CODE OF PRACTICE
FOR THE SUPPLY OF
CONTACT LENSES AND
CONTACT LENS CARE
PRODUCTS

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NZAO Code of Practice for the Supply of Contact Lenses and Contact Lens Care Products.

BACKGROUND

The contact lens industry has changed considerably since 1989. Prior to this, all contact lenses were made to an individual prescription, supplied generally by the prescribing practitioner and replaced after a considerable period, often after twelve months. The procedures of the eye care practitioners were well standardised by best practice methods, so the risks of public harm were minimal.

The advent of mass produced disposable lenses has revolutionised the industry. For the wearer the benefits have been: vast improvements in lens properties and hence better ocular health, reduced costs of lenses, and improved availability. Suppliers are not always eye care practitioners, as disposable lenses have become a consumable item. The potential for public harm may well have increased due to a lack of standardised procedures.

In view of these changes the NZAO council has concerns that there is greater risk for public harm and detriment to the reputation of the contact lens industry.

The following document represents a position statement of the expectations of NZAO optometrists, their suppliers and patients and is compiled in the interests of public safety.

The document represents the consensus view of the Code Development Committee; a group representing contact lens practitioners and other interested professional parties.

It is hoped that others in the industry who supply contact lenses and contact lens products will choose to comply with the code.

The intention is to supplement current legislation not to interpret, dictate, or influence it.

SCOPE

This code of practice specifies protocols for supplying contact lenses and care products for purchase by the public. The intended use of this document is for NZAO members; to ensure uniform practices are employed in the interests of health and safety, and to provide consumers with a statement which confirms the importance of safety and good care in this mode of visual correction. NZAO recommends that this standard is adopted by the contact lens industry.

For the purposes of the code the words “shall” or “will” refer to the practices, which are mandatory for compliance with this document. The words “should” or “may” refer to practices which are advised or recommended.
RELEVANT LEGISLATION

The standard is intended to supplement aspects of the following legislation;

Health Practitioners Competence Assurance Act (2003)
Medicines Act (1981 and its amendments)
Health and Disability Commissioner Act. (1994)
Accident Compensation Act (1982 and its amendments)
Consumer Guarantees Act (1993)
Privacy Act (1993)

RELEVANT CODES OF PRACTICE

Health and Disability Commissioner's Code of Consumer Rights.
NZ Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods Parts 4 and 5. (Ministry of Health 1995)

COMPETENCY

This code does not define practitioner competencies. These are set out by the Optometrists and Dispensing Opticians Board in the Standards Of Clinical Competence For Optometrists which outlines requirements for optometry including contact lens practice.

CULTURAL COMPETENCY

This code acknowledges the importance of culturally appropriate practices and procedures in all aspects of the provision of contact lens related eye care.
DEFINITIONS

A contact lens is an optical and medical device intended to be worn in direct contact with the anterior surface of the eye.

Further classification of contact lenses:
1) Custom made contact lenses intended for daily wear.
2) Custom made contact lenses intended for extended wear.
3) Limited production lenses intended for daily wear.
4) Limited production lenses intended for extended wear.
5) Mass produced contact lenses intended for frequent replacement daily wear (disposable).

“Custom made” refers to a lens manufactured to an individual order.

“Limited production” refers to a process where a small volume of lenses is made and held in stock.

“Mass produced contact lenses” refers to lenses manufactured in large volumes and individually sealed and of the same parameters but usually purchased in packages of multiple lenses.

“Daily wear” means the lens is worn daily and removed for cleaning and disinfecting, or disposal.

“Extended wear” means the lens is not removed for sleep, but is removed after an established period for cleaning and disinfecting or disposal.

“Contact lens care products” includes all products manufactured for the purpose of maintaining and storing a contact lens in a clean and disinfected condition fit for wear, for enhancing comfort during wear and for prolonging the life of a lens.

“Prescribing practitioner” – is defined as the health care practitioner who has a suitable health qualification and meets the Optometrists and Dispensing Opticians Board competency standards for optometric and contact lens practice.

