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FOOD AND DRUGS ACT

Regulations Amending the Medical Devices Regulations

P.C. 2015-1083 July 16, 2015

His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) (see footnote a) of the *Food and Drugs Act* (see footnote b), makes the annexed *Regulations Amending the Medical Devices Regulations*.

REGULATIONS AMENDING THE MEDICAL DEVICES REGULATIONS

AMENDMENTS

1. (1) The definition "safety and effectiveness requirements" in section 1 of the *Medical Devices Regulations* (see footnote 1) is repealed.

(2) Section 1 of the Regulations is amended by adding the following in alphabetical order:

"applicable requirements of sections 10 to 20" means

(*a*) in respect of a decorative contact lens, the requirements set out in section 10, subsections 11(2) and 12(2) and sections 13 to 17; and

(*b*) in respect of any other medical device, the requirements set out in section 10, subsections 11(1) and 12(1) and sections 13 to 20. (*exigences applicables prévues aux articles 10 à 20*)

"decorative contact lens" means a device referred to in section 2.1 of the Act; (*lentilles cornéennes à but esthétique*)

2. Sections 11 and 12 of the Regulations are replaced by the following:

11. (1) A medical device other than a decorative contact lens shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.

(2) A decorative contact lens shall not adversely affect the health or safety of a user, except to the extent that a possible adverse effect of the device constitutes a risk that is compatible with a high level of protection of health and safety.

12. (1) A medical device other than a decorative contact lens shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.

(2) A decorative contact lens shall perform as intended by the manufacturer.

3. (1) Paragraph 21(1)(*h*) of the English version of the Regulations is replaced by the following:

(*h*) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use;

(2) Paragraph 21(1)(*i*) of the Regulations is replaced by the following:

(*i*) the directions for use, unless directions are not required

(i) in the case of a decorative contact lens, for the device to be used safely, and

(ii) in the case of any other medical device, for the device to be used safely and effectively; and

4. (1) Paragraph 32(2)(*d*) of the Regulations is replaced by the following:

(*d*) a copy of the device label;

(2) Paragraph 32(3)(*g*) of the French version of the Regulations is replaced by the following:

g) une copie de l'étiquette de l'instrument;

(3) Paragraph 32(4)(*o*) of the French version of the Regulations is replaced by the following:

o) une copie de l'étiquette de l'instrument;

5. Paragraph 34(*f*) of the Regulations is replaced by the following:

(*f*) in the case of a Class II medical device other than a decorative contact lens, a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented.

6. Paragraph 45(*e*) of the Regulations is replaced by the following:

(*e*) for each manufacturer, in respect of a medical device other than a decorative contact lens, the medical specialities in respect of which the device is imported or distributed;

7. The Regulations are amended by replacing "safety and effectiveness requirements" with "applicable requirements of sections 10 to 20" in the following provisions:

(*a*) subsection 9(1);

(*b*) subsection 25(1) and paragraphs (2)(*b*) and (3)(*b*);

(*c*) paragraphs 32(2)(*b*) and (*c*), (3)(*d*) and (*f*) and (4)(*d*), (*h*) and (*i*);

(*d*) paragraph 33(1)(*b*) and subsection (2);

(*e*) subsection 35(1);

(*f*) the portion of subsection 36(1) before paragraph (*a*) and paragraph (2)(*a*);

(*g*) paragraph 37(*b*);

(*h*) subsection 38(2);

(*i*) section 39; and

(*j*) paragraphs 40(1)(*d*) and (*e*).

COMING INTO FORCE

8. (1) These Regulations, other than section 4, come into force on the day on which *An Act to amend the Food and Drugs Act (non-corrective contact lenses)*, chapter 25 of the Statutes of Canada, 2012, comes into force, but if they are registered after that day, they come into force on the day on which they are registered.

(2) Section 4 comes into force on the day on which these Regulations are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations*.)

Issues

This Regulatory Impact Analysis Statement addresses two issues with respect to the regulation of medical devices: (1) non-corrective contact lenses; and (2) the labelling of Class II medical devices, which are low risk devices, such as surgical gloves, scalpels, and syringes.

Non-corrective contact lenses

In October 2011, proposed legislation to deem non-corrective (decorative) contact lenses as medical devices was introduced in Parliament with the Private Member's Bill C-313, *An Act to amend the Food and Drugs Act (non-corrective contact lenses)*. This Act received royal assent on December 14, 2012. Once this Act comes into force (i.e. 12 months after the day on which this regulatory amendment is published in the *Canada Gazette*, Part II), these products will become subject to the requirements of the *Medical Devices Regulations* (the Regulations). However, non-corrective contact lenses (which have no accompanying therapeutic effects) do not meet the effectiveness requirements set out in the Regulations. Consequently, this regulatory amendment will exempt these products from the effectiveness requirements.

