KNOWLEDGE IS POWER...

ACCESSING NEW MEDICATIONS

BEFORE HEALTH CANADA APPROVAL

As you will read in our Fact Sheet on Clinical Trials, the time to bring a new therapy to market is many years, and the cost is substantial. Before new medications are available in your drug store, it may be possible to obtain access through the Health Canada Special Access Program (SAP). A Healthcare professional can request a drug that is not available for sale in Canada through the SAP for a patient with a serious or life-threatening condition when currently available therapies have failed or are unsuitable. Drugs available under this program must be already approved for use FOR THE SAME CONDITION by either the United States Food and Drug Administration (FDA) or by the European Medicines Agency. Note that the manufacturer must agree to the sale, and manufacturers are under no obligation to do so. Sometimes the physician is required to contact the manufacturer personally to ensure that they are willing and able to provide the drug to Canada, through the Special Access Program.

Most often, the Healthcare professional making the request is a licensed physician. The physician must complete a special request form that contains information about the drug, potential side effects, speciÞc reasons why the drug is needed, and what makes it the best choice for the patient. Information from the medical literature supporting the use of the drug is required, as well as a mechanism to ensure that accurate and accessible records are available to Health Canada on demand. Most hospital pharmacies have staff who are dedicated to working with drugs obtained through the Special Access Program.

Some manufacturers will provide these medications at no cost, if not, the cost is usually covered by the patient. It is the patient, to know this in advance as the cost may be substantial. Once a request is made to Heath Canada, it takes about 24 hours to receive a response. Sometimes additional information is required from the requesting physician before Þnal approval is given. A copy of the Letter of Authorization is provided to both the healthcare professional and the manufacturer. Authorized drugs can only be sent to the ofÞce of the requesting healthcare professional or a pharmacy. They cannot be delivered directly to the patient. By making the decision to request a drug through the Special Access Program, the prescribing practitioner assumes the liability and responsibility for the use of the drug.

If the drug requested is undergoing regulatory review in Canada, prior to being made available to the public, once that approval is received it is no longer available via the Special Access Program. Once a marketed alternative is available, patients should be transitioned to the marketed version as it has undergone the rigorous process of regulatory review in Canada and is compliant with Canadian regulations.

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AFTER HEALTH CANADA APPROVAL

Once a new medication has been approved by Health Canada and is available at your local drug store, a whole new process begins. Who decides which new drugs will be covered for reimbursement under both private and public drug plans?

Usually, private drug plans are quick to add newly approved drugs to their list of insured medications, but there can be exceptions and there can be restrictions placed on who can prescribe the medication and the clinical condition of the patient at the time treatment is initiated. This is true for the public plans as well. The public plans have their own version of the Health Canada Special Access Program and have speciÞc criteria that must be met before the drugs are approved for reimbursement. Certain drug products are not eligible beneÞts and are identiÞed on the exclusion list in the provincial formularies (an ofÞcial list of generic and brand name pharmaceutical drugs designated by a health insurance provider as approved for coverage under the provider's pharmacy plan beneÞts).

Most, but not all, drug manufacturers offer Compassionate Programs so that patients who have no drug plans, or whose drug plans have decided NOT to provide reimbursement, can obtain the drug directly from the manufacturer at the request of their healthcare practitioner. These Compassionate Programs are a wonderful option for patients, but they do not last forever. The drug company can end the program at any time and undoubtedly will not continue coverage after the drug is made available in generic format.

THE ROLE OF CANADA'S DRUG AND HEALTH TECHNOLOGY AGENCY (CADTH)

CADTH is an independent, not-for-proÞt organization that helps health care decision-makers make informed decisions about the best use of health technologies, including drugs. Patients and clinicians are asked to participate in the work of CADTH through committees and panels and are offered input and feedback opportunities.
Once Health Canada has approved a drug for use in Canada, the country's public drug programs and agencies must decide if the drug will be eligible for public reimbursement. The CADTH drug reimbursement review process plays an important role in their decision-making processes. CADTH conducts thorough and objective evaluations of the clinical, economic, patient, and clinician evidence on drugs, and uses these evaluations to provide reimbursement recommendations and advice to federal, provincial, and territorial public drug plans agencies (with the exception of Quebec). CADTH's recommendations are non-binding and each drug program makes its own reimbursement decisions based on CADTH's recommendation, as well as other factors, including Þnancial resources.

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