16/12/2016

The Secretary
Medicines Classification Committee
Medsafe
P O Box 5013
Wellington 6145

Request to Amend Two Conditions for the Sale of Sildenafil by Accredited Pharmacists.

I am a pharmacist working in various community pharmacies & am requesting amendments to two of the specific classification conditions relating to the sale of sildenafill by an accredited pharmacist.

Ingredient	Conditions (if any)	Classification
Sildenafil and its structural analogues	**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	Prescription

[From the database of Medicine Classifications]

Condition 1
"... when sold in the manufacturer's original pack.."

Under the current condition, patients may only purchase these medicines, from accredited pharmacists, in quantities of 4 or 12
(these being the manufacturer's original pack sizes)

For financial, or other reasons, patients often request to purchase less than 4 tablets.

Where patients have had sildenafil prescribed by a medical practitioner, they are able to purchase in quantities less than 4. However, under the current conditions, if they have had a consultation etc with an accredited pharmacist, they are restricted to purchasing in quantities of 4 or 12.

I am unsure of the Medicine Classification Committee's justification for including this condition at the time of the initial deliberation as none of the manufacturer's original packs provide any extra benefits – i.e. these original 4 & 12 packs of Silvasta, Vedafil, Viagra or Silagra contain blisters of the tablets only and do not contain any patient information leaflets or other information.

Condition 2
"... aged 35-70 years..."

Here again, I am unsure of the Medicine Classification Committee's justification for including this specific age range condition at the time of the initial deliberation, other than, on the commencement of any new service, there is an understandable tendency to minimise any perceived risks, by implementing a high threshold, with the intention that this could be reconsidered when subject to a review.

This came to my attention when I recently had a request from a man who would have qualified under the medical, physiological, and pharmacological requirements, but was aged 34. I also acknowledge that whenever any age is stipulated, potential patients just outside the range will be disadvantaged.

The Medsafe Data Sheets contain no mention of any age restrictions.

The supply of sildenafil, by an accredited pharmacist to an approved patient, is a specialised dispensing service, not a "re-packing" operation. As a result of a specific patient request, the product is dispensed & labelled in an identical manner as a result of a prescription generated by either a medical practitioner or an accredited pharmacist.

Recommendations
As these clauses in the classification do not appear to offer any apparent patient benefits, I would like to request;

- that the clause relating to the "manufacturer's original pack" be deleted.
- that the clause stipulating the age range condition be reviewed with the object of reducing the minimum age from 35 to 30 or 25.

Phase 1 Submission

Part A

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

   Comment:
   Sildenafil

2. Proprietary name(s)

   Comment:
   Viagra™, Silvasta™, Vedafil™, Silagra™

3. Name of the company/organisation/individual requesting a reclassification.

   Comment:
   Peter Cooke - community pharmacist

4. Dose form(s) and strength(s) for which a change is sought.

   Comment:
   25mg, 50mg and 100mg

5. Pack size and other qualifications

   Comment:
   Currently in packs of 4 or 12

6. Indications for which change is sought

   Comment:
   No change to the current indication.

7. Present classification of the medicine

   Comment:
   Restricted Medicine or Prescription Medicine

8. Classification sought

   Comment:
   - that the clause relating to the "manufacturer's original pack" be deleted.
   - that the clause stipulating the age range condition be reviewed with the object of reducing the minimum age from 35 to 30 or 25.

9. Classification status in other countries (especially Australia, UK, USA, Canada)

   Comment:
   Not applicable. No change is required to the current medical classification.

10. Extent of usage in New Zealand and elsewhere (eg,sales volumes) and dates of original consent to distribute

Comment:
Not applicable to this submission

11. Labelling or draft labelling for the proposed new presentation(s)

Comment:
Not applicable to this submission

12. Proposed warning statements if applicable

Comment:
Not applicable to this submission

13. Other products containing the same active ingredient(s) and which would be affected by the proposed change

. Comment:
Viagra™ 25mg, 50mg, 100mg, Silvasta™ 25mg, 50mg, 100mg,
Vedafil™ 25mg, 50mg, 100mg, Silagra™ 25mg, 50mg, 100mg,

Part B
Reasons for requesting classification change including benefit - risk analysis

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1. A statement of the benefits to both the consumer and to the public expected from the proposed change.

Comment:
Public - requested change not expected to have any benefits to the public.

Consumer

Pack Size Change – Financial benefit by the flexibility to purchase smaller quantities. It relates to being relative to their requirements &/or financial situation at that time.

Age Decrease – Increases the access to the cohort of patients younger than the current 35 years.

2. Potential risk of harm to the consumer as a result of the proposed change and factors to mitigate this risk

Comment:

Pack Size Change – Any potential risk of harm would in fact decrease. If the quantity is decreased, the potential for accidental overdose – either by the patient or a child discovering the tablets & consuming them must be decreased.

