

GLOSSARY for Ontario Public Drug Programs

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Term	Definition
1st line, 2nd line, 3rd line	See <i>First line, second line, third line</i>
Acute indication/disease	Acute describes the sudden onset of a disease or an illness that is of short duration, progresses rapidly, and requires urgent care.
Adjuvant	<p>Adjuvant treatment is given as an adjunct, or in addition to, the primary treatment, to help reach the ultimate goal.</p> <p>In cancer treatment, adjuvant usually refers to the use of chemotherapy drugs following surgery to help decrease the risk of cancer recurring.</p>
Adverse reaction	A negative, unwanted effect that the administration of drugs may cause. An adverse reaction may occur suddenly or develop over time
Ambulatory	Able to walk, as in the case of an outpatient rather than a bed-ridden or hospitalized patient.
Arm	<p>Refers to any of several treatment groups in a randomized clinical trial.</p> <p>Most randomized clinical trials have two treatment groups, or arms, but some have three or more.</p>
Baseline	<p>In clinical trials, baseline refers to patient information gathered at the beginning of a clinical trial, before participants begin to receive the experimental drug treatment. Similar information gathered during or after the clinical study is assessed against the baseline values.</p> <p>The safety and efficacy of a drug is often determined by monitoring changes from baseline values.</p>
Bias	<p>Bias refers to a point of view that prevents a researcher or clinician from rendering an impartial judgment about issues relating to that point of view. In clinical studies, researchers control for bias by blinding and randomization (See <i>Blind</i> and <i>Randomization</i>).</p> <p>Publication bias occurs when the likelihood of a study being published varies with the results it finds. Usually, this occurs when studies that find a significant positive effect are more likely to be published than studies that do not find a significant positive effect, making it appear from surveys of the published literature that treatments are more effective than is actually the case.</p> <p>Bias occurs when journals prefer and select studies with significant positive results, and when interested parties, such as drug manufacturers, release only selected results.</p> <p>A systematic review (See <i>Systemic Review</i>) tries to detect publication bias by plotting sizes of trials against results. The approach assumes that larger trials are more likely to be published, regardless of their results. If a systematic review finds evidence of publication bias, it should report that. Often, publication bias takes the form of slower or less prominent publication of trials with less interesting results.</p>
Bill 102	(See <i>Transparent Drug System for Patients Act</i>)

Bioavailability	Bioavailability refers to the rate and extent to which a drug is absorbed becomes available at the site in the body that requires treatment. For example, for drugs that work on the whole system, bioavailability refers to the rate and extent to which an active substance is absorbed and becomes available in the body's general circulatory system.
Bioequivalence	Two drugs are considered bioequivalent if they are the same strength of the same medicinal product in the same dosage, and become available to the body at the same time. Drugs are also considered bioequivalent, for example in the case of a brand name or generic product, if they provide the same medicinal product in different chemical form or different dosage form/different strength but become available at the treatment site in the body at the same time and with similar safety and efficacy.
Bioethics	The ethics of medical and biological research and practice.
Blind	A randomized clinical trial is "blind" if the participant is not told which treatment group, or arm, of the trial he or she is participating in. For example, participants are unaware of whether they are in the experimental group, receiving a new therapy, or the control arm of the study. (<i>See Single-blind study and Double-blind study</i>).
Bridge therapy	The traditional management of blood thinning for hospitalized patients is often referred to as "bridge" therapy. Bridge therapy, or an alternative drug, is ordered when a patient needs to have their current drug therapy interrupted for a time to prepare for surgery or another procedure. Physicians prescribe bridge therapy when they feel that keeping the patient on their current drug may be dangerous and result in complications, but when the patient requires some form of drug therapy. Bridge therapy can also refer to the use of a short-term drug that acts as a bridge until the drug used as the regular maintenance treatment can achieve its therapeutic level and is shown to be working.
Budget Impact Analysis (BIA)	An analysis of the impact of a new drug product on drug plan spending.
Canadian Expert Drug Advisory Committee (CEDAC)	The federal government appoints the Canadian Expert Drug Advisory Committee (CEDAC) to make recommendations to federal/provincial/territorial drug benefit plans in Canada (except Quebec) about whether or not to list a drug.
CDR	<i>See Common Drug Review</i>
CEDAC	<i>See Canadian Expert Drug Advisory Committee</i>
Chronic	Lasts indefinitely, or continues virtually unchanged. Often, chronic diseases are considered those that last three or more months. They generally cannot be cured and often come with age.
Clinical guideline	These guidelines are advice, based on experience about what works, that are developed to help physicians and patients make decisions about appropriate health care under specific clinical circumstances.
Clinical review	The critical appraisal of published and unpublished information about the safety, effectiveness, and use of a drug to manage a disease or condition.

