How to obtain emergency drugs

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For a number of years the drugs directorate of the health protection branch of the Department of National Health and Welfare has had the mandate to authorize the sale of new drugs to a specified practitioner for a particular patient when a medical emergency exists and standard therapy is not effective. These are drugs that have not yet received clearance in Canada for marketing or for clinical trials, although they may be marketed in other countries. The regulations under the Food and Drugs Act and Regulations permitting this practice are as follows:

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if

(a) the practitioner has supplied to the Director information concerning
  (i) the medical emergency for which the drug is required,
  (ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,
  (iii) the names of all institutions in which the drug is to be used, and
  (iv) such other data as the Director may require; and
(b) the practitioner has agreed to
  (i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered, and
  (ii) account to the Director on request for all quantities of the drug received by him.

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1) state

(a) the name of the practitioner to whom the new drug may be sold;
(b) the medical emergency in respect of which the new drug may be sold; and
(c) the quantity of the new drug that may be sold to that practitioner for that emergency.

From the bureau of human prescription drugs, drugs directorate, health protection branch, Department of National Health and Welfare

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C.08.011. (1) Nothwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations.

In most cases practitioners telephone or write to selected officers of the drugs directorate during working hours to request a supply of an emergency drug and provide the information outlined in the regulations. Urgent cases are handled by telephone: the officers in the directorate phone the supplier as soon as possible to issue verbal authorization, which is followed by a formal letter of authorization. Most requests are handled by the directorate very promptly, and most North American pharmaceutical companies ship the drugs rapidly within 24 hours.

When requesting such a drug be prepared to supply the name of the drug, the supplier, the quantity and dosage form needed, the age and sex of the patient, the diagnosis and the reason for requesting that particular drug. This service has hitherto generally been limited to office hours — that is, 8:30 to 4:30 Monday to Friday; however, for a number of years a limited after-hours service has existed for practitioners that have known how to contact particular officers of the directorate.

We plan to streamline the daytime and after-hours service as follows: The majority of requests for emergency drugs can probably be made during regular office hours (8:30 to 4:30) and preferably between 9.00 am and 2:30 pm Eastern Standard or Eastern Daylight Time. The reason for the suggested early cut-off time is that some pharmaceutical companies close early in the summer, especially on Fridays, and it is sometimes difficult to contact personnel at their offices after this time.

During office hours the following divisions of the bureau of human prescription drugs and the bureau of biologics of the drugs directorate should be contacted, depending on the class of drug required (the area code is 613 in all cases):

- Central nervous system drugs 993-3203

- Anti-infective drugs, including antibiotics ..... 993-3230 or 993-3660
- Cardiac, renal, respiratory and anti-inflammatory drugs 993-3103
- Endocrine, metabolic and anticancer drugs ..... 993-3660 or 993-3230
- Miscellaneous drugs 993-3100
- Biologicals (vaccines, antisera, blood products, insulin) ..... 992-8140 or 992-5106

If any of the appropriate personnel cannot be reached, Dr. Ian Henderson or I should be called, at (613) 992-4684.

Any time after 4:30 pm Eastern Time on weekdays as well as 24 hours a day on weekends and holidays all practitioners in Canada who urgently require a life-saving drug or a drug for a very serious condition may call (613) 992-9521. An answering service operator will take the name, address and phone number of the practitioner and the name of the drug, then will contact one of the officers of the drugs directorate on duty by means of telephone or pagette. The request call will be returned as soon as possible. If it is received between 11 pm and 9 am it will not usually be returned until after 9 am unless the caller stated that the need for a supply of the drug was critical. Even so, it would be extremely difficult to have a shipment made during the night or early morning, as many of the carriers are not operating then.

This activity of the drugs directorate is a new service and requires the full cooperation of the suppliers of the drugs. The cooperation of members of the Pharmaceutical Manufacturers Association of Canada has already been obtained, and we are in the process of obtaining the cooperation of a few other Canadian manufacturers and some manufacturers in the United States.

The directorate is setting up a stockpile of drugs that are normally available from Europe or other parts of the world and usually take some time to be delivered to Canada. This special service will take a little longer to become functional owing to the time required to purchase these drugs. Initially the service will be provided with the cooperation of the pharmacy of the National Defence Medical Centre in Ottawa. It is expected that about a dozen emergency drugs, including drugs for the treatment of tropical diseases, will be stockpiled and shipped from that pharmacy on the authorization of an officer of the drugs directorate. The directorate does not itself supply emergency drugs but has a mandate to authorize their sale or distribution by providing an exemption to the Food and Drug Regulations.

Callers should be aware that the drugs directorate is not authorized to accept collect calls; however, when calls are returned, special telephone lines available across Canada are used, and we can therefore discuss the requirements at greater length at no additional expense.

We trust that the new extended after-hours service will prove beneficial to Canadian practitioners and their patients. With the cooperation of all parties concerned it should be a success. At present over 3000 calls are received in a single year. Even with the limited number of professional staff in the drugs directorate, we believe that this service has been very useful to a wide variety of patients. With the addition of extended after-hours service it should be even more successful. ■

ABORTION
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2. *Dehler v. Ottawa Civic Hospital*, 25 OR, 2d, 748, 1979
3. *Health Services and Social Services Act*, SQ 1971, sect 114, Govt of Quebec, Quebec City, 1971
4. *The Family Law Reform Act*, SQ 1978, chap 2, sect 65(2), Govt of Ontario, Toronto, 1978
5. *Paton v. British Pregnancy Advisory Service Trustees* [1978], 3 WLR687 (QBD)
6. *Planned Parenthood of Central Missouri v. Danforth*, 428 US, 52, US Supreme Court, 1976
7. *R. v. Brooks*, 5 CCC, 372 (BC Supreme Court), 1901
8. *R. v. Lewis*, 7 CCC, 261 (Ontario Court of Appeal), 1903
9. BADGLEY RF (chmn): *Report of the Committee on the Operation of the Abortion Law*, Ministry of Supply and Services, Ottawa, Jan 1977
10. DICKENS BM: *Medico-Legal Aspects of Family Law*, chaps 3, 6, Butterworths, Toronto, 1979
11. PICARD EI: *Legal Liability of Doctors and Hospitals in Canada*, Carswell, Toronto, 1978: 20–21
12. ROZOVSKY LE: *Canadian Hospital Law: A Practical Guide*, 2nd ed, Can Hosp Assoc, Ottawa, 1979
13. *Code of Ethics*, Can Med Assoc, Ottawa, June 1978