CANADA

Between 2002 and 2014,
38%
of medicines to treat orphan conditions were **rejected for coverage** in Canada [1]

only 39%
of medicines launched globally between 2008 and 2012 were **available in Canada by 2013**.[2]

It takes an average of
449 days
after Health Canada's approval before patients can access a medicine through a Canadian public drug plan.[3]

Restricted and Delayed Access to Treatments in Canada

Canada's current pharmaceutical pricing policies have led to significant delays and access restrictions for patients who require new and innovative medicines.

In addition to regulatory approval, the current coverage and reimbursement process for new drugs includes numerous steps that can impede access: a review of all patented medicines by the Patented Medicine Prices Review Board (PMPRB), assessments that utilize the quality-adjusted-life-year (QALY) conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH),[4] and additional negotiations and product listing agreements with Provincial public drug plans. This complex and many-layered process acts as a barrier to innovate drugs and creates delays in access for patients.

"There's no way I can't try this drug. It's the last thing that might save my life… It's crazy that I live in Canada, but now I'm looking at having to sell my house for coverage of my medication."

Patient with breast cancer in Canada[6]

Orkambi has been approved by Health Canada, but individual provinces can deny coverage. Thousands of children and young adults who live in British Columbia (B.C.) have been denied access to Orkambi, based on the cost effectiveness of the product.[5] Orkambi is the first treatment approved by the FDA to treat underlying cause of cystic fibrosis (CF), which kills half of those afflicted before they reach 31. Canadian Cystic Fibrosis Treatment Council chairman Chris MacLeod said the "drug-approval process is **opaque and discriminates against patients with rare diseases**."[6]

[1] S Mardiguian, M Stefanidou, et al. Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies. (2014).
[2] IMS Institute for Healthcare Informatics. Global Outlook for Medicines Through 2018.
[3] Canadians Facing Delayed Access to New, Innovative Medicines: Report. May 2016.
[4] Guidelines for the Economic Evaluation of Health Technologies: Canada. July 2017.
[5] 'Lives are on the line' Cystic fibrosis patients file class action lawsuit for $250K-a-year drug.' *CBC News*. July 2018.
[6] 'UVic student takes lead in $60-million class-action suit over costly drug.' *The Times Colonist*. July 2018.