Class II medical device labelling

In Canada, medical devices are classified into one of four classes of increasing risk (Classes I to IV) by means of rules set out in the Regulations. The identification of a risk class for a device is largely determined by the product labelling. For Class II devices, however, a manufacturer does not currently need to provide a copy of the product label with a device licence application. Instead, a Class II device licence application requires only an attestation that the label complies with the requirements of the Regulations. This practice has often resulted in the misclassification of certain medical devices into a lower risk class, which do not undergo the same degree of regulatory scrutiny required of devices in higher risk classes. The inconsistencies between the content on the medical device label and the content in the device application could lead to potential health risks. As an example, a device labelled with false and misleading claims could prove harmful to the patient by not providing the anticipated treatment. Additionally, some medical device labels have been found to not meet the labelling requirements stated in the Regulations.

Background

Non-corrective contact lenses

Contact lenses are used primarily to correct vision defects by changing how light is refracted; that is, how it's focussed onto the retina of the eye. This is accomplished by varying the thickness and/or curvature of the lens. A contact lens of equal thickness across its surface is referred to as a non-corrective lens since it has no refractive power. Non-corrective contact lenses are frequently used by consumers for decorative purposes in order to change the appearance of the eye, such as the colour of the iris or the perceived shape of the pupil. These products have no therapeutic effect and, as a result, do not meet the current definition of a device under the *Food and Drugs Act* (the Act).

Non-corrective lenses may also be used for therapeutic purposes, such as when bandage lenses are used to treat damaged corneas. However, non-corrective contact lenses with a therapeutic effect already meet the definition of a device under the *Food and Drugs Act* and, therefore, are outside the scope of this regulatory amendment. For the remainder of this document, "non-corrective contact lenses" refers to non-corrective contact lenses that have no therapeutic effect.

In 2003, Health Canada published the report "Human Health Risk Assessment of Cosmetic Contact Lens." This report concluded that the health hazards associated with non-corrective contact lenses are the same as those associated with corrective lenses. Potential health hazards include scratching of the cornea during the insertion of a contact lens, and conjunctivitis or corneal ulcers caused by bacterial or viral contamination of a contact lens. (see footnote 2) Since 2002, Health Canada has received three incident reports involving corneal scratches and ulcers in patients who have used these products.

Non-corrective contact lenses are currently subject to the *Canada Consumer Product Safety Act* and therefore do not require a licence from Health Canada prior to being imported into or sold in Canada. Once the amendments to the *Food and Drugs Act* set out in Bill C-313 come into force, non-corrective lenses will be

deemed as devices under the *Food and Drugs Act* and will become subject to the existing applicable requirements under the Regulations. Non-corrective contact lenses will be classified as Class II medical devices based on the existing Schedule 1, subsection (1) of Rule 2 of the Regulations, as it is currently the case for corrective contact lenses. As with all Class II devices, non-corrective contact lenses will require a medical device licence held by the device manufacturer prior to their being sold or imported into Canada. These products will also be required to be manufactured in compliance with the Canadian national standard for a quality system (CAN/CSA ISO 13485:2003). A quality system used to manufacture non-corrective contact lenses will have to be certified as being compliant with this standard by a registrar recognized by Health Canada. All importers and distributors of non-corrective contact lenses will need to hold a medical device establishment licence; however, manufacturers and retailers will not require an establishment licence for Class II medical devices. The intention of the regulatory amendment described below is to ensure that Health Canada's regulatory oversight of non-corrective contact lenses respects the distinct nature of these products by exempting them from current legal requirements for effectiveness.

Class II medical device labelling

Nearly 30% of all Class II medical device licence applications have been found to contain vague and unclear information on the medical conditions, purposes, and uses for which the device was manufactured. One example is a reusable endoscope that without adequate instructions could result in improper cleaning between its uses in patients. These situations have necessitated Health Canada to request additional information, usually a copy of the device label. Copies of actual labels have been requested for approximately 70% of all Class II medical device licence applications. These requests slow down the licensing process for this class of medical device. Additionally, for 10% of the cases where the label has been requested, the device in question was found to be misclassified and subsequently reclassified as a higher-risk Class III device. In cases where the label was not requested, between 20% to 30% of these devices have been subsequently discovered, during routine post-market inspections, to be incorrectly classified at a lower risk class.

