Comparison of drug approval between Health Canada and the US Food and Drug Administration

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Background

Differences in drug approval processes between countries can impact patient access to new therapies. The aims of this study were to delineate the Canadian drug approval timeline and to compare the time to drug approval between HC and the US Food and Drug Administration (FDA).

Methods

40 antineoplastic drugs approved by the FDA from 1989 to 2011 were reviewed. For each drug, the following endpoints were determined: publication date of phase I and pivotal phase III trial, date of FDA and HC approval, HC submission date, and funding approval in Alberta (AB). Time intervals between the aforementioned endpoints were calculated.

Results

HC approval occurs an average of 14 months post FDA approval (14.4 months; 95% CI -36.9-66.1, $p<0.0001$). However, there was no significant difference between the mean time from Phase I to FDA approval (48.5 months; 95% CI 21.2-75.8) and Phase I to HC approval (61.5 months; 95% CI 32.4-90.5). Most drugs were approved by the FDA prior to publication of the phase III trial. There was a trend towards faster drug approval from Phase III to FDA approval compared to HC (-14.97 versus 0.1 months, $p = 0.05$). HC submission for drug approval is pre FDA drug approval 77% of the time (average 89 days before; 95%CI: -1772 days to 1303 days, $p = 0.0206$). HC approval occurs on average 17 months post HC submission. AB drug funding occurs on average 22 months after HC approval. The time interval from Phase I to placement on the AB formulary was significantly shorter for targeted compared to cytotoxic agents (mean time 58 vs. 120 months; $p = 0.039$). Of the 55 FDA-approved drugs, 51 drugs are approved by HC with 40 of these drugs available in Alberta.

Conclusion

HC drug approval lags behind FDA approval by about 14 months. Time from Phase III to drug approval tends to be shorter for the FDA compared to HC. This is the first documentation, to our knowledge, of the time required to bring a drug from phase I trial to placement on a provincial drug formulary.

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2012 NOYCIA Selection Committee

Dear Selection Committee:

This letter is to provide confirmation and support for Dr. Doreen Ezeife's application for a Young Investigator Award for her abstract entitled "Comparison of drug approval between Health Canada and the US Food and Drug Adminstration (FDA)," accepted for poster presentation at the 2012 American Society of Clinical Oncology meeting. Dr. Ezeife is very interested in a career in medical oncology and is in her first year of internal medicine residency at the University of Calgary, Canada.

I have worked with her on this research project. Dr. Ezeife has expressed cancer research interests in health services research. She is extremely motivated and diligent. It was a pleasure to supervise her for this project. Dr. Ezeife assumed a primary role in background research, contacting Health Canada and the FDA for necessary information, reviewing and abstracting the relevant data to create a database for analysis, and writing the abstract. She did some of the basic statistical analysis as well. I would estimate her contribution at 80%.

Her project involves an evaluation of the drug development time line in Canada, from phase I to phase III to Health Canada approval. In addition, she evaluated the difference between time to FDA approval and time to Health Canada approval. In her project, she found that time from phase III to drug approval tends to be shorter for the FDA compared to Health Canada.

I strongly recommend her application for this prestigious award.

Sincerely,

Patricia Tang
Medical Oncologist

DOREEN EZEIFE

For this study, I collected and organized the data using online resources and drug company representatives. I contacted and worked with drug company representatives, Health Canada and Food and Drug Administration personnel to obtain the necessary drug development dates. I created the spreadsheets and gathered all of the data onto the spreadsheets. I also did the basic statistical analysis. I wrote the abstract and I am designing the poster.

Contribution percentage: 80