Age Decrease – The suggested change might mask an existing or developing condition in the younger cohort eg diabetes, but this risk would be mitigated by the requirement of a consultation & interrogation by the pharmacist (who would be referring the potential patient with any questionable clinical symptoms to their doctor.)

3. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indication.

Comment:

Pack Size Change – Not applicable

Age Decrease - Requirement of a consultation & interrogation by the pharmacist (who would be referring the potential patient with any questionable clinical symptoms to their doctor.) is the same procedure currently used for the 35+ age group.

4. Relevant comparative data for like compounds

Comment:

Not applicable - The data for this medicine has already been evaluated. No change is being requested to the current application

5. Local data or special considerations relating to New Zealand

Comment:

Not applicable – The data for this medicine has already been evaluated. No change is being requested to the current application

6. Interactions with other medicines

Comment:

Not applicable – The data for this medicine has already been evaluated. No change is being requested to the current application

7. Contraindications and precautions.

Comment:

Not applicable – The data for this medicine has already been evaluated. No change is being requested to the current application

8. Possible resistance

Comment:
Not applicable – The data for this medicine has already been evaluated. No change is being requested to the current application

9. Adverse events - nature, frequency etc

Comment:
Not applicable – The data for this medicine has already been evaluated. No change is being requested to the current application

10. Potential for abuse or misuse

Comment:

Pack Size Change –The potential for abuse would decrease because of the reduced quantity in the possession of the patient.

Age Decrease - A younger cohort might be considered to have an increased potential for misuse because of perceived "bravado", but the pharmacist would be aware of this possibility during the consultation.

- Patient access
  Accessibility of the medicine. Accessibility includes time and location factors. Would improved access increase uptake of appropriate treatments (eg, emergency contraception) or contribute to unnecessary medication use.

Comment:

Pack Size Change - Access will be improved for the patients who will require the reduced quantity, being able to collect the lesser amounts they require.
Implementation of this submission would align patient access with the reduced quantities already available via a doctor's prescription.

Age Decrease - Increased, and easier access to the medicine for an extra cohort of potential users

- Accuracy
  The ability of a consumer and / or healthcare professional to accurately identify a disease or condition, including the understanding of the symptoms and the possibility for alternate conditions or diagnosis. The ability of a consumer to understand how the medicine they are purchasing should be used, particularly when in addition to other healthcare products that the consumer may be using. Accuracy includes a consideration of the consequences of an incorrect understanding or diagnosis (eg, the failure to seek or receive appropriate treatment)

  Comment:

  Pack Size Change - Accuracy criteria is already in place.

  Age Decrease - At the consultation, the pharmacist would be utilising the same discussion topics and criteria currently used for the older age group.

- Efficacy
  The ability of a medicine to produce a desired therapeutic effect (and therefore avoid harm associated with suboptimal therapy and / or an inappropriate risk - benefit balance).

  Comment:
  Therapeutic effect is not in question as this submission relates to an availability classification.

- Precedent
  The availability of medicines with a similar therapeutic purpose.

  Comment:
  Not applicable. Other erectile dysfunction medicines are not available under the accredited pharmacists supply service.

- Therapeutic index
  The margin between therapeutic and toxic effects.

  Comment:
  Not applicable – the therapeutic and toxic effects have already been evaluated.

- Toxicity
  The potential of a medicine to produce adverse effects, taking into consideration the seriousness and frequency of such effects. Safety of the medicine when used inappropriately (eg, when not indicated, inappropriate dosage, inappropriate duration of treatment, against warnings).

  Comment:
  Not applicable – toxicity has already been evaluated.

- Abuse potential
  The use of a medicine for gratification producing effects not required for therapy.

  Comment:
  There is no evidence the suggested changes would be expected to alter the abuse potential.

- Inappropriate use
  Factors relevant to the minor ailment or symptom for which the medicine is indicated, including the suitability of the condition for self monitoring and the likelihood of misdiagnosis. Risk of diversion of treatment to inappropriate patients (eg, children, those with contraindications)

  Comment:
  There is no evidence that a lesser quantity than contained in the manufacturer's original packs would be expected to be used inappropriately.

- Precautions
  Factors relevant to the medicine under consideration such as contraindications, side-effects and interactions with other medicines. Taking into consideration the ability to mitigate these with labelling, patient information, etc.

  Comment:
  Not applicable. Current precautions would still be observed.

- Communal Harm and / or Benefit
  The possibility of community harm and / or benefit resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased immunisation rates)

  Comment:
  There would be no community harm or benefits, however there would be a patient benefit. The suggested changes would simply align the patient's options.