10 January 2007

Medicines Classification Committee
MedSafe
Ministry of Health
PO Box 5013
WELLINGTON

RE: SUBMISSION FOR RE-CLASSIFICATION OF PHARMACY-ONLY EYE PREPARATIONS TO ALLOW SUPPLY BY OPTOMETRIST PRACTICES

The New Zealand Association of Optometrists (NZAO) asks the Medicines Classification Committee to exempt the restriction on pharmacy-only eye preparations to enable sale by retail, or supply in circumstances corresponding to retail sale in an optometry practice.

This application applies to the following medicines for ophthalmic use:

Medicine	Product Trade Names
Antazoline	Antistine-Privine; Otrivine-Antistin; Albalon-A
Levocabastine	Livostin
Lodoxamide	Lomide
Naphazoline	Naphcon Forte; Naphcon-A; Albalon; Albalon-A; Clear Eyes; Clear Eyes ACR; Visine Allergy; Optrex Red Eyes; Antistine-Privine; Optazine
Oxymetazoline	Albalon 8 Hour
Pheniramine	Naphcon-A; Visine Allergy
Sodium cromoglicate	Cromolux; Optrex Hayfever Allergy; Sodium Cromoglycate Eye Drops; Optrex Allergy Eyes; Opticrom
Tetrahydrozoline hydrochloride	Visine Clear; Visine Advanced
Xylometazoline hydrochloride	Otrivine-Antistin

Information specific to these medicines, as set out in Part A and Part B of the submission guide, is provided in the following pages but the case supporting the changes we seek is a general one.

REASONS FOR REQUESTING CLASSIFICATION CHANGE:

Dry eye, allergic conjunctivitis, and red eye without specific cause are common ailments affecting the population.

People seeking relief from these ailments may choose to visit their doctor or optometrist. Doctors and optometrists practicing in the therapeutic scope may provide access to a prescription medicine; optometrists with a general scope of practice will be able to make a diagnosis and suggest an appropriate restricted or pharmacy only medicine. People may also ask a pharmacist for advice about their eye condition and be supplied a restricted medicine.

Alternatively, they may self-diagnose and self-treat by purchasing pharmacy only medicines from a pharmacist's shop.

Since these pharmacy-only medicines are considered sufficiently safe to be sold by a pharmacy assistant we believe there is no increased risk of harm if they were to be sold from an optometry practice.

Extending the same rights of sale for ophthalmic pharmacy-only medicines to optometry include benefits for the consumer and the public which include:

Access:
The person looking for advice or a treatment for their affected eye is likely to receive a more appropriate and accurate recommendation from an optometry practice given the extensive training of optometrists in eye disease and their capacity to diagnose.

Registered optometrists have completed a 4-year Bachelor of Optometry degree that includes significant teaching in the diagnosis and management of eye disease and in ocular pharmacology.

Diagnosis is a principal task in the optometrist scope of practice; this word does not appear in the pharmacist scope of practice.

Quality:
Although the risk of harm from these medicines is low, the consumer is better off if an effective treatment is started immediately. There is less risk of a person continuing to purchase ineffective treatments for an eye condition if they are accessing the medicines through an optometry practice. For many of these preparations serious eye infection is a contraindication.

Repeat purchases are more likely to be noted and the suggestion of an appointment for a proper diagnosis is more likely to occur when it is available on the same premises.

It should be noted that acute and chronic conjunctivitis has been reported after use of OTC ophthalmic decongestant preparations containing naphazoline, tretryzoline, or phenylephrine which has taken several weeks to resolve in some cases (Soparkar CN, et al, 1997)[1]

There is less chance of drug misuse in the context of optometry supply compared to a pharmacist or their assistants. Information that underpins a recommended purchase is sourced from within the discipline of optometry and the risk of an iatrogenic condition continuing to be treated will be reduced.

Timeliness:
It will advantage the many optometrist patients who currently receive an accurate and timely diagnosis to be able to leave the practice with the treatment in hand.

