfactory efficacy data as part of the process of applying for consent to distribute the medicine in New Zealand.</p>

	<p>In conclusion, the Committee felt that the submission was largely satisfactory. The Committee recommended reclassifying guaiphenesin in modified release dose form to general sale, with limits on pack size and daily intakes. Relevant warning statements, including those discussed above, should also be included on the packaging.</p> <p>Recommendation</p> <p>That guaiphenesin should be reclassified from prescription medicine to general sale medicine when:</p> <ul style="list-style-type: none"> • pack size is limited to not more than 5 days' supply • in a modified release dosage form • a maximum daily dose of not more than 2400 mg is recommended • sold in packs approved by the Minister or the Director-General for distribution as general sale medicines. <p>That guaiphenesin should be reclassified from prescription medicine to restricted medicine when:</p> <ul style="list-style-type: none"> • pack size is more than 5 days' but not more than 30 days' supply • in a modified release dosage form • a maximum daily dose of not more than 2400 mg is recommended • sold in packs approved by the Minister or the Director-General for distribution as restricted medicines. <p>That Medsafe should be satisfied with data supporting efficacy, and with the proposed label warnings, of any modified release guaiphenesin product seeking consent to be sold as an over-the-counter medicine.</p>
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22. Name of medicine	Ibuprofen
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; for oral use in tablets or capsules containing up to 400 milligrams per dose form and in packs containing not more than 50 dose units and that have received the consent of the Minister or the Director-General to their distribution as restricted medicines, when sold in the manufacturer's original pack labelled for use by adults or children over 12 years of age</p> <p>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</p> <p>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</p>

Committee deliberations	<p>Item 6.2 of the 35th meeting on 9 June 2006</p> <p>This was a company submission for the reclassification of 400 milligram solid dose forms of ibuprofen from prescription medicine to pharmacy-only medicine when presented for the same indications, dose regime, maximum daily dose and maximum milligrams per pack as for 200 milligram over-the-counter tablets.</p> <p>It was noted that 400 milligram tablets had recently been reclassified to S3 (restricted medicines) in Australia and that the company had changed its request for pharmacy-only classification to restricted medicine classification in order to harmonise with Australian requirements.</p> <p>Although there were still some concerns about confusion of doses and potential to misuse or abuse the product, the Committee felt generally happier that the product would be sold at the restricted medicine level of access rather than as a pharmacy-only medicine. This approach would allow a pharmacist to assess the need for use of a higher dose and provide advice at the point of purchase.</p> <p>Members agreed that the 400 milligram restricted medicine pack should be clearly differentiated from 200 milligram pharmacy-only and general sales packs. In addition the restricted medicine pack should reflect the same warnings as required on the general sale packs. Medsafe should be asked to put in place the mechanisms necessary to ensure that the Committee's recommendation was put into effect.</p> <p>Secretary's note</p> <p>In order to carry out the Committee's recommendation the restricted medicine schedule entry for 400 milligram ibuprofen tablets should follow the format used for pharmacy-only and general sale ibuprofen in that the product should be sold only when in packs approved for sale at this level. Medsafe could then be asked to add the requirements for restricted medicine ibuprofen to the current ibuprofen guidelines in the New Zealand Regulatory Guidelines for Medicines.</p> <p>Recommendation</p> <p>That 400 milligram ibuprofen tablets should be reclassified from prescription medicine to restricted medicine when in packs approved by the Minister or the Director-General to their sale as restricted medicines</p> <p>That Medsafe should be asked to update the relevant section of the New Zealand Regulatory Guidelines for Medicines to reflect the Committee's requirements for the sale of 400 milligram ibuprofen tablets as restricted medicines.</p>
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23. Name of medicine	Lansoprazole
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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 for the relief of heartburn when sold in the manufacturer's original pack containing not more than 14 dosage units</p>
Committee deliberations	Item 5.5 of the 42nd meeting on 3 November 2009

At the 40th meeting on 25 November 2008 the Committee recommended that there should be no change to the current classification of lansoprazole 15 mg capsules as prescription medicine. The Committee was largely satisfied with the present submission, but agreed that appropriate warnings should be included on the pack and that further clarification was required regarding the efficacy of the proposed dose regimen.

At the 41st meeting on 14 May 2009 the issue was not discussed as further information had not been submitted.

The submission was reconsidered now that the sponsor company had provided additional information in support of the classification change from prescription medicine to restricted medicine. The packaging had been revised to include 'alarm signal' warnings. Nine references from the literature were provided displaying the efficacy of the proposed dosage of 15 mg daily.

One pre-meeting comment had been received during the consultation period and this was in support of the reclassification of lansoprazole 15 mg capsules from prescription medicine to restricted medicine.

The Committee noted that the labelling and safety requirements appeared to have been resolved, and that the data provided was supportive. The data was derived from evidence of effect at 24 hours on intragastric pH, and on interim analysis of four and eight week studies following 14 days treatment, and so seemed to demonstrate clear efficacy in terms of symptom resolution. Although the Committee felt that their requests of the sponsor company had not been fully met, there was no evidence to suggest that the risk benefit profile of lansoprazole 15 mg capsules would be significantly different from that seen for pantoprazole and omeprazole which have been reclassified.

The Committee concluded that lansoprazole should be reclassified from prescription medicine to restricted medicine provided that similar requirements were met to those detailed for the over-the-counter sale of both omeprazole and pantoprazole in the New Zealand Regulatory Guidelines for Medicines.

The requirements for lansoprazole as a restricted medicine:

- a. it must be sold in the manufacturer's original pack
- b. the strength in each dose unit should not exceed 15 mg
- c. the maximum daily dose should not exceed 15 mg
- d. the pack size must not exceed 14 dose units
- e. the indication should be limited to the relief of heartburn and short-term, symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over
- f. the following warning statements, or words of similar meaning, are required on the label:
 - i. for short-term use only, except on medical advice
 - ii. do not use the medicine for any purpose other than that specified on the pack, except on medical advice
 - iii. do not use if you are experiencing weight loss, persistent regurgitation of food or vomiting, difficulty swallowing or symptoms of gastro-intestinal bleeding, except on medical advice
 - iv. consult a doctor if symptoms persist, recur or worsen or if new symptoms occur
 - v. consult a doctor or pharmacist before use if you are pregnant or are taking any other medicines
- g. the package insert should include all interactions specified on the data sheet.

	<p>Medsafe should insert these requirements into the appropriate section of the New Zealand Regulatory Guidelines for Medicines.</p> <p>The Committee also recommended that the sponsor company should submit a product application because the product and new indication (ie, relief of heartburn) needed to be approved by Medsafe.</p> <p>Recommendation</p> <p>That tablets or capsules containing 15 mg or less of lansoprazole should be reclassified as a restricted medicine when sold in packs approved by the Minister or the Director-General for distribution as a restricted medicine.</p> <p>That the requirements for lansoprazole to be classified as a restricted medicine should be inserted into the New Zealand Regulatory Guidelines for Medicines by Medsafe.</p> <p>That the sponsor company should submit a product application, including relevant clinical data, for evaluation by Medsafe.</p>
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24. Name of medicine	Levonorgestrel
Classification	<p>Prescription; except when specified elsewhere in this schedule; except in medicines for use as emergency post-coital contraception when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme</p> <p>Restricted; 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</p>
Committee deliberations	<p>Item 6.4 of the 57th meeting on 1 November 2016</p> <p>It was noted that the revised submission included a World Health Organisation document which reviewed the medical eligibility criteria for contraception. It was also noted that the submitters' had addressed all material concerns raised at previous meetings.</p> <p>The Committee focused on the following areas of concern:</p> <ol style="list-style-type: none"> 7. the set of circumstances under which women would be eligible to receive SOC's from a pharmacist 8. the duration a pharmacist would be able to provide this service from the date of an original medical practitioner's prescription 9. confirmation that the submitters will work with the Council and the PSNZ in finalising the training programme and an evaluation.

