Analysis of Gene Therapies Authorized by Health Canada and Comparison with the U.S. Food and Drug Administration, and the European Medicines Agency

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Background

Gene therapies represent a major shift in disease treatment and prevention. Studies assessing differences in gene therapy regulatory actions among Health Canada (HC), the U.S. FDA, and the European Medicines Agency (EMA) are limited.

Understanding differences in regulatory pathways and review timings is critical for assessing their impact on patient access to innovative therapies.

Objectives

We compared the characteristics of gene therapies authorized by HC, FDA, and EMA, including the number of authorizations, authorization time gaps, therapeutic classes, and approved indications across the three agencies.

Methods

Gene therapy regulatory information was obtained from the HC, FDA, and EMA websites.

Approved indications were obtained from HC Product Monographs, U.S. Prescribing Information (USPI), and EU Summary of Product Characteristics (SmPC). Median authorization gaps were calculated by comparing authorization dates across the three agencies. Differences in indication statements were assessed descriptively.

Results

Table 1. Gene Therapies Authorized by Health Canada, FDA, and EMA

Generic Name	Therapeutic Class	Review Time (Days)	Filing Date	Authorization Date			Authorization Gap (Days)	
		HC	HC	HC	FDA	EMA	HC-FDA	HC-EMA
axicabtagene ciloleucel	Antineoplastic and immunomodulating	180	17-Aug-18	13-Feb-19	18-Oct-17	23-Aug-18	483	174
brexucabtagene autoleucel	Antineoplastic and immunomodulating	202	18-Nov-20	8-Jun-21	24-Jul-20	14-Dec-20	319	176
ciltacabtagene autoleucel	Antineoplastic and immunomodulating	342	4-Mar-22	9-Feb-23	28-Feb-22	25-May-22	346	260
etranacogene dezaparvovec	Blood and blood-forming organs	210	27-Mar-23	23-Oct-23	22-Nov-22	20-Feb-23	335	245
exagamglogene autotemcel	Blood and blood-forming organs	209	27-Feb-24	23-Sep-24	8-Dec-23	9-Feb-24	290	227
fidanacogene elaparvovec	Blood and blood-forming organs	209	1-Jun-23	27-Dec-23	25-Apr-24	24-Jul-24	-120	-210
idecabtagene vicleucel	Antineoplastic and immunomodulating	246	22-Sep-20	26-May-21	26-Mar-21	18-Aug-21	61	-84
lisocabtagene maraleucel	Antineoplastic and immunomodulating	505	17-Dec-20	6-May-22	5-Feb-21	4-Apr-22	455	32
onasemnogene abeparvovec	Musculo-skeletal	208	21-May-20	15-Dec-20	24-May-19	18-May-20	571	211
tisagenlecleucel	Antineoplastic and immunomodulating	208	9-Feb-18	5-Sep-18	30-Aug-17	23-Aug-18	371	13
voretigene neparvovec	Sensory organs	348	31-Oct-19	13-Oct-20	19-Dec-17	22-Nov-18	1,029	691

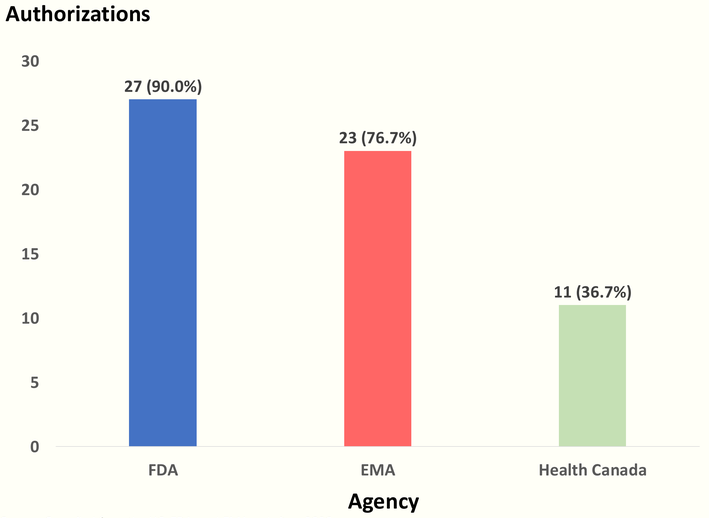
HC = Health Canada; FDA = Food and Drug Administration; EMA = European Medicines Agency
Source: *Compiled from the HC, FDA, and EMA websites, 2026.*

Of the 30 gene therapies authorized by at least one agency, 27 (90.0%) were authorized by FDA, 23 (76.7%) by EMA, and 11 (36.7%) by HC (Figure 1). Among the 11 therapies authorized by all three agencies, FDA authorized 10 (90.9%) first and HC authorized 1 (9.1%) first. The therapeutic classes with the largest number of HC authorizations were antineoplastic and immunomodulating agents (n=6, 54.5%) and blood and blood-forming organs (n=3, 27.3%).

All 11 therapies received orphan designation by FDA and 9 (81.8%) by EMA. HC does not have an orphan drug designation pathway. Eight of the 11 (72.7%) received HC priority review; 2 (18.2%) HC Notices of Compliance with Condition; 5 (45.5%) EMA conditional marketing authorization; and 1 (9.1%) FDA accelerated approval at initial submission, with 3 additional accelerated approvals for new indications. The median authorization gap was 346.0 days (interquartile range (IQR): 164.5 days) between HC and FDA, and 176.0 days (IQR: 213.5 days) between HC and EMA (Table 1).

Between HC and FDA, the most frequent indication differences involved line of therapy (n=5, 45.5%) and disease characteristics (n=3, 27.3%).

Figure 1. Number of Gene Therapies Authorized by Health Canada, FDA, and EMA



Source: *Compiled from the HC, FDA, and EMA websites, 2026*

Between HC and EMA, the most frequent indication differences involved line of therapy (4, 36.4%). Other differences in indications included patient population age groups, disease stage, disease severity, current therapy, and limitations of use.

HC indications were generally more detailed, with pediatric and geriatric safety and efficacy information reflected directly in the indication section.

Conclusions

One third of the gene therapies authorized by the FDA and EMA have been authorized by HC. Median authorization gaps exceeded 11 months between HC and FDA and 5 months between HC and EMA. There were notable differences in the indications of gene therapies authorized by HC, FDA, and EMA.

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