New drug submissions in the United States and Canada 2014-2019: trends and policy implications.

Description

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Abstract

It is generally agreed by patients, government and industry that “new innovative medicines are critical to the Canadian Healthcare system” (Health Canada, 2017) (Health Canada, 2018) (Ernst & Young LLP, 2019). However, Canada may have passed a tipping point where we are no longer considered a premier jurisdiction to launch new medicines. On average the US FDA has approved 12 more New Active Substances (NAS) per year than Health Canada (HC) over the past 5.5 years. This difference peaked in 2018 when they approved 20 more than Health Canada. The time from application to approval, and backlog based on the FDA and HC’s own published metrics is not significantly different between the two jurisdictions. The gap in number seems to stem from companies not applying for review equally. 54% of US approved NAS not yet approved in Canada are to sponsors with no Canadian presence despite the Canadian government’s efforts to attract the biopharmaceutical industry with programs from Global Affairs Canada, Canadian Institutes of Health Research, The National Research Council’s Industrial Research and Assistance Program (NRC-IRAP), Export Development Canada (EDC) and the Business Development Bank of Canada (BDC). Canadians need to determine why these medicines are not being submitted and address the issues with government before we fall any further behind in having access to quality innovative medicines.

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