Quality and quantity of data used by Health Canada in approving new drugs

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Background: This study examined multiple aspects about the approval of new drugs: the characteristics of the drugs, the quality and quantity of information that Health Canada discloses about the demographics of patients enrolled in clinical trials, the characteristics of the trial, and the type of review that it uses. It examines whether there have been changes in these measures between 1 September 2012 and 31 March 2022.

Methods: A list of all new drugs approved, type of review used, and drug characteristics was generated from Health Canada annual reports. Therapeutic categories were identified from the World Health Organization Collaborating Center for Drugs Statistics Methodology. The Summary Basis of Decision documents of Health Canada were used to identify patient demographics in clinical trials and clinical trial characteristics.

Results: Health Canada approved 326 new drugs for 407 indications. The percent of orphan drugs approved increased from 35.6 to 51.3%. The number of indications per drug decreased ($p = 0.0817$) as did the number of pivotal trials per drug ($p = 0.0091$). The percent of Phase 3 trials dropped from 76.3% in 2012–2015 to 64.8% in 2019– 2022 ($p = 0.005$). There was also a statistically significant decrease in the percent of trials that were randomized, controlled, and blinded. The clinical trial characteristics of orphan drugs and the type of review used were both significantly different compared with non-orphan drugs. The percent of trials which had information about the number of patients enrolled, the percent of trials that provided the age of the patients, and the sex breakdown all significantly increased.

Conclusion: The results show that there has been a change in regulatory standards that may be due to them becoming less rigorous, because of an adaptation to the number of orphan drugs being submitted or a combination of both reasons. At the same time, there has been some improvement in the transparency of data. Health Canada has recently embarked on a series of reforms in drug regulation and clinical trial management. These changes need to be closely evaluated to be sure that they enhance the efficacy and safety of new drugs.