The Committee assessed and discussed the set of circumstances under which women may be eligible to receive SOCs from a pharmacist. The five scenarios discussed are provided below:

- k. New Zealand woman who has run out of her SOCs
- l. overseas woman who has run out of her SOCs
- m. woman collecting ECP, and is a previous SOC user
- n. woman wanting to restart contraception, and is a previous SOC user
- o. woman wanting postpartum contraception, and is a previous SOC user.

The Committee discussed the switching of formulations and when this was appropriate against the proposed five scenarios. The Committee noted that a switch in SOCs would only be appropriate in two situations:

- 5. when a woman from overseas had run out of her SOCs, and
- 6. when a woman who was a previous SOC user wanted postpartum contraception.

The Committee considered that a switch in formulation was not appropriate in the other circumstances. In the circumstance where a woman had come from overseas, the Committee did not have any concerns for a switch from a formulation that was not available in New Zealand but considered that a switch should be made to a formulation that is the most similar to the originally prescribed oral contraceptive.

The Committee discussed the circumstances of a woman wanting postpartum contraception who was a previous SOC user, and had either breastfed her baby or had chosen not to breastfeed her baby.

The Committee considered an extra provision should be added to women wanting SOCs postpartum who were a previous SOC user should require a medical consultation. The Committee considered that a comprehensive medical consultation should be required as there are a number of options that would not be able to be provided by pharmacists and should be discussed. Thus, for a woman wanting SOCs postpartum who was a previous SOC user and had not breastfed her baby could be supplied with the same SOC. Whereas women wanting SOCs postpartum who were a previous SOC user but had breastfed her child could be supplied with selected POPs to give them enough time to have a consultation with a medical practitioner and decide which contraception is best.

The representatives confirmed that they understood the Committee's concerns regarding the switching of SOCs for women who were previous SOC users and wanted postpartum contraception after breastfeeding their baby and confirmed that referrals to their medical practitioner would take place in this situation or if the women indicated they were considering other contraception options.

The Committee also noted the final recommendation made by the Australian Delegate at the Advisory Committee on Medicine Scheduling meeting in March 2015, which was no change to the reclassification of SOCs as the use of a checklist as proposed is not an adequate alternative to a comprehensive medical evaluations. However, the Committee considered that the revised submission had the potential to address all previous and present concerns.

The Chair reminded the Committee of the recommendation made at the 54th meeting, that it had recommended the supply of SOCs for three years from the date of an original medical practitioner's prescription, and that consideration of another length of period should only be considered on the grounds of new evidence.

The Committee noted the study included in the comment provided by the RNZCGP. The results of the survey, of 141 general practitioners did not highlight any new evidence with regards to the safety of SOCs. The Committee also noted that the training tool had, to an extent, accounted for any previous concerns regarding awareness and detection of sexually transmitted infections.

The Committee considered the length of period against the five scenarios and established that a:

- g. one year period would be too short as it is no different from current practice
- h. two year period would be insufficient when taking into account the realistic timelines of a woman wanting postpartum oral contraception
- i. five year period would be too long as the Committee considered there was a higher possibility of changes in the woman's health potentially affecting her risk.

The Committee reviewed the training tools and the two checklists provided for the combined SOCs and selected POPs. The Committee noted that these documents were still under development with the Council and the PSNZ.

The Committee requested that the programme be monitored and an evaluation be provided to the Committee as it would be interested to see the effect of the reclassification.

Recommendation

That the prescription medicine entry for selected oral contraceptives (SOC) (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) should be amended to prescription medicines except when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme that is accredited by the Pharmacy Council and the Pharmaceutical Society of New Zealand, when indicated for oral contraception in women who have previously been prescribed a SOC within the last three years from the date of an original medical practitioner's prescription and meet one of the following five scenarios with the conditions that there is no switching between selected combined oral contraceptive pill formulations, except where the formulation is not available in New Zealand as the woman has come from overseas:

- k. NZ woman who has run out of her SOC
- l. overseas woman who has run out of her SOC
- m. woman collecting the emergency contraceptive pill who is a previous SOC user
- n. woman wanting to restart contraception who is a previous SOC user
- o. woman wanting postpartum contraception who is a previous SOC user.

In the case where women are previous SOC users who have been breastfeeding and are wanting postpartum contraception, they can be supplied with selected progesterone only pills and are to be referred to their medical practitioner. That Green Cross Healthcare Limited and Natalie Gauld Ltd should update Medsafe of the changes required to the training and monitoring procedures to reflect the Committee's recommendations.

That market sales should be collected and analysed to monitor the success of the scheme in improving access to oral contraceptive pills. The Committee is interested in being updated on the outcomes of this recommendation.

25. Name of medicine	Loperamide
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Pharmacy-only; in packs containing not more than 20 tablets or capsules; except in divided solid dosage forms for oral use containing 2 milligrams or less of loperamide per dosage form when sold in a pack containing not more than 8 dosage forms approved by the Minister or the Director-General for distribution as a general sales medicine for the symptomatic treatment of acute non-specific diarrhoea</p> <p>General sale; in divided solid dosage forms for oral use containing 2 milligrams or less of loperamide per dosage form when sold in a pack containing not more than 8 dosage forms approved by the Minister or the Director-General for distribution as a general sales medicine for the symptomatic treatment of acute non-specific diarrhoea</p>
Committee deliberations	<p>Item 6.4 of the 43rd meeting on 13 April 2010</p> <p>It was noted that the safety of the product was derived to some extent from the proposed limited pack size of eight caplets or capsules. The Committee noted that if reclassified to general sale medicine, there were no restrictions at the retail level, other than cost, preventing a consumer from purchasing multiple packs.</p> <p>The Committee had some concern that retail sale could lead to inappropriate long-term use of loperamide. However, it was noted the Periodic Safety Update Reports submitted showed loperamide was widely available and used overseas at the general sale level. Also that its use was not associated with reports of significant harm.</p> <p>The Committee suggested that the safe use of the product could be further enhanced by adding warning statements on the label, for example do not take for over 24 hours without seeking advice from a healthcare practitioner and if symptoms persist for more than 48 hours see a Doctor, or words of similar meaning.</p> <p>The Committee also discussed the concern that reclassification of loperamide could lead to inappropriate use of the product in occupations where individuals with a diarrhoeal illness should be temporarily excluded for example food handling. The Committee considered that this issue could be addressed by inclusion of general advice about hydration and hygiene if suffering from diarrhoea.</p> <p>The Committee concluded that with appropriate labelling the safety profile of loperamide supported its reclassification to general sale medicine for the symptomatic treatment of acute non-specific diarrhoea.</p> <p>Recommendation</p> <p>That loperamide should be reclassified from pharmacy-only medicine to general sale medicine in divided solid dosage forms for oral use containing 2 mg or less of loperamide when sold in a pack containing not more than eight approved by the Minister or the Director-General for distribution as a general sale medicine, for the symptomatic treatment of acute non-specific diarrhoea.</p> <p>That the label should include the following warning statements, or words of similar meaning:</p> <ol style="list-style-type: none"> a. do not take for over 24 hours without seeking advice from a healthcare practitioner b. if symptoms persist for more than 48 hours see a Doctor.

