Fraser Alert

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Access to New Oncology Drugs in Canada Compared with the United States and Europe

by Nigel S.B. Rawson, Ph.D.

Main Conclusions

- **Of 33 new oncology drugs, 30 were approved in the United States, 26 in the European Community, and 24 in Canada between 2003 and 2011.**
- **The median review times (the time within which 50% of the drugs were approved) of these drugs were 182 days in the United States, 410 days in Europe, and 356 days in Canada.**
- **Of the 24 drugs approved in Canada, the median review time was 182 days in the United States and 408 days in Europe. Twenty-three of the drugs took longer to be approved in Canada than in the United States; 43% of the times were longer by at least 180 days.**
- **Twenty-five (83%) of the 30 drugs approved in the United States received an expedited review (median and average approval times of 182 and 217 days, respectively) compared with only eight (33%) of the 24 drugs approved in Canada that received a priority review (median and average approval times of 326 and 422 days, respectively).**
- **As a result of longer approval times in Canada, the Canadian government delayed access to the 21 drugs approved by all three agencies by more than 180 days after the corresponding dates for 10 of the drugs in the European Community and for 19 of the drugs in the United States.**
- **By the end of March 2012, only three of the 24 drugs approved in Canada were covered to some degree by government insurance in all 10 provinces, while seven others had government subsidized access in some provinces. Most importantly, almost 60% had no government subsidized access in any province.**

Introduction

Cancer is the leading cause of premature death in Canada. The numbers of new cases of breast, colorectal, ovarian, prostate, and kidney cancer, and leukemia and lymphoma have changed little over the last 20 years (CCS, 2012). Moreover, the five-year survival rates (the proportion of patients surviving for at least five years after diagnosis) for lung and ovarian cancer have remained more or less the same over the last two decades and those for breast, colorectal, and kidney cancer and lymphoma have shown only modest progress (CCS, 2012). Consequently, new, better treatments are needed as soon as they can be introduced.

Unfortunately, the timeliness of the review and approval of new drugs for use in Canada in comparison with other industrialized countries has been a concern to patients and physicians for many years (Rawson, 2000, 2003; Rawson and Kaitin, 2000, 2003; Rawson et al., 1998; Rovere and Skinner, 2012). Nevertheless, it has been suggested that most new drugs cannot be considered "major medical advances," so that the slow approval of these drugs is of little concern (Lexchin and Mintzes, 2000). However, oncology drugs are vitally important to patients needing hope and to physicians seeking even moderately effective therapies (Lakdawalla et al., 2012; Romley et al., 2012; Seabury et al., 2012).

A recent comparison of 35 new oncology drugs approved in the United States and the European Community between 2003 and 2010 demonstrated that, despite claims to the contrary, these drugs were approved significantly faster in the United States than in Europe (Roberts et al., 2011). Two of the 35 drugs are used in cancer patients to counteract adverse effects of oncology therapy and were excluded, leaving 33 for this analysis. Eighteen of these drugs were indicated for the treatment of a solid tumour (breast, colorectal, lung, ovary, prostate, kidney, and osteosarcoma) and 15 were designed to treat leukemia, lymphoma, multiple myeloma, or myelodysplastic syndrome. The number of these oncology drugs approved in Canada and the time taken for their review are examined in this report (details of the methods used in the analysis are presented at the end of the report).

Review and approval

Of the 33 oncology drugs, 30 (91%) were approved in the United States, 24 (73%) in the European Community, and 22 (67%) in Canada between 2003 and 2010. Two of the 33 drugs approved in the United States (cabazitaxel for prostate cancer and erbulin for breast cancer) received approval in Europe and Canada in 2011 and were included in the analysis. Thus, 26 (79%) and 24 (73%) drugs were approved in the European Community and Canada, respectively, by the end of 2011 (see table 1).

At 356 days, the median Health Canada review time of the 24 drugs approved in this country is almost twice as long as the median FDA time of 182 days for its approval of 30 drugs, but is approximately two months less than the median EC approval time of 410 days for the 26 drugs approved in Europe (see table 2). When the analysis was limited to the 24 drugs approved in Canada, the median FDA and EC approval times remained virtually the same at 182 and 408 days, respectively.

Although one drug (tositumomab) had a shorter review time in Canada than in the United States, the review times of all the other drugs approved in Canada were longer than the corresponding times in the United States by 41 to 712 days (see figure 1), with 43% being longer by at least 180 days. The Canadian review time was longer than the EC approval time for 45% of the drugs.

