BREAKING DOWN THE LANGUAGE OF DRUG APPROVALS IN CANADA

Canada's drug approval processes involve three main elements - regulatory review, health technology assessment and price negotiation. Below, we explain the complex terms involved in the drug approval process in Canada.

Regulatory Agencies

The regulatory assessment is the process of analysing the benefit and risk balance of a medicine, which is based on results from clinical trials.

STEP 1

Health Canada HPFB: Health Products and Food Branch - Reviews drugs for safety and efficacy, and authorizes market access in Canada.

STEP 2

PMPRB: Patented Medicine Prices Review Board - Protects consumers by ensuring that the prices of patented medicines are not excessive.

Health Technology Agencies

The Health Technology Assessment (HTA) is the process of informing reimbursement and coverage decisions by insurers and national health systems through an analysis of efficacy, use in clinical practice and economic evaluations.

CADTH: Canadian Agency for Drugs and Technology in Health - Determines the value of a treatment and makes reimbursement recommendations to the provinces.

STEP 3

L'INESS: Institut national d'excellence en santé et en services sociaux - Determines the value of a treatment and makes reimbursement recommendations for the province of Quebec.

Price Negotiation Agencies

CDA: Canadian Drug Agency - Aims to make prescription drugs more affordable by assessing the effectiveness of new drugs, negotiating drug prices on behalf of Canada's drug plans and recommending drugs that represent the best value-for-money to be included in a future national formulary.

STEP 4

pCPA: Pan-Canadian Pharmaceutical Alliance - Aims to achieve greater value for publicly funded drug programs and patients in Canada through collective negotiation.