	<p>That the product information to be inserted into the pack should include advice on:</p> <ol style="list-style-type: none"> checking with an employer if diarrhoea may put others in the workplace at risk hand washing and hygiene hydration (in addition to what is already provided) recognising dehydration.
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26. Name of medicine	Loratadine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Pharmacy-only; for oral use; except in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply</p> <p>General sale; in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 10 days' supply</p>
Committee deliberations	<p>Item 6.2 of the 46th meeting on 15 November 2011</p> <p>The Committee considered the reclassification of cetirizine hydrochloride 10 mg tablets and loratadine 10 mg tablets together.</p> <p>The safety, efficacy and abuse potential of both cetirizine hydrochloride and loratadine were similar to fexofenadine. Fexofenadine had been recommended for reclassification as a general sale medicine at the 42nd meeting on 3 November 2009. At the 42nd meeting the Committee accepted that seasonal allergic rhinitis was self-diagnosable.</p> <p>The Committee concluded that both cetirizine hydrochloride and loratadine should be reclassified from pharmacy-only medicine to general sale medicine when in packs containing sufficient tablets for only five days' supply and when used for Seasonal Allergic Rhinitis.</p> <p>Recommendation</p> <p>That loratadine should be reclassified from pharmacy-only medicine to general sale medicine when in packs containing sufficient tablets for only five days' supply and when used for Seasonal Allergic Rhinitis.</p>

27. Name of medicine	Mepyramine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p>

	Pharmacy-only; for dermal use General sale; for external use in medicines containing 2% or less in packs not exceeding 25 grams
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including mepyramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

28. Name of medicine	Morphine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>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</p>

Committee deliberations	N/A
Medsafe comment	Added by means of an update to the Medicines Regulations 1984, the Medicines Amendment Regulations 2011. Medsafe Team went through the Schedules to the Misuse of Drugs Act 1975 to identify substances that had a therapeutic purpose. Those substances were then included in Schedule 1. This was done because if a medicine is also a controlled drug, then the Medicines Act 1981 and Misuse of Drugs Act 1975 both apply. Where there is any inconsistency between the two sets of legislation, the Misuse of Drugs legislation takes precedence over the Medicines legislation. For substances scheduled only in Misuse of Drugs Act 1975, some of the Medicines Act 1981 controls (with respect to labelling or advertising) that should apply to a prescription medicine would not.

29. Name of medicine	Nizatidine
Classification	Prescription; except when specified elsewhere in this schedule 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
Committee deliberations	Item 8.1.3 of the 29th meeting on 22 May 2003 The MCC had requested that the scheduling of nizatidine be returned to prescription medicine in both schedules if there were no products containing nizatidine marketed in Australia. The NDPSC had responded that there were over-the-counter nizatidine products on the Australian market. The Committee agreed therefore that the change to pharmacy-only should be made in the New Zealand schedule in the interest of harmonisation. As no products were marketed in New Zealand consultation was not necessary and the change could be put into effect immediately. Recommendation That nizatidine should be reclassified from restricted medicine to pharmacy-only medicine when in medicines which have received the consent of the Minister or the Director-General to their sale as pharmacy-only medicines and which are sold in the manufacturer's original pack containing not more than 14 days' supply.

30. Name of medicine	Norethisterone
Classification	Prescription; except when supplied for oral contraception to women who meet the clinical and eligibility criteria of the Pharmacy Council and the Pharmaceutical Society of New Zealand approved training programme on oral contraception, when sold in the manufacturer's original pack that has received the consent of the Minister or Director-General to their

	distribution as medicines, containing not more than 6 months' supply by a registered pharmacist who has successfully completed the approved training programme
Committee deliberations	<p>Item 6.4 of the 57th meeting on 1 November 2016</p> <p>It was noted that the revised submission included a World Health Organisation document which reviewed the medical eligibility criteria for contraception. It was also noted that the submitters' had addressed all material concerns raised at previous meetings.</p> <p>The Committee focused on the following areas of concern:</p> <ol style="list-style-type: none"> 10. the set of circumstances under which women would be eligible to receive SOC's from a pharmacist 11. the duration a pharmacist would be able to provide this service from the date of an original medical practitioner's prescription 12. confirmation that the submitters will work with the Council and the PSNZ in finalising the training programme and an evaluation. <p>The Committee assessed and discussed the set of circumstances under which women may be eligible to receive SOC's from a pharmacist. The five scenarios discussed are provided below:</p> <ol style="list-style-type: none"> p. New Zealand woman who has run out of her SOC's q. overseas woman who has run out of her SOC's r. woman collecting ECP, and is a previous SOC user s. woman wanting to restart contraception, and is a previous SOC user t. woman wanting postpartum contraception, and is a previous SOC user. <p>The Committee discussed the switching of formulations and when this was appropriate against the proposed five scenarios. The Committee noted that a switch in SOC's would only be appropriate in two situations:</p> <ol style="list-style-type: none"> 7. when a woman from overseas had run out of her SOC's, and 8. when a woman who was a previous SOC user wanted postpartum contraception. <p>The Committee considered that a switch in formulation was not appropriate in the other circumstances. In the circumstance where a woman had come from overseas, the Committee did not have any concerns for a switch from a formulation that was not available in New Zealand but considered that a switch should be made to a formulation that is the most similar to the originally prescribed oral contraceptive.</p> <p>The Committee discussed the circumstances of a woman wanting postpartum contraception who was a previous SOC user, and had either breastfed her baby or had chosen not to breastfeed her baby.</p> <p>The Committee considered an extra provision should be added to women wanting SOC's postpartum who were a previous SOC user should require a medical consultation. The Committee considered that a comprehensive medical consultation should be required as there are a number of options that would not be able to be provided by pharmacists and should be discussed. Thus, for a woman wanting SOC's postpartum who was a previous SOC user and had not breastfed her baby could be supplied with the same SOC. Whereas women wanting SOC's postpartum who were a previous SOC user but had</p>

breastfed her child could be supplied with selected POPs to give them enough time to have a consultation with a medical practitioner and decide which contraception is best.

The representatives confirmed that they understood the Committee's concerns regarding the switching of SOC for women who were previous SOC users and wanted postpartum contraception after breastfeeding their baby and confirmed that referrals to their medical practitioner would take place in this situation or if the women indicated they were considering other contraception options.

The Committee also noted the final recommendation made by the Australian Delegate at the Advisory Committee on Medicine Scheduling meeting in March 2015, which was no change to the reclassification of SOC as the use of a checklist as proposed is not an adequate alternative to a comprehensive medical evaluations. However, the Committee considered that the revised submission had the potential to address all previous and present concerns.

The Chair reminded the Committee of the recommendation made at the 54th meeting, that it had recommended the supply of SOC for three years from the date of an original medical practitioner's prescription, and that consideration of another length of period should only be considered on the grounds of new evidence.

The Committee noted the study included in the comment provided by the RNZCGP. The results of the survey, of 141 general practitioners did not highlight any new evidence with regards to the safety of SOC. The Committee also noted that the training tool had, to an extent, accounted for any previous concerns regarding awareness and detection of sexually transmitted infections.

The Committee considered the length of period against the five scenarios and established that a:

- j. one year period would be too short as it is no different from current practice
- k. two year period would be insufficient when taking into account the realistic timelines of a woman wanting postpartum oral contraception
- l. five year period would be too long as the Committee considered there was a higher possibility of changes in the woman's health potentially affecting her risk.

The Committee reviewed the training tools and the two checklists provided for the combined SOC and selected POPs. The Committee noted that these documents were still under development with the Council and the PSNZ.

The Committee requested that the programme be monitored and an evaluation be provided to the Committee as it would be interested to see the effect of the reclassification.