Finally, the information on approximately half of all Class II labels requested under the Regulations has been found to be deficient. Deficiencies have included inconsistencies with what was provided in the corresponding medical device licence application, basic administrative requirements (such as name, address and catalogue number), and/or instructions for use which were incomplete or incorrect. These labelling deficiencies may not necessarily be related to device classification; some Class II devices are simply improperly labelled.

Objectives

The objective of the Regulations for non-corrective contact lenses is to enable proportional regulatory oversight with regard to the manufacture and safe use of non-corrective lenses, without imposing an undue burden on the manufacturer. Specifically, the amendments will exempt non-corrective contact lenses from effectiveness requirements, but will allow for the application of the same safety, quality and labelling standards to all contact lenses sold in Canada.

The Regulations with respect to labelling of Class II medical devices is intended to address concerns of (1) non-compliant labelling, thereby ensuring, prior to sale in Canada, that the claims and instructions for use for a device are accurate and complete; and (2) inappropriate risk classification of medical devices so that the level of oversight applied to a device is proportional to the risk presented by its use. In addition, the Regulations will remove potential delays in the licensing process for Class II devices, resulting from requests for copies of labels that were not provided voluntarily, and to therefore enable more timely access to these products.

Description

These amendments introduce two sets of changes to the Regulations, both involving the licence application requirements for Class II medical devices.

The first amendment addresses the absence of therapeutic effect in non-corrective contact lenses. With their being deemed as devices under the *Food and Drugs Act*, non-corrective contact lenses will be subject to all of the licensing requirements for Class II devices under the Regulations. However, an exemption is made so that manufacturers of non-corrective contact lenses will not be required to demonstrate therapeutic effectiveness for these products. The amendments to the Regulations to exempt non-corrective contact lens and to the *Food*

and Drugs Act will come into force at the same time.

The second amendment to the Regulations will require manufacturers of all Class II devices to submit a copy of the product label as part of the Class II medical device licence application.

"One-for-One" Rule

The "One-for-One" Rule does not apply to these amendments. The first regulatory amendment exempts manufacturers of non-corrective contact lens from the Class II device requirements to demonstrate therapeutic effectiveness. In addition, the change in requirements for Class II device labelling involves the provision of a product label for which an attestation of regulatory compliance would have already been made. This does not change the administrative costs to business. Furthermore, this reduces compliance costs by avoiding possible delays in the filing process when ensuing requests are made by Health Canada for information already prepared by the manufacturer.

Small business lens

The small business lens does not apply, as there are no incremental costs associated with these amendments.

Consultation

Stakeholders affected by the amendment for non-corrective contact lenses include Canadian consumers, health care professionals, provincial and territorial health regulators, and manufacturers, importers, distributors, and retailers of these products.

When Bill C-313 was presented to the House of Commons Standing Committee on Health in February 2012 and to the Standing Senate Committee on Social Affairs, Science and Technology in November 2012, the witnesses included representatives from three eye care professional associations and one industry stakeholder. The eye care professional associations all supported the proposed regulatory amendment, citing the health hazards associated with non-corrective lenses and the need for the same level of oversight for these products as currently exists for corrective lenses. The industry stakeholder expressed concerns that the Regulations of non-corrective lenses could increase the retail cost of these products and therefore encourage consumers to seek out less expensive, unlicensed non-corrective lenses on the Internet. It is the position of Health Canada that, even if some consumers choose to purchase unlicensed products, the Regulations of non-corrective lenses as Class II medical devices will provide a net benefit to the overall health and safety of Canadians.

A Notice of Intent that outlined this amendment was published in the *Canada Gazette*, Part I, on August 10, 2013. This notice is available online at http://gazette.gc.ca/rp-pr/p1/2013/2013-08-10/html/notice-avis-eng.html. No comments were received in the intervening time period.

With regard to Class II labelling requirements, Health Canada communicated its intention to proceed with this regulatory amendment to Canada's Medical Technology Companies (MEDEC), and no objections were raised. Over the past several years, Health Canada also presented the proposal to stakeholders at various technical workshops. This resulted in approximately 70% of the manufacturers of medical devices in Canada having been notified of the proposal. No objections were subsequently raised.

Comments received following publication of the Regulations in the *Canada Gazette*, Part I

Following the publication in the *Canada Gazette*, Part I, on October 18, 2014, five stakeholders submitted their comments during the 75-day comment period. Comments were generally supportive of both regulatory amendments. The comments received and Health Canada's responses are summarized below.

Definition/scope of "decorative contact lens"

An industry association suggested that the definition of "decorative contact lens" in the regulatory amendment should be modified to make it clear that the definition does not include prescription (i.e. corrective) decorative contact lenses.

