From: **Accelerated Approval Is Not Conditional Approval: Insights From International Expedited Approval Programs**

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Table. Comparison of International Expedited Approval Programs[a]

Regulatory health authority (country/union)	Expedited program (year initiated)	Eligible applications[b]	Postmarketing requirements	Approval expiration
US Food and Drug Administration (United States)	Accelerated approval (1992)	New molecular entities and supplements	Confirmatory trial that verifies the clinical benefit in the same or a related population	No
Health Canada (Canada)	Notice of Compliance with conditions (1998)	New molecular entities and supplements	Confirmatory trial(s) that verify the clinical benefit	No (annual progress reports required until the conditions have been met or removed)
			Annual progress reports of confirmatory trials and other ongoing trials	
			Postmarketing surveillance	
European Medicines Agency (European Union)	Conditional marketing authorization (2006)	New molecular entities	Complete specific obligations to confirm positive benefit-risk balance	Yes (valid for 1 y, must renew)
Pharmaceuticals and Medical Devices Agency (Japan)	Conditional approval (2017)[c]	New molecular entities and supplements	Confirmatory studies or other clinical data (including database-based studies) that reaffirm the clinical efficacy and safety in the target population	No
Therapeutic Goods Administration (Australia)	Provisional approval (2018)	New molecular entities and supplements	Continuation of trials	Yes (must be renewed every 2 y and completed in 6 y)
			Submission of confirmatory efficacy and safety data required for full registration within the provisional registration period	
Swissmedic (Switzerland)	Temporary authorization (2019)	New molecular entities	Fulfillment of conditions determined at the time of approval	Yes (valid for 2 y, may be extended in exceptional cases)
Medicines and Healthcare Products Regulatory Agency (United Kingdom)	Conditional marketing authorization (2021)	New molecular entities	Complete specific obligations to confirm positive benefit-risk balance	Yes (valid for 1 y, must renew)

[a] Adapted from Friends of Cancer Research.[2]

[b] US Food and Drug Administration categories used for consistency.

[c] Regenerative medicine products (cell and gene therapy) are considered under the program Conditional, time-limited approval.

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