Clinical reviewer	A reviewer who conducts a clinical review.
Cochrane Collaboration	A group of more than 6,000 specialists in health care that systematically reviews randomized trials of the effects of treatments and, when appropriate, the results of other research. Cochrane reviews are published in the Cochrane Database of Systematic Reviews section of the Cochrane Library. <i>See Systematic Review.</i>
Cohort	A group of individuals with some characteristics in common
Common Drug Review (CDR)	CDR is a single national process for undertaking reviews and providing recommendations to provincial drug plans about whether to list new drugs and whether to approve new indications of existing drugs.
Conditional listing	<p>A 'conditional listing' is a new listing on the Formulary that is intended to provide access to new and existing drugs under certain conditions, based on the recommendations of the CED. Conditional listings are established through negotiated agreements between manufacturers and the Executive Officer. They may include:</p> <ul style="list-style-type: none"> • a commitment to promote appropriate use; • requirements to collect further outcome data; • a requirement to gather more evidence related to clinical or economic information, for CED's consideration; and • expenditure contracts. <p>The Formulary publishes its criteria for reimbursement as therapeutic notes. It is the prescriber's responsibility to prescribe the drug to patients in accordance with the listed criteria. Conditional listings allow recipients to access new drugs on a conditional basis, while the Committee to Evaluate Drugs collects and reviews information that might support continued listing. Conditional listings also ease the administrative burden on prescribers because they do not require forms or limited use codes. (<i>See Limited Use</i>)</p> <p>Through open channels of communication with manufacturers, the CED will review their ODB reimbursement recommendations when new information becomes available and the ministry will continue to assess opportunities to enter into conditional listing agreements with manufacturers.</p>

Confidence interval	<p>The range of numerical values in which we can be confident (to a computed probability, such as 90 or 95%) that the population value being estimated will be found.</p> <p>Confidence intervals suggest the strength of evidence. Where confidence intervals are wide, they indicate less precise estimates of effect. The larger the trial's sample size, the larger the number of outcome events and the greater the confidence that the true relative risk reduction is close to the value stated. When the confidence intervals are narrow, "precision" is increased.</p> <p>In a "positive findings" study, the lower boundary of the confidence interval, or lower confidence limit, should still remain important or clinically significant if the results are to be accepted. In a "negative findings" study, the upper boundary of the confidence interval should not be clinically significant if the result is to be accepted with confidence.</p>
Contraindication	<p>A specific situation in which a drug, procedure, or surgery is not indicated and should NOT be used, because it may harm the patient. For example, some medications may cause dangerous reactions in people who have allergies, high blood pressure, or are pregnant. The medications may interact with other drugs, so they are contraindicated in these situations. Partial contraindication means that physicians should use caution when prescribing two drugs or procedures together. Absolute contraindication means that using this drug or procedure in a specific situation could be life-threatening.</p>
Control group	<p>The group by which another group receiving experimental treatment is evaluated. In many clinical trials, one group of patients is given an experimental drug or treatment, while the control group receives either a standard treatment for the illness or a placebo. Also see <i>Placebo</i> and <i>Standard treatment</i>.</p>
Controlled clinical trial (CCT)	<p>A trial in which participants are assigned to two or more different treatment groups, where treatment is assigned by a method other than random allocation. Also see <i>Randomized Control Trial (RCT)</i>.</p> <p>Non-randomized controlled trials are more likely to suffer from bias than RCTs.</p>
Cost-effectiveness	<p>How well something works in relation to how much it costs.</p> <p>A cost-effectiveness analysis is an economic study that considers both the comparative costs associated with the use of a drug and the clinical effects it achieves. Those effects are measured either as effectiveness, usefulness, or clinical outcomes (for example, quality of life, or dollars.)</p> <p>Pure clinical units (effectiveness) or "natural units" refer to clinical endpoints such as heart attacks, minor side effects, strokes, premature deaths or other adverse reactions.</p> <p>Also see <i>Cost-utility Analysis</i></p>
Cost-utility analysis	<p>A form of cost-effectiveness analysis in which the units of effectiveness are expressed as quality-adjusted life years (QALYs).</p>
DIDFA	<p>See <i>Drug Interchangeability and Dispensing Fee Act</i></p>