Recommendation

That the prescription medicine entry for selected oral contraceptives (SOC) (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) should be amended to prescription medicines except when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme that is accredited by the Pharmacy Council and the Pharmaceutical Society of New Zealand, when indicated for oral contraception in women who have previously been prescribed a SOC within the last three years from the date of an original medical practitioner's prescription and meet one of the following five scenarios with the conditions that there is no

	<p>switching between selected combined oral contraceptive pill formulations, except where the formulation is not available in New Zealand as the woman has come from overseas:</p> <ul style="list-style-type: none"> p. NZ woman who has run out of her SOC q. overseas woman who has run out of her SOC r. woman collecting the emergency contraceptive pill who is a previous SOC user s. woman wanting to restart contraception who is a previous SOC user t. woman wanting postpartum contraception who is a previous SOC user. <p>In the case where women are previous SOC users who have been breastfeeding and are wanting postpartum contraception, they can be supplied with selected progesterone only pills and are to be referred to their medical practitioner. That Green Cross Healthcare Limited and Natalie Gauld Ltd should update Medsafe of the changes required to the training and monitoring procedures to reflect the Committee's recommendations.</p> <p>That market sales should be collected and analysed to monitor the success of the scheme in improving access to oral contraceptive pills. The Committee is interested in being updated on the outcomes of this recommendation.</p>
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31. Name of medicine	Omeprazole
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>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</p>
Committee deliberations	<p>Items 6.4 and 6.5 of the 40th meeting on 25 November 2008</p> <p>6.4 Omeprazole 10 milligram modified release capsule (AstraZeneca)</p> <p>This was a company submission for reclassification of 10 milligram modified release capsules from prescription medicine to restricted medicine for relief of reflux-like symptoms (eg, heartburn) in patients aged 18 and over. This submission was considered in conjunction with the submission below for 10 milligram Omezol capsules.</p> <p>Subject to meeting the requirements in agenda item 6.5 below for sale as a restricted medicine, the Committee agreed that 10 milligram omeprazole capsules should be reclassified to restricted medicine.</p> <p>Recommendation</p> <p>That tablets or capsules containing 10 milligrams or less of omeprazole should be reclassified from prescription medicine to restricted medicine when sold in packs which have received the consent of the Minister or the Director-General to their sale as restricted medicines and are sold in the manufacturer's original pack.</p> <p>6.5 Omeprazole 10 milligram modified release capsules (Omezol, Pacific)</p>

This was a company submission for reclassification from prescription medicine to restricted medicine for 10 milligram modified release capsules for the short-term, symptomatic relief of reflux-like symptoms in sufferers aged 18 years and over. This submission was discussed in conjunction with the submission in agenda item 6.4 above.

The Committee agreed that both submissions were largely acceptable for over-the-counter sale. Any outstanding issues relating to such matters as dosage and pack warning statements could be dealt with by requiring products to be sold over-the-counter only when in packs approved for sale at that level. Medsafe should then include the requirements for over-the-counter sale of omeprazole in the appropriate section of the New Zealand Regulatory Guidelines for Medicines.

The following requirements should be included in the Guidelines for the sale of omeprazole as a restricted medicine:

- the indication should be for the same as that required in the UK for over-the-counter sale, that is, for the short-term, symptomatic relief of reflux-like symptoms in sufferers aged 18 years and over
- dose units should not exceed 10 milligrams
- doses should not exceed 20 milligrams and this should be reduced to 10 milligrams once symptomatic relief has been attained.
- packs should contain not more than 14 dose units
- the following should be required on the label:
 - use should not be prolonged except on medical advice
 - directions for use
 - the 4 main alarm symptoms as in the GORD guidelines:
 1. weight loss
 2. persistent regurgitation of food or vomiting
 3. dysphagia
 4. symptoms of GI bleeding
 - an instruction to inform the pharmacist about use of other medicines (may be included on the package insert if there is insufficient space on the label)
 - a statement instructing consumers to inform the pharmacist if pregnant (may be included on the package insert if there is insufficient space on the label)
- the interactions on the package insert should be the same as those on the data sheet.

Comments specific to this submission

- The training material was considered to be inadequate and needed to be developed in collaboration with the Pharmaceutical Society and the New Zealand Society of Gastroenterologists.
- Reference to helicobacter pylori and ulcers should be removed from the package insert.
- There should be a clear statement on the outside of the pack as to what the medicine should be used for.

Recommendation

	That tablets or capsules containing 10 milligrams or less of omeprazole should be reclassified from prescription medicine to restricted medicine when sold in packs which have received the consent of the Minister or the Director-General to their sale as restricted medicines and are sold in the manufacturer's original pack
Medsafe comment	Omeprazole was reclassified as a pharmacy-only medicine following the 44 th meeting on 2 November 2010.

32. Name of medicine	Opium
Classification	Prescription; except when specified elsewhere in this schedule 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
Committee deliberations	N/A
Medsafe comment	Added by means of an update to the Medicines Regulations 1984, the Medicines Amendment Regulations 2011. Medsafe went through the Schedules to the Misuse of Drugs Act 1975 to identify substances that had a therapeutic purpose. Those substances were then included in Schedule 1. This was done because if a medicine is also a controlled drug, then the Medicines Act 1981 and Misuse of Drugs Act 1975 both apply. Where there is any inconsistency between the two sets of legislation, the Misuse of Drugs legislation takes precedence over the Medicines legislation. For substances scheduled only in Misuse of Drugs Act 1975, some of the Medicines Act 1981 controls (with respect to labelling or advertising) that should apply to a prescription medicine would not.

33. Name of medicine	Oxymetazoline
Classification	Pharmacy-only; except for nasal use when sold at an airport; except for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; except for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less General sale; for nasal use when sold at an airport; for ophthalmic use when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for nasal use in medicines containing 0.05% or less when sold in the manufacturer's original pack with a pack size of 20 millilitres or less
Committee deliberations	Item 5.5 of the 51st meeting on 8 April 2014

Pharmaceutical Solutions responded to the Committee's previous recommendation, stating that they could meet two of the suggested packaging requirements:

- a. a pack size not exceeding 20 mL
- b. a sealed container where the lid cannot be removed.

A potential product sponsor addressed the recommendation that general sale oxymetazoline should have a child resistant cap. The company stated that their product would comply with the requirements of the Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines, which specifies that a child resistant cap is not required for medicines that are in a liquid spray presentation and in a sealed container where the lid cannot be removed. The company sought clarification as to whether this was an acceptable standard for medicines supplied in New Zealand. The Committee agreed that this was an appropriate closure device to minimise the risk of harm to children through accidental ingestion of oxymetazoline solutions.

Pharmaceutical Solutions specified that they could meet two of the recommended labelling requirements:

- a. do not use in children under 12 except under the advice of a doctor, nurse, or pharmacist
- b. do not use in children under two.

Pharmaceutical Solutions proposed that instead of the recommended labelling statement 'do not use for longer than three days', the labelling would read 'do not use for longer than 3 days unless advised by your healthcare professional'. The Committee felt that this change decreased the impact of the warning statement, intended to prevent cases of rebound congestion, and were not satisfied with this proposal.

Pharmaceutical Solutions also proposed that instead of including the recommended labelling statement 'seek advice from a doctor, nurse or pharmacist if you have any medical conditions or are taking any other medications', the labelling would read 'seek advice from your healthcare professional if you are using any other medicines given nasally'. The Committee believed that this proposed change altered the intent of the statement and did not provide adequate warnings of the potential for contraindications against oxymetazoline.

The Committee noted that products intended to be sold in supermarkets needed to be labelled with clear and unambiguous advice to support appropriate consumer self-selection. It is inappropriate to direct the consumer to seek health professional advice when sale is intended for an environment with no such supervision.