Health Canada has concluded that because the definition in the Regulations is meant to be read together

with the definition of “device” in the Act and the amendments to the Act introduced by Bill C-313, it is unnecessary to explicitly exclude decorative prescription (i.e. corrective) contact lenses from the definition of “decorative contact lens” in the regulatory amendment. This is because any decorative contact lenses that are prescription (i.e. corrective) in nature are already captured by the definition of “device” under section 2 of the *Food and Drugs Act* and regulated as medical devices because they have a therapeutic purpose.

Comments about the coming into force

A health care professional association suggested the new section 2.1 of the Act and the accompanying regulatory exemption of non-corrective contact lenses from the applications requirement for therapeutic effectiveness under the Regulations come into force immediately following publication.

In response, Health Canada notes that a delay in the coming-into-force date is needed for this set of regulatory amendments to meet Canada’s obligations on technical barriers to trade and to allow manufacturers of non-corrective contact lenses to bring their operations into compliance with the new requirements.

Other comments

Various stakeholders suggested additional changes that were out of scope of the regulatory amendments; for example, a health care professional association stated their concern respecting the regulatory oversight of Internet sales.

While these amendments were not modified in response to this request, Health Canada will continue to address non-compliant Internet sales via its compliance and enforcement activities.

Stakeholder comments related to the operationalization of the amendments in respect of labelling Class II medical devices will be addressed in guidance.

Rationale

Following a review of the available evidence, Health Canada has concluded that both corrective and non-corrective contact lenses carry similar potential risks of eye injury since they interact with the eye in the same way. While the passage of Bill C-313 will effectively standardize the Regulations of all contact lenses and minimize the potential risks of harm, the regulatory amendments will recognize the distinct nature of non-corrective lenses by exempting them from the inapplicable therapeutic effectiveness requirements of the Regulations.

The regulatory amendment for Class II labelling requirements will result in no additional cost to Class II medical device manufacturers. Manufacturers must currently attest to having a completed label when their device licence application is filed with Health Canada. Manufacturers will benefit from the regulatory amendment since delays in screening Class II medical device licence applications, due to follow-up requests for labels or other additional information, will likely be eliminated. Likewise, consumers will benefit from knowing that all medical devices are subject to an appropriate level of regulatory scrutiny relative to their risk classification, and that Class II medical device labels consistently meet the requirements of the Regulations.

Implementation, enforcement and service standards

With the deeming of non-corrective contact lenses as devices under the *Food and Drugs Act*, these products will be classified as Class II medical devices and subject to the labelling and licensing requirements for this class of devices, as set out in the Regulations. As part of the product licensing of non-corrective contact lenses, manufacturers will require a quality systems certificate issued by recognized third party auditing organizations called the Canadian Medical Devices Conformity Assessment System (CMDCAS). Distributors and importers of non-corrective contact lenses will require a medical device establishment licence. Existing guidance documents will be updated to provide additional information on regulatory compliance to manufacturers, distributors and importers of non-corrective contact lenses.

Health Canada charges user fees for activities performed when regulating medical devices. The *Fees in Respect of Drugs and Medical Devices Regulations* set out the respective fees for examining and renewing a Class II medical device licence application and an establishment licence application. The user fees to process

device and establishment licence applications for non-corrective lenses will be applicable upon the coming into force of the amended *Food and Drugs Act*, and these products being deemed as devices under this Act.

The amendment for Class II medical device labelling will not alter the existing compliance mechanisms under the provisions of the *Food and Drugs Act* and the Regulations, enforced by the Health Products and Food Branch Inspectorate.

Coming into force

The regulatory amendment relating to non-corrective contact lenses will come into force on the day on which *An Act to amend the Food and Drugs Act (non-corrective contact lenses)*, chapter 25 of the Statutes of Canada, 2012, comes into force. That Act will come into force 12 months after the day on which the Order in Council to fix that Act's coming-into-force date is made. This delay is necessary to meet Canada's obligations on technical barriers to trade and to allow manufacturers of non-corrective contact lenses to bring their operations into compliance with the new requirements.

The amendments to address Class II device labelling will come into force on the day on which the Regulations are registered.

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Footnote a
S.C. 2012, c. 19, s. 414

Footnote b
R.S., c. F-27

Footnote 1
SOR/98-282

Footnote 2
Health Canada, Product Safety Bureau (Dillon Consulting Limited.) *Human Health Risk Assessment of Cosmetic Contact Lenses*, Final Report, September 2003. Project No. 03-1503.

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