There is no advantage to having an extra step delaying the process when no further safety is achieved but it does require extra time and inconvenience.

There will be increased likelihood of a timely resolution if the condition is not amenable to self-management and optometrist intervention is available.

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[1] Soparkar CN, et al. Acute and chronic conjunctivitis due to over-the-counter ophthalmic decongestants. Arch Ophthalmol 1997; 115: 38-8. Martindale

Consultation with product sponsors:

The New Zealand Association of Optometrists (NZAO) has contacted each of the product sponsors by telephone and discussed this application with them. Responses have generally been positive with Alcon and Aventis strongly supporting the application in respect of their products.

A copy of the draft application has been sent to the product sponsors in respect of each of their medicines and we will provide their responses as part of the application if received prior to the application close date. Later responses may be forwarded under separate cover to Medsafe.

Available product data sheets and consumer information sheets are appended.

It is our understanding that the MCC is considering reclassifying Dibromopropamidine and Propamidine from pharmacy only to general sale for ophthalmic use and we have therefore not included these in our application at this time. However, we would ask that they be considered as part of this application if reclassification to general sale is not approved.

Additional Note:

Three Pacific Eyecare products; two containing only polyvinyl alcohol and one containing polyvinyl alcohol and povidone, are classified as pharmacy only products. As these ingredients do not appear on the classification schedule we cannot include them in the application which follows. However, these products (Pacific Eye Care PVA Tears, Pacific Eye Care PVA Forte Tears, and Pacific Eye Care PVA Povidone Tears) would, in our view, be suitable for supply by optometrists.

Summary table of product sponsors for reference

Product	Sponsor
Sodium Cromoglycate Eye Drops	Rex Medical
Opticrom	Sanofi-Aventis
Cromolux	AFT
Lomide Eye Drops	Alcon
Naphcon Forte	Alcon
Naphcon-A	Alcon
Albalon	Allergan
Albalon-A	Allergan
Albalon 8 Hour	Allergan
Clear Eyes	Aspen
Clear Eyes ACR	Aspen
Livostin Eye Drops	Janssen-Cilag
Antistine-Privine	Novartis
Otrivine-Antistin	Novartis
Visine	Pfizer Consumer Healthcare
Visine Advanced Relief	Pfizer Consumer Healthcare
Visine Allergy with Antihistamine	Pfizer Consumer Healthcare
Optrex Allergy Eyes	Reckitt Benckiser
Optrex Red Eye Relief	Reckitt Benckiser
Brolene Eye Drops and Ointment	Sanofi-Aventis
Optrex Hayfever Allergy	Sanofi-Aventis
Optazine	Wyeth

PART A

1. **International Non-Proprietary Name of the Medicine**

Antazoline

2. **Proprietary Names(s)**

Antistine-Privine; Otrivine-Antistin; Albalon-A

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Antistine-Privine;	Eye drops, solution	0.5%
Otrivine-Antistin;	Eye drops, solution	0.5%
Albalon-A	Eye drops, solution	0.5%

5. **Pack size**

Antistine-Privine;	bottle, plastic, 10mL
Otrivine-Antistin;	bottle, dropper, 10mL
Albalon-A	bottle, dropper, 15mL, single use dropper 5 X 3ml (5 dose units)

6. **Indications for which change is sought**

Eye irritation, allergic conjunctivitis

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. Classification status in other countries

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Some potential for enhancing the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Alcohol should be avoided in excess. Should not be used in conjunction with monoamine oxidase inhibitors, adrenergic neurone blockers, TCAs

Contraindications: Narrow angles, serious eye infection, soft contact lenses, hypertension, heart disease;

Possible resistance: Not applicable

Adverse Events: CNS depression including drowsiness and sedation; systemic effects including headache, blurred vision; occasionally, palpitations and arrhythmias

Potential misuse: Not applicable for ophthalmic preparations, although some antihistamines have been abused for their mental effects

PART A

1. **International Non-Proprietary Name of the Medicine**

Levocabatine

2. **Proprietary Names(s)**

Livostin

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Livostin	Eye drops, solution	0.5mg/mL