Disease-free survival	Time from clinical trial randomization until recurrence of disease or until death from any cause. Disease-free survival is sometimes used in clinical studies to assess the efficacy of a treatment, especially in situations where survival may be prolonged, making measurement of overall survival impractical. (<i>See overall survival.</i>)
Double-blind study	A clinical trial designed so that neither the participating individuals nor the study staff knows which participants receive the experimental drug and which receive the placebo or standard of therapy. (<i>See Placebo</i>) Blinding ensures that investigators' preferences or expectations, or participants' desire to please investigators or hope of improvement, does not influence and distort results. <i>See single-blind.</i>
Drug Interchangeability and Dispensing Fee Act (DIDFA)	The <i>Drug Interchangeability and Dispensing Fee Act</i> and its accompanying regulations, Ontario Regulations 935 and 936, govern the designation of drugs as interchangeable in the ODB Formulary.
Drug Quality and Therapeutics Committee (DQTC)	Former name of the Committee to Evaluate Drugs.
Drug System Secretariat	The Ministry of Health and Long-Term Care established the Drug System Secretariat at the direction of the Minister of Health and Long-Term Care to conduct an objective, system-wide review of Ontario's entire drug system. The Secretariat developed a package of recommendations to reform the provincial drug system. The recommendations consider five main areas: pricing and reimbursement of drug products; access to drug products; need for more appropriate use partnerships; innovation; and, strengthening the governance and operations of Ontario's drug system. The Drug System Secretariat has now become the Ontario Public Drug Programs Office.
Effectiveness	The way we measure the benefit resulting from an intervention for a health problem under usual conditions of clinical care for a particular group. This form of evaluation considers both the effect of an intervention and its acceptance by those to whom it is offered, answering the question, "Does the practice do more good than harm to the people to whom it is offered?"
Efficacy	A measure of the benefit that results from intervening for a given health problem under ideal conditions. It answers the question, "Does the practice do more good than harm to people who fully comply with the recommendations?"
Endpoint	The overall outcome that the protocol is designed to evaluate. Common endpoints include severe toxicity, disease progression, or death.
EO	<i>See Executive Officer</i>
Evidence	Information upon which a decision or guidance is based. Evidence is obtained from a range of sources including randomized controlled trials, observational studies, and expert opinion (of clinical professionals and/or patients).

Exceptional Access mechanism	<p>The ministry's Exceptional Access/ Individual Clinical Review (ICR) mechanism is a comprehensive approach to help patients access medications where formulary drugs were ineffective, not tolerated or no alternative was available on the Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index (Formulary). The mechanism ensures appropriate prescribing based on cost-effective, evidence-based care.</p> <p>The current ICR mechanism is being changed to a new, more streamlined Exceptional Access mechanism that will handle requests for drugs that are not funded as conditional listings in a way that minimizes the impact on prescribers and make it more transparent to prescribers and patients.</p>
Executive Officer (EO)	<p>The Executive Officer (EO) of the Ontario Public Drug Programs is responsible for creating a new enterprise to manage all activities dealing with the publicly-funded Ontario Drug Benefit. Specifically, the EO keeps, maintains and publishes the Formulary; decides on funding/drug coverage through Ontario's drug programs and the Exceptional Access mechanism; decides which products are designated interchangeable, negotiates agreements with manufacturers of drug products, and provides payments under the Ontario public drug programs.</p> <p>Performing the functions of Chief Executive Officer, the EO ensures efficient organization through planning, execution, issues' management, program review and performance measurement processes.</p>
F/P/T	Federal/Provincial/Territorial
FDA	<i>See Food and Drugs Act</i>
FDA	<i>See Food and Drug Administration</i>
First line, second line, third line	<p>A first-line therapy is the standard first treatment option for a specific medical condition and patient.</p> <p>A second-line therapy is one a physician uses if first-line therapy was not successful or if the normal first option for treatment is not appropriate for that patient, because of his or her medical condition or allergies, for example.</p> <p>Third-line therapy is used when first- or second-line therapy is not successful or is inappropriate.</p>