Recommendation

That oxymetazoline for nasal use, should be reclassified from pharmacy-only medicine to general sale medicine, with the agreed packaging requirements:

- a. pack size not exceeding 20 mL
- b. sealed container where the lid cannot be removed
- c. packaging that complies with the Therapeutic Goods Order No. 80

and the original label statement requirements proposed at the 50th meeting:

- a. do not use in children under 12 except under the advice of a doctor, nurse or pharmacist
- b. do not use in children under two

	<p>c. do not use for longer than three days</p> <p>d. seek advice from a doctor, nurse or pharmacist if you have any medical conditions or are taking any other medications.</p>
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34. Name of medicine	Pantoprazole
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>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</p>
Committee deliberations	<p>Item 6.3 of the 41st meeting on 14 May 2009</p> <p>This was a company submission for the reclassification from prescription medicine to restricted medicine of pantoprazole 20 mg enteric coated tablets. Pack size was proposed to be limited to not more than 14 days' supply and the medicine was indicated for the symptomatic relief of heartburn, acid regurgitation and other symptoms associated with gastro-oesophageal reflux disease (GORD) in patients aged 18 and over.</p> <p>It was noted that another protein pump inhibitor (PPI), 10mg omeprazole, had been recommended for reclassification from prescription medicine to restricted pump medicine at the previous meeting.</p> <p>The current submission for pantoprazole was deemed to have similar merits to the omeprazole submission. In addition, pantoprazole may be faster acting and associated with fewer drug interactions than some PPIs on the market.</p> <p>The only significant concerns expressed by the Committee related to a need for suitable warning and precaution statements on labels, particularly if pregnant, and the need to use terminology easily understood by the consumer. These issues could be resolved by permitting pantoprazole to be sold as a restricted medicine only when in packs approved for sale at that level.</p> <p>Based on this, the Committee agreed to the reclassification of pantoprazole provided that the medicine met requirements similar to those detailed for the over-the-counter sale of omeprazole in the New Zealand Regulatory Guidelines for Medicines. The requirements for the over-the-counter sale of pantoprazole are:</p> <ul style="list-style-type: none"> • It must be sold in the manufacturer's original pack • The maximum daily dose should not exceed 20 mg • The pack size must not exceed 14 dose units • The indication should be limited to the short-term, symptomatic relief of gastric reflux-like symptoms in sufferers aged 18 years and over • The following warning statements, or words of similar meaning, are required on the label: <ol style="list-style-type: none"> 1. For short-term use only, except on medical advice 2. Do not use the medicine for any purpose other than that specified on the pack, except on medical advice

	<p>3. Do not use if you are experiencing weight loss, persistent regurgitation of food or vomiting, difficulty swallowing or symptoms of gastro-intestinal bleeding, except on medical advice</p> <p>4. Consult a doctor if symptoms persist, recur or worsen or if new symptoms occur</p> <p>5. Consult a doctor or pharmacist before use if you are pregnant or are taking any other medicines</p> <ul style="list-style-type: none"> • The package insert should include all interactions specified on the data sheet • Medsafe should insert these requirements for the over-the-counter sale of pantoprazole into the appropriate section of the New Zealand Regulatory Guidelines for Medicines. • The Committee also recommended that Medsafe check the labelling of any pantoprazole product seeking consent to be sold as an over-the-counter medicine to ensure that: <ul style="list-style-type: none"> ○ consumer-appropriate language is used, and ○ any statement regarding use during pregnancy is consistent with the international pregnancy category of that medicine. <p>Recommendation</p> <p>That tablets or capsules containing 20 mg or less of pantoprazole should be reclassified from prescription medicine to restricted medicine when sold in packs approved by the Minister or the Director-General for distribution as restricted medicines.</p> <p>That Medsafe should be satisfied with proposed pregnancy statements and the terminology used on the labels of any pantoprazole product seeking consent to be sold as an over-the-counter medicine.</p>
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35. Name of medicine	Pheniramine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>Pharmacy-only; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; 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 pheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This</p>

	<p>would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including pheniramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these 25 medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

36. Name of medicine	Pholcodine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>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</p>
Committee deliberations	N/A
Medsafe comment	<p>Added by means of an update to the Medicines Regulations 1984, the Medicines Amendment Regulations 2011. Medsafe went through the Schedules to the Misuse of Drugs Act 1975 to identify substances that had a therapeutic purpose. Those substances were then included in Schedule 1. This was done because if a medicine is also a controlled drug, then the Medicines Act 1981 and Misuse of Drugs Act 1975 both apply. Where there is any inconsistency between the two sets of legislation, the Misuse of Drugs legislation takes precedence over the Medicines legislation. For substances scheduled only</p>

	in Misuse of Drugs Act 1975, some of the Medicines Act 1981 controls (with respect to labelling or advertising) that should apply to a prescription medicine would not.
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37. Name of medicine	Promethazine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012.</p> <p>When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the</p>

	medicine. However, there were a number of medicines (including brompheniramine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.
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38. Name of medicine	Ranitidine
Classification	<p>Prescription; except when specified elsewhere in this schedule 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 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply General sale; in medicines containing 300 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply</p>
Committee deliberations	<p>Item 6.3 of the 37th meeting on 17 May 2007 This was a company submission for the reclassification from pharmacy-only medicine to general sale medicine of ranitidine when in packs containing no more than 7 days' supply of 150 mg tablets. A similar submission had been considered by the NDPSC at its February 2007 meeting. The NDPSC had agreed that ranitidine should be exempt from scheduling when sold in the manufacturer's original pack in divided preparations for oral use containing 150 milligrams or less per dose unit and in packs containing not more than 7 days' supply. MCC members agreed that there appeared to be no significant problems associated with masking of more serious conditions. Studies on history of use at over-the-counter level had shown that there appeared to have been no marked increase in the delayed diagnosis of more serious problems due to over-the-counter use of ranitidine. One study from the United States found some consumers taking ranitidine to have warning symptoms. It was noted that patients in New Zealand can see a doctor for a relatively low cost, in contrast to the United States, but that prominence of appropriate warnings was desirable. The Committee was happy with the safety of the product for general sale when in the pack size proposed in the submission. It was thought that the safety of the product was likely to be similar to that of antacids although antacids needed to be taken more frequently. Members agreed that the product was more effective than antacids. Ranitidine was thought to have no harmful outcomes when taken during pregnancy. However, it was agreed that it was best avoided during pregnancy. The Committee was concerned that a warning against use during pregnancy was not included on the outer package. Although the warning appeared in the consumer information leaflet inside the pack, the Committee was concerned that pregnant women would not be aware of the warning until after the purchase had been made.</p>

Members considered the increased possibility of death from the use of ranitidine and concluded that this risk was probably less than for non-steroidal anti-inflammatory medicines. As such occurrences were idiosyncratic, the risk would be the same at any level of access.

There was discussion about use of ranitidine at the proposed level for the treatment of dyspepsia. Such doses did not provide protection for the gastric lining. However, in view of the fact that the product was for short-term use only, this was not seen to be of sufficient significance to rule out a change from pharmacy-only to general sale.

One of the members had consulted with a number of specialists and reported that the specialists consulted had had difficulty making a case either for or against the change to general sale medicine when in the pack sizes proposed in the submission.

Discussion followed on pack warnings. Members confirmed that they would like to see a warning on the outer pack to inform pregnant women before a purchase was made. They noted that there were not many warnings on the pack. Although the box was not very large they would like to see more warnings on the outer pack. In a pharmacy there was a reasonable chance that a customer would be asked about prior use of the product and use with other medicines, particularly proton pump inhibitors or other dyspepsia medicines. There was no chance at all of this happening in a supermarket or other general sale outlet. Therefore, it was felt that as many warnings as possible should be shown on the outer pack in order to inform customers at the point of sale.