5. **Pack size**

Livostin	bottle, dropper, 4mL

6. **Indications for which change is sought**

Allergic conjunctivitis

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. **Classification status in other countries**

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Some potential for enhancing the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Alcohol should be avoided in excess. Should not be used in conjunction with monoamine oxidase inhibitors, adrenergic neurone blockers, TCAs

Contraindications: Nil

Possible resistance: Not applicable

Adverse Events: CNS depression including drowsiness and sedation may occur in some people; systemic effects including headache, blurred vision; occasionally, palpitations and arrhythmias. The most common adverse effects reported with levocabastine eye drops are transient stinging and burning of the eyes, uticaria, dyspnoea, drowsiness and headache.

Potential misuse: Not applicable for ophthalmic preparations, although some antihistamines have been abused for their mental effects

PART A

1. **International Non-Proprietary Name of the Medicine**

Lodoxamide

2. **Proprietary Names(s)**

Lomide

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Lomide	Eye drops, solution	1mg/mL

5. **Pack size**

Lomide	bottle, plastic, droptainer, 10mL, 5mL

6. **Indications for which change is sought**

Allergic conjunctivitis, particularly vernal conjunctivitis

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. Classification status in other countries

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Nil

Contraindications: Nil

Possible resistance: Not applicable

Adverse Events: Most side effects are minor and occur in the eye including: burning or stinging, itchy eyes, and blurred vision. Eye effects that occur quite rarely include swelling, pain, discharge, corneal erosion, dim or dull vision. Occasional effects in the rest of the body include flushing, headache, nausea, dizziness, tiredness, dry nose, sneezing, and skin rash

Potential misuse: Nil

PART A

1. **International Non-Proprietary Name of the Medicine**

Naphazoline

2. **Proprietary Names(s)**

Naphcon Forte; Naphcon-A; Albalon; Albalon-A; Clear Eyes; Clear Eyes ACR; Visine Allergy; Optrex Red Eyes; Antistine-Privine; Optazine

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Naphcon Forte;	Eye drops, solution	0.1%
Naphcon-A;	Eye drops, solution	0.025%
Albalon;	Eye drops, solution	0.1%
Albalon-A;	Eye drops, solution	0.05%
Clear Eyes;	Eye drops, solution	0.01%
Clear Eyes ACR;	Eye drops, solution	0.01%
Visine Allergy;	Eye drops, solution	0.25mg/mL
Optrex Red Eyes;	Eye drops, solution	0.01%
Antistine-Privine;	Eye drops, solution	0.025%
Optazine;	Eye drops, solution	0.05%

5. **Pack size**

Naphcon Forte;	bottle, dropper, 15mL
Naphcon-A;	bottle, dropper, 15mL, 3mL
Albalon;	bottle, dropper, 15mL, single use dropper 5 X 3ml (5 dose units)
Albalon-A;	bottle, dropper, 15mL, single use dropper 5 X 3ml (5 dose units)
Clear Eyes;	bottle, dropper, 15mL, 6mL
Clear Eyes ACR;	bottle, plastic, 15mL, 30mL
Visine Allergy;	bottle, plastic, 15mL
Optrex Red Eyes;	bottle, dropper, 10mL
Antistine-Privine;	bottle, plastic, 10mL
Optazine;	bottle, dropper, 15mL

6. **Indications for which change is sought**

Topical ocular vasoconstrictor

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. **Classification status in other countries**

Current applicant was not able to source this information

10. **Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute**

Not known to current applicant

11. **Labelling**

As existing

12. **Warning statements**

As existing

13. **Other products affected by change**

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Naphazoline is a sympathomimetic medicine and systemic absorption may occur. Patients under therapy with with Monoamine oxidase inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. If absorbed, naphazoline may cause interaction with antihypertensive drugs, adrenergic neurone blockers, TCAs.

Contraindications: Narrow angle glaucoma or anatomically narrow angles, serious eye infection, soft contact lenses, hypertension, heart disease.