The prescribing practitioner:
a) uses trial contact lenses and inspects their behaviour on the eye,
b) evaluates the response of the eye,
c) determines the resulting vision,
then derives a prescription that the patient can use to purchase contact lenses.

“Retail supplier” refers to the person who supplies contact lenses to a client’s prescription.
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The following categories, while overlapping at times, apply to this code of practise.

1. **The contact lens** – protocols to be observed by the manufacturer, wholesaler or importer.

2. **The prescription** – protocols to be observed by the prescriber.

3. **The prescribing practitioner** – protocols to be observed in prescribing and caring for the continued ocular health of the wearer of daily wear and extended wear contact lenses.

4. **The retail supplier** - protocols to be observed when supplying to a prescription.

5. **Contact lens care products** – procedures to be observed in supplying contact lens care products;
   a) by the wholesaler.
   b) by the retailer.

6. **The patient** – documented procedures to be observed by contact lens patients.
THE CONTACT LENS

1. It is expected that manufacturers and product suppliers comply with all applicable legislation and standards in relation to the materials, manufacturing and distribution of contact lenses and contact lens care products.

1.1. In particular it is essential there is compliance with international standards and NZ codes on:

- accuracy of parameters.
- maintenance of sterility.
- notification of manufacturers or distributors details on lens packages.
- correct labeling information (including batch numbers, lot numbers and expiry dates).
- permanent labeling.
- correct packaging.
- provision for recall procedures.

1.2. There should also be comprehensive product information for the practitioner and separate material for the consumer.

Practitioner information shall include:

- lens material properties (polymer, Dk, ionicity, water content etc).
- design properties (front surface, back surface).
- range of parameters.
- tints available.
- availability (stock, custom).
- recommended wearing modality.

Consumer information should include a general description of the type of lens and its proposed use.
THE CONTACT LENS PRESCRIPTION

A contact lens prescription is unique for each patient and shall be distinguished from the spectacle prescription.

2.1. a) The practitioner shall make available on request to the patient, or their nominee, the full contact lens prescription, which shall be signed and dated by the practitioner.
   b) In supplying a contact lens prescription details to another practitioner or supplier, the practitioner should do so by hard copy, facsimile or email, but may communicate verbally in urgent situations.

2.2. The prescription shall include all relevant information required to duplicate the lenses. This shall include such specifics as:
   • back central optic radius,
   • overall diameter,
   • back vertex power,
   • a reasonable expiry date of prescription, no greater than two years,
   • lens material properties (polymer, Dk, water content),
   • lens design properties (peripheral curves, front and back toricity),
   • wear modality,

   and may include;
   • intermediate and peripheral curve radii,
   • intermediate and peripheral curve width,
   • toricity, assymetry, asphericity, lenticulation,
   • centre thickness,
   • tint,
   • prism,
   • markings,
   • solutions to be used.
THE PRESCRIBING PRACTITIONER

3 The prescribing practitioner must hold a suitable qualification and have shown competency in contact lens practice. It is expected that practitioners meet current accepted best practice standards of care in the prescribing process including, but not limited to: having an acceptable level of appropriate functioning equipment, meeting accepted levels of hygiene, and performing all appropriate procedures.

Of particular importance:

3.1. The practitioner must be satisfied the lenses are performing well with no compromise in ocular health before writing a prescription.

3.2. The practitioner is responsible for informing the patient of potential problems which may occur with contact lens wear and how to minimise and manage these.

3.3. The practitioner shall ensure the patient is proficient in safe handling and lens care procedures prior to supply of the initial lenses.

3.4. In prescribing daily wear lenses the practitioner shall inform the patient of the need for regular after care examinations.

3.5. In prescribing lenses for special cases such as post keratoplasty, orthokeratology, keratoconus, diabetics, children and extended wear, the practitioner shall ensure the ocular health is monitored at a frequency appropriate to the increased risk, in accordance with current best practice.

3.6. In prescribing lenses for extended wear, the practitioner has a responsibility to ensure the patient is informed of the increased risks and added complications with this wearing modality. The patient shall also be advised of the symptoms which may occur and on what action to take, and who to contact should problems arise.