Term	Definition
First review	First Review refers to the first time the CED reviews and discusses a manufacturer's submission. Once a submission is determined to comply with Ontario's regulations, its status is noted as complete and the submission is sent to one or more CED reviewers. CED members or reviewers drawn from a roster of external consultants review the submissions. When the Ministry has received all reviews of a particular product, the submission is then scheduled as a First Review agenda item for the next available CED meeting. The submission is ranked in the meeting agenda according to the date the Ministry deemed it complete. First review submissions, both single-source and multiple-source, are considered first on the CED meeting agenda. After the CED considers first-review submissions, it moves on to second-review submissions and finally items submitted for reconsideration. Within each category (first review, second review, reconsideration), submissions are ranked in the agenda according to the date each submission was deemed complete. Drug products designated for "rapid review" are given a preferred status. (See Rapid Review)
Food and Drug Administration	The United States Food and Drug Administration
Food and Drugs Act	Canada's Food and Drugs Act. Before drug products are authorized for sale in Canada, Health Canada reviews them to assess their safety, efficacy and quality. Drug products include prescription and non-prescription pharmaceuticals, disinfectants and sanitizers with disinfectant claims. Prior to receiving market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality, as the Food and Drugs Act and its regulations require. When a product is offered for sale in Canada to treat or prevent diseases or symptoms, it is regulated as a drug under the Food and Drugs Act.
Formulary	<p>A formulary is a list of drugs that are covered as benefits. Each drug plan determines its own list. The Ontario Drug Benefit Formulary/Comparative Drug Index defines the benefits provided for eligible recipients of the Ontario Drug Benefit (ODB) program. The Formulary is developed in consultation with the ministry's external expert drug advisory committee, the CED. For many years, the Formulary has set the provincial standard for price, quality and interchangeability of drug products. For example, it serves as a guide to:</p> <ul style="list-style-type: none"> • practitioners and pharmacists regarding drug products that are eligible for coverage under the ODB program. • professional committees in hospitals and institutions as they select drug products. • drug product interchangeability. • comparative pricing guide for drug products.

General Benefit	General Benefit (GB) drugs products are reimbursed without specific restrictions to recipients eligible for the Ontario Drug Benefit. There are currently more than 2,500 drug products reimbursed and listed on the Formulary as GB products.
Generic drug	See <i>Multiple-source Drug</i>
Grey literature/reports	Unpublished studies or ones that have limited distribution, and are not included in the common bibliographic retrieval systems.
Head-to-head	A clinical trial that compares a new product with current standard therapy.
Health economics	The application of economic theory to phenomena and problems associated with health.
Health technology	Any method used by those working in health services to promote health, prevent and treat disease and improve rehabilitation and long-term care. Technologies in this context are not confined to new drugs or sophisticated equipment, but include surgical procedures, devices and other forms of therapeutic intervention such as physiotherapy and psychology
ICR	See <i>Exceptional Access</i>
Incremental cost-effectiveness ratio (ICER)	The ratio of the difference between the cost of two alternatives and their effectiveness.
Indication	In medicine, a sign, symptom, or medical condition that leads to the recommendation of a treatment, test, or procedure.
Induction therapy	Treatment designed as a first step toward shrinking cancer and evaluating response to drugs and other agents. Induction therapy is followed by additional therapy to eliminate whatever cancer remains.
Interchangeable	The Executive Officer has the authority to designate a product as interchangeable with one or more other products when it is in the public interest to do so, and when it meets requirements and conditions set out in legislation. Legislation defines an interchangeable product as a drug or combination of drugs in a particular dosage and strength identified by a specific product name or manufacturer and designated as interchangeable with one or more such products.
Internal criteria	Criteria the Committee to Evaluate Drugs (CED) developed to facilitate speedy internal screening and review of Individual Clinical Review (ICR)/Exceptional Access requests by pharmacists in the ministry's Individual Eligibility and Review Branch (IERB). If requests do not meet the CED's internal criteria, they are sent "externally" to a CED expert consultant for review.
Lifetime approval	Lifetime approval is a term used to describe the period of coverage that the CED has recommended, and that the ministry provides, for Individual Clinical Review/Exception Access requests for certain drugs and/or indications.

