



The Canadian Special Access Program

By Janet N. Chong

In Canada, the marketing of drugs and medical devices requires prior approval by Health Canada, the government department roughly equivalent to the US Department of Health & Human Services. Through a narrow, request-based regulatory exemption called the Special Access Program, Canadian doctors (and patients) can gain access to otherwise unauthorized drugs and medical devices. This article explains this regulatory mechanism and the procedures involved.

Rationale for the Special Access Program

The Special Access Program was established to provide healthcare practitioners discretionary access to drugs and medical devices that are unavailable for sale in Canada. The program for drugs is administered by Health Canada's Health Products and Food Branch, while the program for medical devices is administered by its Medical Devices Bureau.

Access to unapproved drugs is restricted to the treatment, diagnosis or prevention of serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable or are unavailable. Special access to drugs is supported by sections C.08.010 and C.08.011 of the *Food and Drug Regulations*,¹ which is a subordinate regulation to the Canadian *Food and Drugs Act*.² The Special Access Program grants a manufacturer the authorization to sell a drug that is otherwise not approved for sale or distribution in Canada.

Drugs that may be authorized for release under the program include pharmaceutical, biologic and radiopharmaceutical products. According to Health Canada, most of the drugs authorized by the program treat patients with conditions such as intractable depression, epilepsy, transplant rejection, hemophilia and other blood disorders, terminal cancer and AIDS. The program may also be used to provide access to nonmarketed drugs in response to specific health crises such as an outbreak of a communicable disease.

An authorization from Health Canada for the sale of an unapproved drug is limited to a quantity equivalent to a six-month supply for chronic treatments. Additional access to the same drug for the same patient requires submission of a renewal request to the program.

Upon receiving authorization, the manufacturer has the final say as to whether to supply the drug and the right to impose restrictions or conditions on its release. The manufacturer may only send the drug to the healthcare practitioner or an inpatient pharmacy, not to retail pharmacies.

Special access to unlicensed medical devices is also restricted. Patients may access custom-made and unlicensed medical devices for emergency use or when conventional therapies have failed, are unavailable or are unsuitable to provide diagnosis, treatment or prevention.

This access is supported by Part 2 of the *Medical Devices Regulations*³ under the *Food and Drugs Act*. The program grants authorization to import and sell the unlicensed device in Canada.

It should be noted that custom-made devices, i.e., devices created for a particular patient or use by a practitioner on a practitioner's orders, are a special case. Class I or II devices do not require authorization under the program, while Class III or IV devices do.

Procedure and Conditions

A healthcare practitioner interested in using a particular unapproved drug or medical device is responsible for initiating a request to the Special Access Program on behalf of a patient by completing the requisite forms.

As mentioned above, the regulatory authority of the program administrators is discretionary. A decision to authorize or deny a request is made on a case-by-case basis considering the urgency of the situation, the condition of the patient, the availability of marketed alternatives and the information provided in support of the request relating to the use, safety and efficacy of the requested drug or medical device. However, the cost of the requested drug or device and the cost of marketed alternatives are not part of the decision, as funding for the delivery of healthcare falls under provincial jurisdiction.

The conditions for authorizing the sale of a nonmarketed drug are listed in C.08.010 of the *Food and Drug Regulations*. In the application, a practitioner must explain the medical emergency for which the drug is required and supply any data in his or her possession with respect to the use, safety and efficacy of the drug.

Future use requests are permissible in circumstances where nonmarketed drugs are required in anticipation of patients facing a medical emergency. A medical emergency is broadly interpreted for the purpose of the program to include serious or life-threatening conditions for which conventional therapies have failed or are unavailable to achieve an adequate response. However, the practitioner must explain why the drug is required in advance rather than on a patient-specific basis.

The conditions for authorizing the importation and sale of a nonmarketed medical device are listed in section 72 of the *Medical Devices Regulations*. A requesting practitioner must explain why a particular unlicensed device is required for diagnosis, treatment or prevention for the patient. The practitioner must also identify the patient's medical condition and why conventional therapies or licensed devices have failed or are unsuitable. Lastly, he must discuss the risks and benefits associated with the use of the unlicensed device. The application will be refused if the potential risks of the device outweigh its potential benefits, or if a similar medical device is already licensed for sale in Canada.



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Practitioners must provide a report on the results of the use of drugs and medical devices released through the program, especially information on any adverse events encountered.