There was considerable debate as to which of the key risk warnings should be included on the pack. Ideally, the Committee thought that as many as possible of the red flag warnings in the package insert should be included on the outer pack. However, given the size of the current packet, this would probably not be possible. Options such as extending the size of the pack and removing some of the unnecessary words on the currently proposed pack were explored. Eventually the Committee concluded that recommendation for a change to general sale medicine should be deferred. Meanwhile, the company should be asked to suggest a way of modifying the outer pack to see if some, if not all, of the key warnings could be added. These included warnings about:

- use in pregnancy
- unexplained weight loss
- vomiting and/or diarrhoea
- black stools
- ulcer
- use if over 40 years of age
- recent change in symptoms

The company should also be asked to provide information about which warning statements were included on packs retailing at a similar general sale status in other countries, particularly the United States of America and the United Kingdom. The matter would be considered again at the next meeting.

Recommendation

That there be no change to the current pharmacy-only classification of ranitidine 150 milligram packs.

	<p>Item 5.2.7 of the 38th meeting on 14 December 2007</p> <p>At the previous meeting the Committee had considered a company submission for the reclassification of 150 milligram ranitidine tablets from pharmacy-only medicine to general sale medicine when in packs containing no more than 7 days' supply.</p> <p>While the Committee had been satisfied overall with the safety of the product to justify a change to general sale medicine, there were still some issues to be resolved around pack warning statements.</p> <p>Members agreed that the company had responded with a vastly improved pack containing all but one of the pack warnings that they had requested. They agreed that it was acceptable for the warning about black stools to be omitted as it was covered in the package insert.</p> <p>The Committee was impressed with the robust response to its request for improved labelling and agreed that the company should be congratulated on this.</p> <p>Recommendation</p> <p>That ranitidine should become a general sale medicine when in packs containing 7 days' supply or less and in tablets or capsules containing not more than 150 milligrams.</p>
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39. Name of medicine	Rizatriptan
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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 wafers containing 5 milligrams or less per wafer and when sold in a pack containing not more than 2 wafers approved by the Minister or the Director-General for distribution as a restricted medicine</p>
Committee deliberations	<p>Item 6.6 of the 43rd meeting on 13 April 2010</p> <p>The Committee considered that the safety profile of rizatriptan was not significantly different from that of the other triptan medicines it had recently considered and recommended for reclassification. It was noted that as nausea and vomiting often accompany migraine, the availability of a medicine as a wafer offers advantages to patients over tablets or capsules. The Committee agreed that consumer convenience was enhanced if a range of similar medicines were available at the same classification.</p> <p>The Committee had some concern that the product information did not provide clear advice on the maximum dose that can be taken to treat a single headache, and considered that the triptan family of medicines should all include advice that chronic use can result in rebound headache.</p> <p>Recommendation</p>

	<p>That rizatriptan 5 mg wafers should be reclassified from prescription medicine to restricted medicine for the acute treatment of migraine with or without aura.</p> <p>That Medsafe should be satisfied the concerns raised by the Committee during discussion have been dealt with in the educational material developed by the company.</p>
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40. Name of medicine	Sildenafil and its structural analogues
Classification	Prescription; except sildenafil in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35–70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand
Committee deliberations	<p>Item 6.7 of the 50th meeting on 13 November 2013</p> <p>The Committee agreed that sildenafil is an efficacious medicine with a well-established acceptable safety profile aside from a few very rare idiosyncratic events including the potential for cardiovascular adverse events such as hypotension when taken in combination with nitrates.</p> <p>The Committee discussed the potential benefits of the proposed reclassification including:</p> <ol style="list-style-type: none"> an additional method of detecting cardiovascular disease providing access to patients who may be too embarrassed to speak to their general practitioner mitigation of internet purchases, providing a community benefit. <p>One Committee member noted that the cardiovascular screening does not include a cholesterol check or a blood glucose test. Other members of the Committee agreed that they were uncomfortable with patients not receiving a comprehensive cardiovascular check, especially if this were to reduce the number of patients visiting their general practitioner.</p> <p>One Committee member was also uncomfortable with pharmacists performing just cardiovascular screening, as they felt consultation about erectile dysfunction should cover psychological assessment. It was pointed out that particularly in younger men (aged 35 to 45), erectile dysfunction is often a result of a confidence or anxiety issue that can be resolved with just one or two treatments using sildenafil. The Committee agreed that these patients may become unnecessarily over-treated.</p> <p>The Committee discussed equipment used by pharmacists for checking blood pressure. Committee members questioned whether the equipment would need to be audited and recalibrated annually, to prevent the loss of accuracy over time. This then raised the question of what mechanism would be used to monitor the checks.</p> <p>The Committee discussed the application, which included a proposal to share information from the patients' forms with the University of Otago, which would be used for service evaluation, monitoring, and research purposes. One Committee member pointed out previous studies had shown that patients were often supportive of their information being used for research, so long as the outcomes of the research were presented back to them. The Committee debated the ethics of the</p>

proposed research and whether an opt-out option should be included; as having patient information shared may produce a barrier to access. However, it was pointed out by the observers that this would limit the tracking of misuse. The Committee noted that the current proposed option meant those who chose not to have their information shared would be denied access to the medicine and referred to their general practitioner. The Committee agreed that this approach was not fair and contradicted the proposed benefit of the submission, which is to increase access to sildenafil. The need for a post-market study was also discussed as it was not clear what the benefit may be, particularly in light of the well-established safety profile of the medicine.

The Committee discussed potential border control issues if sildenafil were to be reclassified. One of the aims of the submission was to reduce the importation of unregulated sildenafil. The Committee was aware that wording of the reclassification would be very important. Simply reclassifying sildenafil as a restricted medicine would prevent the Medsafe Investigation and Enforcement team from being able to stop sildenafil at the border.

The Committee concluded that the risk profile of sildenafil reclassification is satisfactory. However, Committee members disputed the claimed benefit that there would be greater access to the medicine, stating that most men who are too embarrassed to talk to their general practitioner would also be too embarrassed to talk to their pharmacist and that there was little evidence in the submission to suggest otherwise. The Committee agreed that the proposed screening tool was inadequate as it did not provide a comprehensive cardiovascular risk check or the necessary psychological assessment required for the treatment of erectile dysfunction. The Committee felt that this sort of mechanism would work best in an integrated family health centre-type model.

Recommendation

That sildenafil 25 mg, 50 mg and 100 mg film coated tablets (Silvasta) should not be reclassified from prescription medicine to restricted medicine, when supplied by a pharmacist who has successfully completed the approved training programme and is accredited to supply sildenafil, for the treatment of erectile dysfunction in males aged 35-70 years.

[Item 5.1.1 of the 51st meeting on 8 April 2014](#)

A valid objection was received to the recommendation made by the Committee at the 50th meeting. The objection stated that some of the intended points of the proposal were not completely understood by the Committee, and in addition the objector provided further supporting data on the safety and benefits of the proposed reclassification.

The objection stated that in the time since the recommendation had been made by the Committee at the 50th meeting, the company had consulted with two cardiologists, and four general practitioners about the screening tools and process. The company felt that the intent of the screening tool had been misinterpreted as a method to reduce the workload of general practitioners. The company stated that on the contrary, the intent would be to increase the number of men visiting their general practitioners following referral after the screening process. The company reiterated that men presenting with erectile dysfunction and seeking the supply of sildenafil are displaying a potential warning sign of cardiovascular risk, and the proposed screening process would allow pharmacists to initiate the conversation of heart health and diabetes checks with their general practitioner.