Limited use	<p>The CED recommends limited use drugs as having value in specific circumstances, but not appropriate for general listing in the Formulary. Limited use drugs may:</p> <ul style="list-style-type: none"> • have the potential for widespread use outside the indications for which benefit and cost-effectiveness have been demonstrated; • be clinically useful, but associated with predictable severe adverse effects; • be costly, and have a lower-cost alternative available as a general benefit. <p>Limited use products are listed in the Formulary with specific clinical criteria/conditions for use. These products will be reimbursed under the ODB program only when prescribed for an ODB-eligible recipient in accordance with the applicable criteria, after the prescriber has provided the Reason for Use Code for the prescription in writing, electronically or verbally. The ministry is reviewing limited use products and will ultimately transfer them to either general benefit or conditional listing.</p>
Line extension	<p>A new strength, formulation or reformulation of an existing drug product.</p>
Maintenance therapy	<p>Various kinds of treatment (usually medical) given to patients to enable them to maintain their health in a disease-free, or limited-disease, state.</p> <p>In cancer, maintenance chemotherapy may be given to patients with cancer in remission to prevent a relapse.</p>
Median overall survival	<p>The length of time from the start of treatment at which half of the patients with a disease are found to be still alive. It is a common measurement used in cancer treatment studies to determine the efficacy of a therapy.</p>
Meta-analysis	<p>Meta-analysis is the use of statistical methods to combine the results of individual studies. This allows us to make the best use of all the information we have gathered in our systematic review by increasing the power of the analysis.</p> <p>By statistically combining the results of similar studies we can improve the precision of our estimates of the effects of treatment, and assess whether those effects are similar in consistent situations.</p>
Multiple-source Drug	<p>A multiple-source or generic drug is identical, or bioequivalent, to a "brand name" drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.</p> <p>In Ontario, to be considered for an interchangeable listing designation in the Formulary, a multiple-source/generic drug product must meet the requirements of Ontario Regulation 935 under the <i>Drug Interchangeability and Dispensing Fee Act</i>.</p>
National Pharmaceutical Strategy (NPS)	<p>In September 2004, Canada's First Ministers directed their Health Ministers to establish a Ministerial Task Force to develop a National Pharmaceuticals Strategy, as part of the 2004 10-Year Plan to Strengthen Health Care. The five priorities of the Strategy are: Real World Safety and Effectiveness, Expensive Drugs for Rare Diseases, Drug Pricing and Purchasing Strategies (bulk purchasing and potential negotiations), Catastrophic Drug Coverage, and Common Formulary (expansion of CDR).</p>