Possible resistance: Not applicable

Adverse Events: Naphazoline has mainly alpha-agonist effects. Local irritation, stinging, blurred vision, increased or decreased intraocular pressure, mydriasis; systemic effects include nausea, headache and dizziness.

Potential misuse: Overdosage or accidental dosage by mouth may cause CNS depression including drowsiness. Care must be taken in use for children. Use of naphazoline in high doses may liberate pigment granules from the iris, particularly in elderly patients.

Comment:- This product is better suited to optometric supply than pharmacy supply as ongoing use can lead to rebound hyperemia which can mask more severe eye problems. The redness may even lead to an erroneous adverse reaction report or report of product failure.

PART A

1. **International Non-Proprietary Name of the Medicine**

Oxymetazoline

2. **Proprietary Names(s)**

Albalon 8 Hour

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Albalon 8 Hour;	Eye drops, solution	0.02%

5. **Pack size**

Albalon 8 Hour	unknown

6. **Indications for which change is sought**

Conjuntival decongestant

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. **Classification status in other countries**

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Oxymetazoline is a direct-acting sympathomimetic with marked alpha-adrenergic activity. Since oxymetazoline is absorbed through the mucosa interactions may follow topical application. Patients under therapy with with Monoamine oxidase inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. If absorbed, naphazoline may cause interaction with antihypertensive drugs, adrenergic neurone blockers, TCAs.

Contraindications: Narrow angle glaucoma or anatomically narrow angles, serious eye infection, soft contact lenses, hypertension, heart disease. Oxymetazoline has been associated with acute attacks of porphyria and is considered unsafe in porphyric patients.

Possible resistance: Not applicable

Adverse Events: Local irritation, stinging, increased intraocular pressure, mydriasis; occasionally, systemic effects including nausea, headache and dizziness.

Potential misuse: Nil

Comment:- This product is better suited to optometric supply than pharmacy supply as ongoing use can lead to rebound hyperemia which can mask more severe eye problems. The redness may even lead to an erroneous adverse reaction report or report of product failure.

PART A

1. **International Non-Proprietary Name of the Medicine**

Pheniramine

2. **Proprietary Names(s)**

Naphcon-A; Visine Allergy

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Naphcon-A	Eye drops, solution	0.3%
Visine Allergy	Eye drops, solution	0.3%

5. **Pack size**

Naphcon-A	bottle, dropper, 15mL 3 mL
Visine Allergy	bottle, plastic, 15mL

6. **Indications for which change is sought**

Allergic conjunctivitis, eye irritation

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. Classification status in other countries

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: May enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Should not be used in conjunction with monoamine oxidase inhibitors, adrenergic neurone blockers, TCAs

Contraindications: Nil

Possible resistance: Not applicable

Adverse Events: Most common adverse effect is CNS depression including drowsiness and sedation; systemic effects including headache, psychomotor impairment, blurred vision; occasionally, palpitations and arrhythmias.

Potential misuse: Not applicable for ophthalmic preparations, although some antihistamines have been abused for their mental effects

PART A

1. **International Non-Proprietary Name of the Medicine**

Sodium Cromoglicate

2. **Proprietary Names(s)**

Cromolux; Optrex Hayfever Allergy; Sodium Cromoglycate Eye Drops; Optrex Allergy Eyes; Opticrom

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Cromolux;	Eye drops, solution	2%
Optrex Hayfever Allergy;	Eye drops, solution	2%
Sodium Cromoglycate Eye Drops;	Eye drops, solution	2%
Optrex Allergy Eyes;	Eye drops, solution	2%
Opticrom	Eye drops, solution	2%
Opticrom	Eye ointment	4%

5. **Pack size**

Cromolux;	bottle, plastic, 10mL
Optrex Hayfever Allergy;	bottle, plastic, 10mL
Sodium Cromoglycate Eye Drops;	bottle, plastic, 5mL
Optrex Allergy Eyes;	bottle, plastic, 10mL
Opticrom	bottle, plastic, 10mL
Opticrom	tube, aluminium, 5g

