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Commentary

When exceptions blur into the rule: toward an operational framework for exceptional drug access in Québec University hospitals

Denis Lebel, Nicole Déry, Marc Simard, André Bonnici, Patrice Lamarre, Marie-Claude Langevin, Martin Darveau

Extract

Québec's hospital drug coverage system aims to balance timely access, evidence-based practice, and stewardship of public resources. Medications are listed on the provincial *List of medications—Institutions* (hereafter referred to as the List) [1] and publicly covered once 1- Health Canada has issued marketing authorization, 2- the Québec health technology assessment agency (*Institut national d'excellence en santé et en services sociaux*, INESSS) has provided an assessment and recommendation to the Minister of Health and Social Services, and 3- the latter has authorized their inclusion on the List. The Act respecting health services and social services (*Loi sur la gouvernance du système de santé et de services sociaux*, LGSSSS) [2] governs this process and authorizes institutions to approve, on a case-by-case basis through pharmacy and therapeutics (P&T) committees, drugs that are not on the List. Although conceived as a seldom-used exception, this mechanism is routinely invoked. Gaps between patient need and drug availability on the List can arise at every stage of the pathway, from the absence of a manufacturer's submission to Health Canada or INESSS, through evaluation timelines, to funding decisions for high-cost therapies, making exceptional access a critical bridge between policy and bedside care.