New Chemical Entity (NCE)	A compound that has not previously been described in the literature or marketed in Canada, or which Health Canada has not previously approved for sale in Canada.
NOC or NOC/c	See <i>Notice of Compliance</i> or <i>Notice of Compliance with Conditions</i>
Non-inferiority study	<p>Non-inferiority studies are designed to show that the effect of a new treatment is <u>not worse</u> than that of another treatment (e.g. an established standard) by more than a specified margin.</p> <p>Non-inferiority studies differ from superiority studies, which assess whether one treatment is better than another, and equivalence studies (typically bioequivalence studies), which assess whether two treatments are equal within a specified margin.</p>
Notice of Compliance or Notice of Compliance with Conditions	The notice that Health Canada provides to manufacturers authorizing them to market a drug, sometimes under specific conditions.
NPS	See <i>National Pharmaceutical Strategy</i>
ODBA	See <i>Ontario Drug Benefit Act</i>
Off-Formulary Interchangeability (OFI)	The application of interchangeable designations to drug products that are not listed as Ontario Drug Benefit (ODB) benefits in the Formulary. OFI became effective April 1, 2007 when changes to Regulation 935 under the <i>Drug Interchangeability and Dispensing Fee Act</i> (DIDFA) came into force. The CED or the Ministry approves listed off-formulary interchangeable drug products. Once the Executive Officer approves them, they are deemed interchangeable with the name-brand non-benefit products.
OFI	See <i>Off-Formulary Interchangeability</i>
Ontario Drug Benefit (ODB) program	<p>The Ontario Drug Benefit (ODB) program is one of the most generous drug benefit programs in Canada, reimbursing patients for more than 3,200 drug products, including nutrition products and diabetic testing agents. Non-Formulary drug products are also considered for coverage on a case-by-case basis, through the Ministry's Exceptional Access/Individual Clinical Review (EA/ICR) mechanism.</p> <p>The ODB program provides community-based/outpatient drug coverage to Ontario residents with valid Ontario Health Cards. Deductibles and co-payments vary according to the category of recipient, including:</p> <ul style="list-style-type: none"> • seniors (those aged 65 or older); • people on social assistance (Ontario Disability Support Program and/or Ontario Works); • people residing in special-care homes and long-term care facilities; • people receiving professional home care services and; • registrants in the Trillium Drug Program (TDP).

Ontario Drug Benefit Act (ODBA)	The <i>Ontario Drug Benefit Act</i> and its accompanying regulation, Ontario Regulation 201/96, allows the Ministry of Health and Long-Term Care to pay pharmacies, dispensing physicians and other providers to supply drug products and other substances to eligible persons. This Act also stipulates who is eligible for benefits, what drugs are included and the prices the government will pay for listed drugs. The Act specifies the applicable dispensing fees and appoints inspectors to examine the records of drug manufacturers and pharmacists and to levy penalties when necessary.
Open-label /Open-label trial	A situation during a research study when both the researcher and the participant know which treatment the participant is receiving.
Outcome	A measure of the results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See <i>Endpoint</i> .
Overall survival	The time from clinical trial randomization until death from any cause. Overall survival provides the most objective measurement of how efficacious a treatment is. It is also the preferred endpoint for clinical trials because it has the greatest relevance to patients.
P value	The statistical value for the probability that an observed or greater difference occurred by chance, if it is assumed that there is in fact no real difference between the effects of interventions. If this probability is less than 1/20 (which is when the P value is less than 0.05), then the result is conventionally regarded as being "statistically significant".
Patented Medicines Prices Review Board (PMPRB)	A quasi-judicial body that Parliament established in 1987. Its mandate is: <u>regulatory</u> , to ensure that prices manufacturers charge in Canada or patented* drugs are not excessive. That determination is based on a comparison with existing drugs for the same disease, and the median of prices charged in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The PMPRB does not have the authority to prevent the sale of a patented medicine based on its price or to remove it from the market, but it can order a price reduction; and <u>reporting</u> , to report on pharmaceutical trends and R&D spending by pharmaceutical patentees.
Pharmacoeconomics	Pharmacoeconomics is the application of the methods of economic evaluation of health care programs to interventions involving pharmaceutical products.
Pharmacoeconomic review	The critical appraisal of published and unpublished information about costs and consequences of drugs and their impact on individuals, health care systems and society (in other words, value for money of drugs).
Pharmacokinetics	The processes (in a living organism) of absorbing, distributing, metabolising and excreting a drug or vaccine.
Pharmacology	The study of drugs, their sources, their nature their properties and their interactions with living organisms.