Implications for Healthcare Professionals

In considering the special access request, Health Canada does not conduct a comprehensive evaluation on the validity of drug or medical device information or assertions from the manufacturer with respect to safety, efficacy and quality. Therefore, the authorization given for any drug or medical device by no means constitutes an opinion that it is safe or efficacious. It is thus incumbent upon healthcare practitioners to ensure their decision to recommend the drug or medical device is made after an appropriate risk/benefit analysis in the best interests of the patient and is supported by credible evidence found in the medical literature or provided by the manufacturer. And, as is the case for any method of treatment, the practitioner must ensure that patients are well informed of the possible risks and benefits of the drug or medical device and have consented to the treatment.

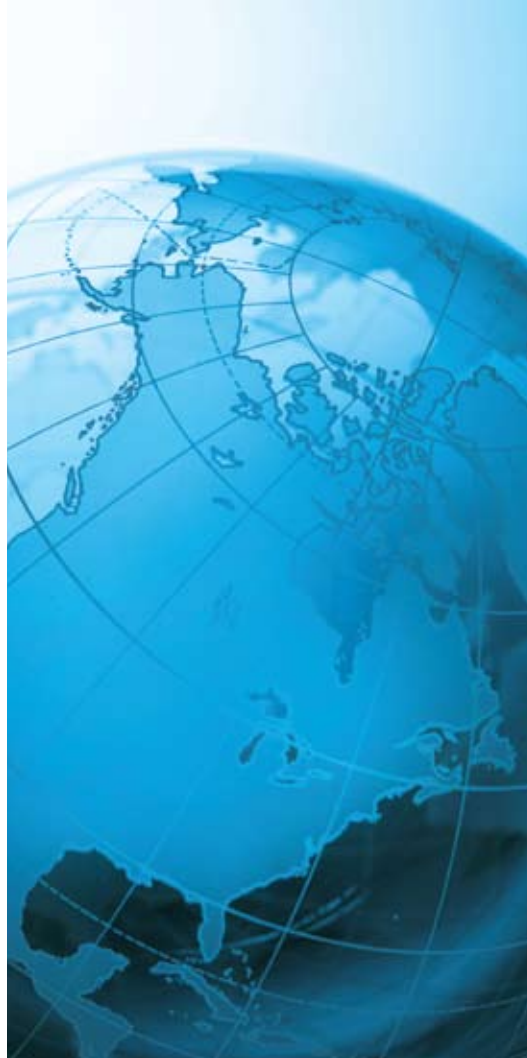
The program may request an accounting of the disposition of all quantities of the drug received, so practitioners must keep accurate and accessible records.

Implications for Manufacturers and Importers

It is worth noting that the Special Access Program only permits the sale and importation of unapproved drugs and medical devices. It does not authorize the administration of these drugs or the use of these devices by a healthcare practitioner. That authority falls within the practice of medicine, which is regulated at the provincial level.

Health Canada is currently conducting a comprehensive review of the program as a result of increasing concern about the timeliness of Canadians' access to new drugs and medical devices through the program. The outcome of the review will help modernize the policy and regulatory frameworks that support the program.

As a final note, it is important to realize that the program is not a shortcut or an alternative to the regular approval process for marketing new drugs and medical devices in Canada. It is not intended to promote the early use of drugs or to circumvent the clinical trials review and approval process. Rather, it provides compassionate access to drugs on a patient-by-patient basis. Most importantly, the way the program is tied to particular practitioners and their patients means that it cannot be used by manufacturers, importers or individuals. It is likely that any manufacturer who advised doctors that its



products "are available by special access" either openly or *sotto voce* would be opening itself up to regulatory action by Health Canada. Such actions would have certain parallels with promoting off-label use.

Advertising to the public about drugs provided through the program is in theory prohibited, since all direct-to-consumer advertising of prescription drugs is prohibited in Canada.

Conclusion

It may be tempting for manufacturers and patients to see the Special Access Program as a channel for marketing unauthorized drugs and unlicensed medical devices in Canada. However, given the limitations of the program and the strict conditions that must be fulfilled before access is granted, it is in no way an avenue for bypassing the regular approval process.⁴

References

1. Consolidated Regulations of Canada, chapter 870.
2. Revised Statutes of Canada 1985, chapter F-27.
3. SOR/98-282.
4. Further guidance on the Special Access Program for drugs can be found on Health Canada's website at <http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-eng.php>.

Author

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