	<p>The Committee noted that the consultation with general practitioners and cardiologists had created a significant improvement to the application. The Committee felt that the recommended changes to the screening process from the cardiologists were an improvement, and that the emphasis on encouraging men presenting with erectile dysfunction to visit their general practitioner for a heart health and diabetes check was appropriate. The Committee suggested that the application overall would have benefited from a more comprehensive critique from medical professionals.</p> <p>The Committee were still unsatisfied with the post-marketing study, and questioned the value that this would add to the management of risks. One Committee member pointed out that they were not comfortable reclassifying a medicine if it would need a post-marketing study to ensure that it is safe.</p> <p>The Committee were concerned with the fact that the company would essentially be taking on responsibility for accreditation of pharmacists and that the post-marketing study would be a vehicle for the company to monitor and regulate pharmacists. The Committee were concerned that this undermined the role of the Pharmacy Council.</p> <p>The Committee were in agreement that the proposed reclassification would be acceptable with some amendments. These would include minor changes to the screening tool such as including an obligation for the pharmacist to contact the patient's general practitioner, but with the option for the patient to opt-out if they were not comfortable with their general practitioner being contacted. The Committee also felt that the mystery shopper and post-marketing study were not essential prerequisites for the reclassification.</p> <p>In addition, the Committee noted that the pack size would need to be defined for future proofing. The Committee agreed that the current packaging containing not more than 12 tablets was appropriate.</p> <p>The Committee concluded that the reclassification could be progressed, providing the applicant agreed to the required amendments. The Committee noted that reclassification of sildenafil to a restricted medicine would prevent the Medsafe Investigation and Enforcement team from being able to intercept sildenafil at the border. For this reason the Committee agreed that it would be important that the reclassification was worded as a 'prescription medicine except when...'. Recommendation That the company should be offered the opportunity to proceed with the reclassification of sildenafil from a prescription medicine to a prescription medicine; except when supplied by a pharmacist who has successfully completed the approved training programme for the treatment of erectile dysfunction in males aged 35-70 years. That the screening tool should require pharmacists to contact the patient's general practitioner, with the option for the patient to opt-out. That if unhappy with the proposed amendments, the company should be offered the opportunity to withdraw their application.</p>
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41. Name of medicine	Sumatriptan
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Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p>
Committee deliberations	<p>Item 6.5 of the 35th meeting on 9 June 2006</p> <p>This was a company submission for the reclassification from prescription medicine to restricted medicine of 50 milligram tablets in packs of two tablets for the treatment of migraine.</p> <p>Although cost might be a barrier to use by some sectors of the community, members agreed that there would be considerable customer convenience for the right group of people. They felt that this medicine would be suitable for over-the-counter sale in that migraine was a self-limiting condition. Once the condition had been correctly diagnosed it was easily recognised by the consumer.</p> <p>The safety profile had been thoroughly investigated by the Medicines and Healthcare products Regulatory Agency (MHRA) in Britain and the Committee was satisfied that the safety profile for sumatriptan was acceptable for over-the-counter sale provided that adequate safety information was provided with the product. This included warnings on the package against:</p> <ul style="list-style-type: none"> • use of the product with irregular heartbeat • use with allergy to sulfonamides • use with other migraine medicines <p>The Committee liked the wording of the indication approved in the United Kingdom for over-the-counter sumatriptan – ‘for the acute relief of migraine attacks, with or without aura, in patients who have a stable, well-established pattern of symptoms’. Members agreed that a history of migraine should first have been diagnosed either by a doctor or by a pharmacist using the questionnaire proposed by the company. They agreed that over-the-counter sale should not be for a first attack or for a consumer over the age of 65.</p> <p>It was noted that misuse of the medicine would be limited by the pack size of two tablets as well as by the cost of the product. A further safeguard would be effected by the need for either the use by the pharmacist of the Migraine Treatment Questionnaire before making an initial sale or by the subsequent presentation of a migraine card by the consumer. The Committee felt that the proposed protocol for sale of the product and the requirement for an annually updated Migraine Treatment Card to be carried by the consumer, would provide an effective tool to ensure proper diagnosis and to ensure that the product was not misused for cluster headaches or analgesic abuse headaches caused by excessive use. It would also ensure that the consumer could be referred to a doctor if the results of the questionnaire or the questions asked by the pharmacist in the protocol for sale indicated that referral was appropriate. There was discussion about whether or not the consumer migraine card should be valid in other pharmacies once it had been issued. The Committee concluded that the card should be valid only at the pharmacy of issue and that the consumer would need to complete another Treatment Questionnaire if he or she wished to make a purchase at a different pharmacy.</p>

	<p>The Committee concluded that, provided the above requirements were met, packs containing two sumatriptan tablets should be available as restricted medicines.</p> <p>Recommendation</p> <p>That 50 milligram sumatriptan tablets should be reclassified from prescription medicine to restricted medicine when sold in packs containing no more than two 50 milligram tablets and:</p> <ul style="list-style-type: none"> • are indicated for the acute relief of migraine attacks with or without aura, in patients who have a stable, well-established pattern of symptoms. • when contraindications to use, including a warning about possible cross allergy to sulfonamides, are included on the pack • the Migraine Treatment Questionnaire protocol is used by the pharmacist at each consultation unless it has previously been completed in the same pharmacy within the previous 12 months.
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42. Name of medicine	Triamcinolone
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; for buccal use in medicines containing 0.1% or less of triamcinolone acetonide and in pack sizes of 5 grams or less</p> <p>Pharmacy-only; for the treatment or prophylaxis of allergic rhinitis in adults and children over 12 years of age and when in aqueous nasal sprays delivering up to 55 micrograms per actuation when the maximum recommended daily dose is no greater than 220 micrograms and the medicine has received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine</p>
Committee deliberations	<p>Item 6.3 of the 31st meeting on 21 May 2004</p> <p>This was a company submission for reclassification from restricted medicine to pharmacy-only medicine for aqueous nasal sprays containing 55 micrograms per actuation and in packs containing 120 actuations. The submission also sought a change to the over-the-counter indication to 'allergic rhinitis' in line with recent changes to other over-the-counter corticosteroid nasal sprays. The Committee agreed that the classification change and change to indications which had already occurred with other aqueous corticosteroid nasal spray was also appropriate for triamcinolone nasal sprays and the change to pharmacy-only medicine should be made when the product was in packaging compliant with the requirements for over-the-counter sale in Volume 1 of the New Zealand Regulatory Guidelines for Medicines.</p> <p>Recommendation</p> <p>That triamcinolone should be classified as a pharmacy-only medicine when in aqueous nasal sprays delivering up to 55 micrograms per actuation when the maximum recommended daily dose was no greater than 220 micrograms and the medicine had received the consent of the Minister or the Director-General to its distribution as a pharmacy-only medicine</p>

43. Name of medicine	Trimeprazine
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; 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</p> <p>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 trimeprazine or when at least 1 of the other therapeutically active ingredients is a sympathomimetic decongestant</p>
Committee deliberations	<p>Item 6.1 of the 20th meeting on 19 November 1998</p> <p>At the last meeting the Committee had recommended that all sedating antihistamines and other medicines marketed for insomnia or anxiety should be classified as restricted medicines when in packs containing up to 5 days' supply, and as prescription medicines in packs greater than 5 days' supply. Medsafe had not supported the recommendation on the grounds that most products on the market would become prescription medicines rather than restricted medicines. This would cause them to be removed from the market as they would not be prescribed. Companies had not been consulted on the possibility of their products being changed to prescription medicines. Nor did the recommendation harmonise with the Australian classification for these medicines.</p> <p>The matter had been resolved by means of a postal consultation held in October 1998. The 5 respondents had agreed to limit the maximum pack size for sale as restricted medicine to 10 doses rather than to 5 days' supply. This would bring the pack size limits into line with those of Australia.</p> <p>Medsafe had written guidelines for medicines marketed for sedation or anxiety which harmonised with the proposed Australian guidelines for sedating antihistamines. The New Zealand guidelines were already on the website and would be incorporated into the new edition of The New Zealand Regulatory Guideline for Medicines, Volume 1 which was currently under preparation.</p> <p>The <i>Gazette</i> notice to implement the classification changes was due for publication on 26 November.</p>
Medsafe comment	<p>The <i>Gazette</i> notice to implement the changes was published on 26 November 1998.</p> <p>The wording 'when sold in the manufacturer's original pack' wasn't added until a <i>Gazette</i> notice published on 02/02/2012. When the classification of a medicine is changed from prescription to over-the-counter, conditions are often imposed, such as limits on pack size, strength or indications. These conditions are generally included in the classification statement of the medicine. However, there were a number of medicines (including trimeprazine) for which these conditions were instead reflected in the New Zealand Regulatory Guidelines for Medicines. To achieve consistency, the classification statements for these medicines were updated in the <i>Gazette</i> notice published on 02/02/2012 with the conditions added.</p>