Pivotal study	<p>A pivotal or crucially important study is judged according to the following criteria, in that it must:</p> <ul style="list-style-type: none"> • be controlled using placebo or a standard therapy; • have a double-blinded design when such a design is practical and ethical; be randomized; and be of adequate size.
Placebo	<p>An inactive pill, liquid, or powder that has no treatment value, such as sugar and water, given in the control group of a clinical trial. Ideally, a placebo is identical in appearance and taste or feel to the experimental treatment and believed to lack any disease specific effects.</p>
Placebo-controlled study	<p>A method of investigating drugs, in which one group of participants receives an inactive substance (the placebo) while another group receives the drug being tested. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.</p>
Placebo effect	<p>A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the hope of the participant and, often, the expectations of the person administering the substance.</p>
PMPRB	<p>See <i>Patented Medicines Prices Review Board</i>.</p>
Priority review	<p>Preferred status in the review queue and on the CEDAC agenda. Provided only to drugs meeting specific criteria. All steps in the CDR procedure are completed and timelines are not cut short.</p>
Progression-free survival	<p>The length of time from the start of clinical trial randomization until there is progression of a patient's disease or until death occurs. Progression-free survival is one of the measures used in clinical studies to assess how well a treatment works. Because it only measures the amount of time that the disease does not worsen, an improvement in progression-free survival does not necessarily translate into a prolonged overall survival. (<i>See overall survival.</i>)</p>
Quality Adjusted Life Year (QALY)	<p>A method for comparing health outcomes, which assigns each year of life a weight, from 1 (perfect health) to 0 (judged equivalent to death), dependent on the individual's health-related quality of life during that year. A total score of years multiplied by weight can then be compared across different interventions. There is disagreement about the best methods for measuring health-related quality of life.</p>
Rapid review	<p>As a result of the changes made through the <i>Transparent Drug Systems for Patients Act, 2006</i>, the ministry can now consider submissions from manufacturers of drug products that have not yet received Notices of Compliance (pre-NOC submissions) from Health Canada, if the submissions meet specific criteria. (Previously, the ministry only accepted submissions after Health Canada had issued a NOC.)</p> <p>The new Rapid Review mechanism encompasses both pre-NOC and post-NOC submissions. The Rapid Review process has replaced the previous "Fast Track" mechanism.</p> <p>When considering pre-NOC submissions that meet the criteria and arrive at least 60 days before an NOC is issued, the Minister has indicated that the ministry will try to make a decision about listing the drug within 30 days after the manufacturer receives the NOC.</p>

Recommendation letter	The letter the ministry issues responding to a manufacturer's submission for funding consideration of a drug product in Ontario. The letter follows the completed review by the Committee to Evaluate Drugs. The letter includes the CED's rationale and recommendation to the Executive Officer about whether the product should be funded in Ontario. Recommendation letters are issued after first and second CED reviews.
Reconsideration	If a manufacturer responds within a six-month period to a second negative funding recommendation the CED has made, then the Committee will reconsider the submission, as the agenda permits.
Resubmission	A request by a manufacturer, drug plan or the Advisory Committee of Pharmaceuticals (ACP) to have the Common Drug Review review an original submission again, on the basis of new information that was not previously provided.
SAP	See <i>Special Access Program</i>
Second review	A manufacturer has six weeks from the date the first recommendation letter is issued to respond to the CED's concerns or questions, while maintaining the submission's existing review ranking. If the manufacturer fails to meet the deadline, then the product loses its ranking and will be reviewed a second time only as the CED agenda permits.
Side effects	Any undesired actions or effects of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects. See <i>Adverse Reaction</i> .
Single-arm study	A study in which all participants are given the same drug (i.e., there is no control group that is given an alternative drug or a placebo). The lack of a control group limits the interpretability of data because comparisons cannot be made between the effects of the study treatment and those of an alternative treatment or a placebo.
Single-blind study	A study in which one party, either the investigator or the participant, is unaware of what medication the participant is taking. Blinding is used together with randomization. Single-blinding means the participant doesn't know whether he or she is receiving the experimental product, an established treatment for that disease, or a placebo. The research team, however, does know what the participant is receiving. Blinding is done to make sure factors such as investigators' preferences or expectations, or participants' desire to please investigators or hopes of improvement, cannot influence and distort results. See <i>Double-blind</i> .
Single-source drugs	Drugs containing a unique chemical, strength, dosage form and route of administration, sold by one manufacturer. Once a generic drug comes onto the market, these drugs become referred to as "brand name" drugs. In Ontario, to be considered for listing in the Formulary, a single-source drug (often referred to as "brand product" or "original product"), must meet the requirements of Ontario. Reg. 201/96 under the <i>Ontario Drug Benefit Act</i> .