3.7. The practitioner shall provide the patient with a contact phone number, or an alternative eye care provider to be used if problems arise outside the normal hours of business.

3.8. Practitioners, in using diagnostic contact lenses, shall adhere strictly to the current best practice recommendations in relation to minimising the risk of cross contamination.

3.9. Continuing Education: contact lens practitioners will attend continuing education lectures specifically related to contact lens practice, as part of fulfilling their normal NZAO continuing professional education requirement.
THE RETAIL SUPPLIER

Suppliers shall meet the following requirements:

4.1. Prior to supplying contact lenses, the parameters shall be verified where possible to ensure they match the prescription.

4.2. Custom made RGP lenses should be checked for correct performance on the eye at the time of supply by the prescribing practitioner.

4.3. Limited production lenses, custom made soft lenses, and mass produced soft lenses might not necessarily be checked on the eye, but the patient should be advised that if comfort, vision or the appearance of the eye is not normal, they should consult a prescribing practitioner promptly.

4.4. The supplier must neither substitute another brand of contact lens, nor another lens of different parameters, unless a substitute is specified in the prescription, or the substitute lens has been viewed on the eye, by a prescribing practitioner.

4.5. It is recommended a contact lens should not be supplied to an expired prescription without at least an anterior eye health evaluation. A recommendation for a full eye examination shall be given.

4.6. If the supplier suspects lenses are in some way faulty, specified recall procedures shall be followed, in accordance with the NZ code of Good Manufacturing and Distribution of Therapeutic Goods, Parts 4 and 5.
Contact Lens Care Products

5. Procedures to be maintained in supplying contact lens care products.

It is expected that manufacturers and product suppliers comply with all applicable legislation and standards in relation to the materials, manufacturing and distribution of contact lens care products.

Protocols expected of the wholesaler:


5.2. Products should not be supplied to the retailer when the expiry date is less than six months in advance of the dispatch date.

5.3. An awareness of and adherence to uniform recall procedures as in NZ Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods Part 5.

5.4. Provision of consumer information for the customer.

5.5. Provision of product information for the supplier.

Protocols expected of the retailer:

5.6. Expired solutions shall not be supplied.

5.7. When requested, the retailer should have information available to advise the consumer of the intended use of the product they purchase.

5.8. There shall be no substitution of products if specified in a contact lens prescription.

5.9. If faulty product is suspected, specified recall procedure shall be followed, in accordance with the NZ code of Good Manufacturing and Distribution of Therapeutic Goods Part and 5.
THE CONTACT LENS PATIENT

The contact lens wearer is an important element in the process and he or she has an important role in the maintenance of good eye health when contact lenses are worn.

The following sets out best practice requirements for the contact lens wearer in terms of this Code of Practice.

It is hoped that contact lens patients will choose to comply with the Code.

6.1. It is important that the patient takes responsibility for maintaining good hygiene practices involving hands, face, lenses and storage container.

6.2. The patient shall adhere to recommended maximum wearing schedules.

6.3. The patient shall comply with instructions on circumstances where the lenses shall not be worn.

6.4. The patient shall become familiar with the signs and symptoms which may indicate potential problems and an appropriate course of action should they occur.

6.5. All wearers of contact lenses shall agree to regular eye health evaluations. Wearers of extended wear contact lenses shall agree to a program of wear and care as stipulated by the practitioner.

6.6. Wearers of extended wear lenses shall be aware of the signs and symptoms of conditions which have a higher risk of occurring with this modality. They must agree to a contingency plan should signs and symptoms arise.

6.7. All contact lens wearers should be advised they have a unique prescription which may under no circumstances be loaned, sold or in any way transferred to another person.

   Particular care should be taken for wearers of plano cosmetic lenses and a clear statement given to the patient that they should on no account share their lenses with anyone else.

   The risk of contracting sight threatening eye infections and possibly hepatitis, HIV and other diseases transmitted by body fluids, is real.