44. Name of medicine	Zinc
Classification	<p>Prescription; for internal use in medicines containing more than 25 milligrams per recommended daily dose; except for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose in packs that have received the consent of the Minister or the Director-General to their distribution as general sale medicines, when sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except in parenteral nutrition replacement preparations</p> <p>General sale; for external use except zinc chloride in medicines containing more than 5%; for internal use in medicines containing 25 milligrams or less per recommended daily dose; for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose and in packs which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except in parenteral nutrition replacement preparations</p>
Committee deliberations	<p>Item 6.2.2 of the 38th meeting on 14 December 2007</p> <p>The New Zealand schedule and the Australian SUSDP were already harmonised on the classification of zinc as a general sale medicine in oral preparations containing 25 milligrams or less per recommended daily dose and a prescription medicine in oral preparations containing more than 25 milligrams per recommended daily dose. However, the SUSDP also allowed oral products containing up to 50 milligrams per recommended dose to be unscheduled as long as they bore appropriate warning statements. This meant that it was possible for products containing more than 25 milligrams and up to 50 milligrams per recommended daily dose to be unscheduled products in Australia but prescription medicines in New Zealand. The proposal was for New Zealand to harmonise as closely as possible on the less restrictive classification. Supporting data for a new medicine application for an oral product containing more than 25 milligrams but less than 50 milligrams were expected but the company had not been able to supply this information in the required timeframe. The Committee noted that zinc was claimed to be effective in the prevention of macular degeneration. The Committee also noted that zinc was available without prescription in Britain in doses of up to 50 milligrams. Members agreed that products containing up to 50 milligrams should be available as general sale medicines provided those products containing more than 25 milligrams carried a warning statement similar to that required in Australia. They agreed that products in this dose range should carry a warning that the product should not be used for long periods except on medical advice.*</p> <p>Although this move would appear to harmonise with the Australian scheduling, it was noted that the New Zealand Dietary Supplements Regulations 1985 allowed no more than 15 milligrams per recommended daily dose to be contained in dietary supplements. That meant that, even though zinc in recommended daily doses of up to 50 milligrams would be classified as general sale, any product containing more than 15 milligrams would need to be granted consent to market as a general sale medicine in order to be supplied lawfully, regardless of the requirement for a warning statement on the pack. Products containing more than 15 milligrams of zinc per recommended daily dose which do not have consent to be marketed as</p>

	<p>general sale medicines would continue to be non-compliant dietary supplements. In effect, this recommendation for reclassification should have no regulatory effect on current compliant dietary supplements.</p> <p>Recommendation</p> <p>That zinc should be classified as a general sale medicine in:</p> <ul style="list-style-type: none"> • medicines containing 25 milligrams or less per recommended daily dose • medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods or words of similar meaning. <p>*Secretary's note</p> <p>Unscheduled zinc products in Australia containing more than 25 milligrams and up to 50 milligrams per recommended daily dose are required to carry one of the following warning statements: either: May be dangerous if taken in large amounts or for long periods or: Contains zinc which may be dangerous if taken in large amounts or for long periods</p> <p>In order to ensure harmonised labelling on both sides of the Tasman, the Chairman has agreed that New Zealand products should carry the same warning statement as required in Australia or words of similar meaning.</p>
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45. Name of medicine	Zolmitriptan
Classification	<p>Prescription; except when specified elsewhere in this schedule</p> <p>Restricted; in a pre-filled nasal spray device containing not more than 5 milligrams of zolmitriptan, for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms and when sold in a pack of not more than 2 devices approved by the Minister or the Director-General for distribution as a restricted medicine</p>
Committee deliberations	<p>Item 5.7 of the 42nd meeting on 3 November 2009</p> <p>At the 41st meeting the Committee recommended that:</p> <ol style="list-style-type: none"> a. a single pre-filled nasal spray device containing not more than 5 mg of zolmitriptan should be reclassified from prescription medicine to restricted medicine when sold in packs approved by the Minister or the Director-General for distribution as a restricted medicine b. controls around the sale of a single pre-filled nasal spray device containing not more than 5 mg zolmitriptan should be the same as those already in place for sumatriptan; these controls include the: <ol style="list-style-type: none"> 1. indication should be limited to the acute relief of migraine attacks, with or without aura, in patients who have a stable, well-established pattern of symptoms 2. inclusion of suitable contraindications on the label, particularly regarding possible cross allergy to sulfonamides

	<p>3. inclusion of other warnings on the label, including use of the product with irregular heartbeat and use with other migraine medications</p> <p>4. Migraine Treatment Questionnaire is used by the pharmacist at each consultation unless it has previously been completed in the same pharmacy in the previous 12 months</p> <p>c. Medsafe should be satisfied with the proposed warning labels of any zolmitriptan product seeking consent to be sold as an over-the-counter medicine.</p> <p>Since the 41st meeting the sponsor company had advised Medsafe that the single pack of Zomig nasal spray 5 mg was no longer available, the smallest pack size now being two devices per pack. The sponsor company had sought advice from their head office regarding the possibility of repackaging the two device pack into singles, however this was not permitted. The Committee considered the reclassification of zolmitriptan from prescription medicine to restricted medicine when sold in packs of two devices. A number of points were raised by the Committee. There had not been an additional submission from the sponsor company displaying the packaging of a two device pack. It was noted there was no experience for New Zealand migraine sufferers with this medicine as it had not been on the market here, and usually nasal sprays were used with one spray in each nostril. However, pharmacists would be able to advise clearly the single dose only and that there are two separate devices in the pack. The packaging should include warnings about use during pregnancy; one nasal spray equates to one dose; the dose should not be repeated within 24 hours, and advertising should be in line with the dosing instructions. Medsafe should insert these requirements into the appropriate section of the New Zealand Regulatory Guidelines for Medicines.</p> <p>The Committee concluded that they had no objection to the reclassification of zolmitriptan from prescription medicine to restricted medicine when sold in packs of two devices under the conditions discussed.</p> <p>Recommendation</p> <p>That a prefilled nasal spray device containing not more than 5 mg of zolmitriptan should be reclassified from prescription medicine to restricted medicine when sold in packs of not more than two devices which have been approved by the Minister or the Director-General for distribution as a restricted medicine.</p> <p>That the controls around the sale of a prefilled nasal spray device containing not more than 5 mg zolmitriptan when sold in packs of not more than two devices should be the same as those already in place for sumatriptan.</p> <p>That the requirements for zolmitriptan to be reclassified as a restricted medicine should be inserted into the New Zealand Regulatory Guidelines for Medicines by Medsafe.</p> <p>That Medsafe should be satisfied with the proposed warning labels of any zolmitriptan product seeking consent to be sold as an over-the-counter medicine.</p>
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