Of the 30 drugs approved in the United States, 25 received an expedited review with a median review time of 182 days (average: 217; range: 78-1016). In Canada, eight of the 24 drugs received a priority review (median time: 326 days; average: 422; range 197-820). Only three drugs had an expedited review in Europe as the system was only recently introduced.

About the author

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Table 1: The 33 Oncology Drugs Approved by the End of 2011

Drug name	Approved in the United States	Approved in the European Community	Approved in Canada
Azacitidine	Yes*	Yes	Yes†
Bendamustine hydrochloride	Yes*	Yes	No
Bevacizumab	Yes*	Yes	Yes†
Bortezomib	Yes*	Yes	Yes
Cabazitaxel	Yes	Yes	Yes
Cetuximab	Yes*	Yes	Yes†
Clofarabine	Yes*	Yes	Yes
Dasatinib	Yes*	Yes	Yes
Decitabine	Yes	No	No
Degarelix acetate	Yes	Yes	Yes
Eribulin mesylate	Yes*	Yes	Yes
Erlotinib hydrochloride	Yes*	Yes	Yes†
Everolimus	Yes	Yes	Yes
Histamine dihydrochloride	No	Yes	No
Ixabepilone	Yes*	Submission withdrawn	No
Lapatinib ditosylate	Yes*	Yes	Yes
Lenalidomide	Yes*	Yes	Yes
Mifamurtide sodium	No	Yes	No
Nelarabine	Yes*	Yes	Yes
Nilotinib hydrochloride monohydrate	Yes	Yes	Yes
Ofatumumab	Yes*	Yes	No
Panitumumab	Yes*	Yes	Yes
Pazopanib hydrochloride	Yes	Yes	Yes
Pemetrexed disodium	Yes*	Yes	Yes†
Pralatrexate	Yes*	No	No
Romidepsin	Yes	No	No
Sipuleucel-T	Yes*	No	No
Sorafenib tosylate	Yes*	Yes	Yes
Sunitinib malate	Yes*	Yes	Yes†
Temsirolimus	Yes*	Yes	Yes†
Tositumomab	Yes*	No	Yes†
Trabectedin	No	Yes	Yes
Vorinostat	Yes*	Submission withdrawn	Yes

*Expedited review (priority, accelerated, or fast track)
†Priority review

Sources: Roberts et al., 2011; Health Canada, 2010; Health Canada, 2011a.

Twenty-one of the 33 drugs were approved by all three agencies with the median review times shown in table 3. At 362 days, the median Health Canada review time for the 21 drugs is twice as long as the 182 day median FDA review time, but 43 days less than the median EC approval time for the same drugs.

The dates of the submissions to Health Canada for the 21 drugs were within a period of 90 days before or after the submission dates to the EMA and FDA for 10 and seven of the drugs, respectively. However, later submissions and longer review times in Canada resulted in the Canadian marketing authorization date being delayed by more than 180 days after the European Commission and FDA marketing authorization dates for 10 and 19 of the 21 drugs, respectively (see figure 2). For nine drugs, the Canadian marketing approval date was more than 18 months after the US marketing approval date. The median delay between marketing authorization in Canada and Europe was 133 days and between Canada and the United States was 364 days.