6. **Indications for which change is sought**

Prophylaxis and treatment of seasonal and perennial allergic conditions of the eye including acute and chronic allergic conjunctivitis and vernal keratoconjunctivitis

7. Present Classification of medicine

Pharmacy only

8. Classification sought

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. Classification status in other countries

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Sodium cromoglycate has been used for the treatment of a variety of indications in man, and it has been the subject of many animal drug interaction studies. No evidence of interaction with other drugs has been observed. Sodium cromoglicate has no intrinsic vasoconstrictor or antihistaminic activity.

Contraindications: Nil.

Possible resistance: Not applicable

Adverse Events: Transient stinging and burning may occur after instillation of eye drops

Potential misuse: Nil

PART A

1. **International Non-Proprietary Name of the Medicine**

Tetryzoline

2. **Proprietary Names(s)**

Visine; Visine Advanced

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Visine;	Eye drops, solution	0.05%
Visine Advanced;	Eye drops, solution	0.05%

5. **Pack size**

Visine	bottle, dropper, 15mL
Visine Advanced	bottle, dropper, 15 mL, 2mL

6. **Indications for which change is sought**

For topical relief of ocular congestion, itching, and minor irritation, and to control hyperemia in patients with superficial; corneal vascularity

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. Classification status in other countries

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: If absorbed, tetryzoline may cause interaction with monoamine oxidase inhibitors, antihypertensive drugs, adrenergic neurone blockers, TCAs

Contraindications: Angle closure glaucoma or other serious eye disease.

Possible resistance: Not applicable

Adverse Events: The incidence of serious adverse effects from tetryzoline is low, however, use in the eye may cause blurred vision, irritation and mydiasis. Occasionally, ophthalmic use may cause systemic sympathomimetic effects such as headache, weakness, sweating, palpitation, and tremors.

Potential misuse: Use of tetryzoline in high doses may liberate pigment granules from the iris, particularly in elderly patients. Overdosage may produce CNS depression with drwsiness, decreased body temperature, bradycardia, shock-like hypotension, apnea, and coma.

Comment:- This product is better suited to optometric supply than pharmacy supply as ongoing use can lead to rebound hyperemia which can mask more severe eye problems. The redness may even lead to an erroneous adverse reaction report or report of product failure.

PART A

1. **International Non-Proprietary Name of the Medicine**

Xlyometazoline

2. **Proprietary Names(s)**

Otrivine-Antistin

3. **Name of organisation requesting reclassification**

NZ Association of Optometrists Inc

Contact Details:
Dr Lesley Frederikson
National Director
NZAO
PO Box 1978
Wellington

Email: nzao.nd@clear.net.nz

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

	Dose form(s):	Strength(s):
Otrivine-Antistin;	Eye drops, solution	0.05%

5. **Pack size**

Otrivine-Antistin	bottle, dropper, 10mL

6. **Indications for which change is sought**

Conjuntival decongestant

7. **Present Classification of medicine**

Pharmacy only

8. **Classification sought**

Exemption to classify as general sale for ophthalmic use when sold from an optometry practice

9. **Classification status in other countries**

Current applicant was not able to source this information

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

Not known to current applicant

11. Labelling

As existing

12. Warning statements

As existing

13. Other products affected by change

No other products should be affected by the change other than those noted above. Change is sought only for ophthalmic use.

PART B

The reasons for requesting the classification change (Part B items 1-4) are outlined in the general case made in the introduction (pp 1-2).

Interactions: Monoamine oxidase inhibitors, adrenergic neurone blockers, antihypertensive drugs, TCAs

Contraindications: Narrow angle glaucoma, serious eye infection, soft contact lenses, hypertension, heart disease

Possible resistance: Not applicable

Adverse Events: Local irritation, dilated pupil, increased intraocular pressure; more rarely, systemic effects including nausea, headache and dizziness.

Potential misuse: Overdosage or accidental dosage by mouth may cause CNS depression including drowsiness.