Special Access Program (SAP)	Patients can only access drugs that have not been approved for sale in Canada and have not received a Notice of Compliance through Health Canada's Special Access Program. The program acts as a broker between the manufacturer and the physician; it is not a funding mechanism. If access is approved through the SAP, it is up to the manufacturer to supply the medication and to decide whether to sell it or to provide it free of charge.
Standard treatment	A treatment currently in wide use, approved as safe and effective in the treatment of a specific disease or condition.
Statistical significance	The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends upon the number of participants studied and the observations made, as well as the magnitude of differences observed.
Statistically significant	Means that the findings of a study are unlikely to have arisen by chance. Significance at the commonly cited 5% level ($P < 0.05$) means that the observed difference or greater difference would occur by chance in only 1 of 20 similar cases.
Surrogate marker	An indirect measurement or indication of the way a disease is progressing, or of a drug's effectiveness. A surrogate marker can predict a patient's clinical outcome without relying on traditional clinical endpoints, such as death or the development of a major infection. For example, the T-cell count of an HIV patient is a surrogate marker.
Synthesis of evidence	A generic term to describe methods used to summarize (compare and contrast) evidence in order to answer a defined clinical question. This can include systematic review (with or without meta-analysis), and qualitative and narrative summaries.
Systematic review	A systematic review is a literature review using explicit methods, focused on a single question that tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question, and to combine valid studies. Systematic reviews are generally regarded as the highest level of medical evidence.
TDSPA	See <i>Transparent Drug System for Patients Act, 2006</i>

<p>Transparent Drug System for Patients Act, 2006</p>	<p>The <i>Transparent Drug System for Patients Act, 2006</i> (formerly Bill 102) incorporates legislative changes required to implement drug system strategies to:</p> <ul style="list-style-type: none"> • improve patient access to drugs through conditional listings and rapid drug reviews; • ensure better value for money through changes to drug pricing and reimbursement; • recognize the valuable role pharmacists play in patient care by paying them to provide enhanced patient counselling about the appropriate use of medications; • invest in innovative health system research by establishing a fund to show that drugs produce positive outcomes in other parts of the system; • reduce paperwork for doctors by replacing a cumbersome process previously known as Section 8; and • strengthen transparency and accountability in the drug system by giving patients a role in drug listing decisions and by appointing an Executive Officer to manage the publicly funded drug system.
<p>Validity</p>	<p>The soundness or rigour of a study. A study is internally valid if the way it is designed and carried out results in unbiased results and an accurate estimate of the effect being measured. A study is externally valid if its results are applicable to people encountered in regular clinical practice.</p>

Most of the glossary has been compiled and adapted from the following sources:

TITLE: PRINCIPLES FOR THE DEVELOPMENT OF NICE GUIDANCE DATE: 8 DECEMBER 2005

CDR Definitions: In the Terms of Reference of the Advisory Committee on Pharmaceuticals, the following definitions apply, unless otherwise provided. CADTH ADVISORY COMMITTEE ON PHARMACEUTICALS- Terms of Reference

<http://www.clinicalevidence.com/ceweb/resources/glossary.jsp>

<http://www.med.ualberta.ca/ebm/define.htm>

<http://www.medterms.com/script/main/hp.asp>

<http://www.emea.europa.eu/pdfs/human/ewp/140198en.pdf>

<http://www.nlm.nih.gov/medlineplus/ency/article/002314.htm>

<http://clinicaltrials.gov/ct/info/glossary;jsessionid=25425349D87971BE830BC3F89D4F60C4>

http://www.cancer.gov/Templates/db_alpha.aspx?CdrID=45768

<http://www.fda.gov/oc/speeches/surrogates8.html>

http://www.fda.gov/fdac/features/2007/207_trials.html

<http://www.cadth.ca/index.php/en/publication/35>