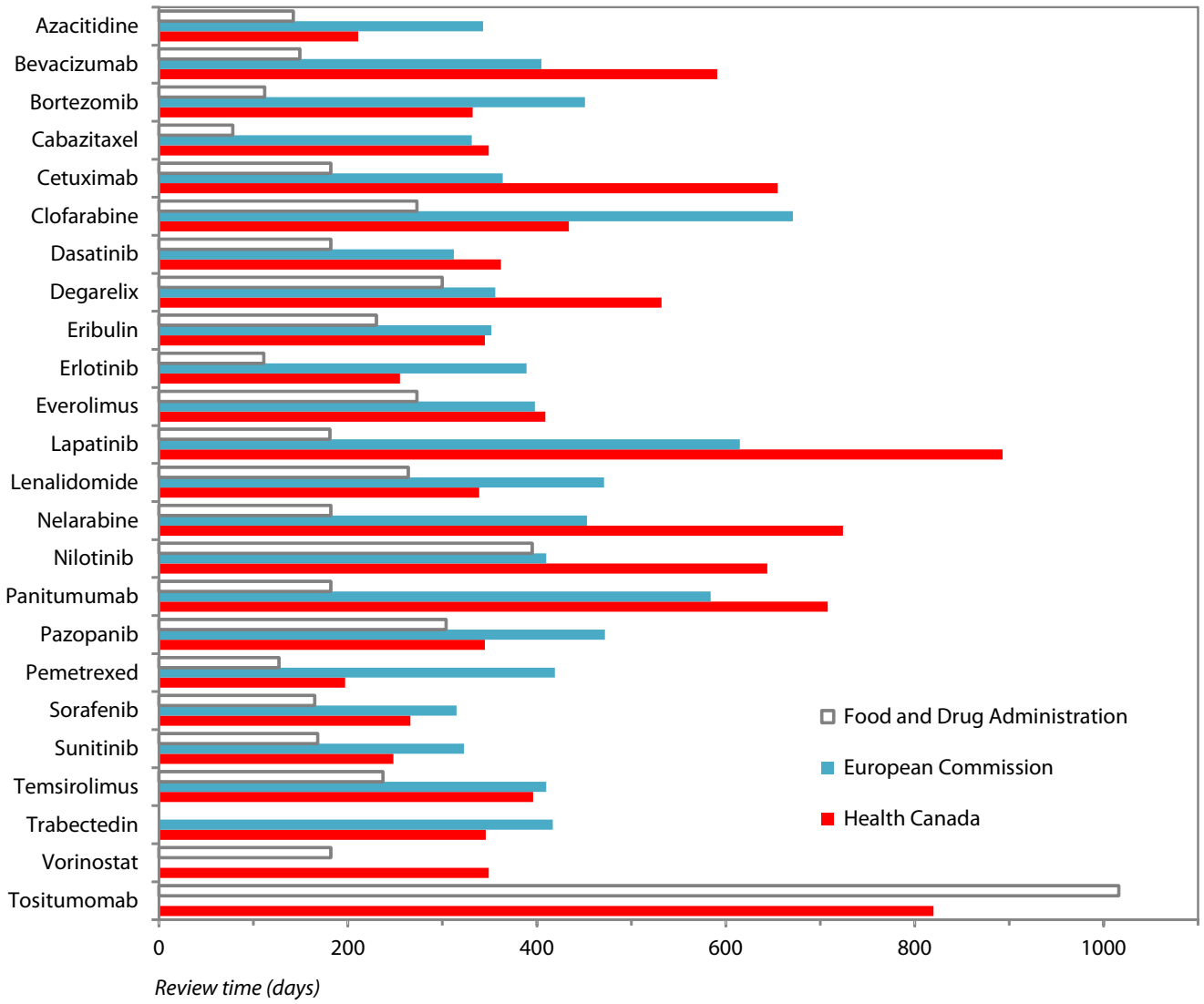
To assess whether there has been any change between mid-decade and more recent years, the review times of the oncology drugs approved in Canada between 2005 and 2007 and between 2008 and 2011 were compared. Since the median times and ranges in these periods were 362 days (average: 441; range: 197-820) and 349 days (average: 454; range: 211-893), respectively, it can be seen that there has been little change in Canada since 2005.

Table 2: Number of Oncology Drugs Approved by Each Agency and their Median, Average, and Range of Review Times (in days)

Agency	Period	Number of drugs reviewed	Median approval (days)	Average approval time (days)	Range of review times (days)
US Food and Drug Administration	2003-10	30	182	230	78-1016
European Commission	2004-11	26	410	439	116-854
Health Canada	2005-11	24	356	448	197-893

Sources: Roberts et al., 2011; Health Canada, 2010; Health Canada, 2011a.

Figure 1: Review times of the 24 oncology drugs approved in Canada by the end of 2011 compared with those in the United States and Europe



Sources: Roberts et al, 2011; Health Canada, 2010; Health Canada, 2011a.

Table 3: Median, Average, and Range of Review Times of the 21 Oncology Drugs Approved by All Three Agencies

Agency	Median approval time (days)	Average approval time (days)	Range (days)
US Food and Drug Administration	182	202	78-395
European Commission	405	421	312-671
Health Canada	362	440	197-893

Sources: Roberts et al., 2011; Health Canada, 2010; Health Canada, 2011a.

Safety

The submissions to the EMA for two drugs (ixabepilone and vorinostat) were withdrawn before they received marketing authorization due to concerns about the benefit-risk profile from the Committee for Medicinal Products for Human Use (EMA, 2008, 2009). However, both were approved in the United States and vorinostat was approved in Canada. None of the oncology drugs discussed here was withdrawn from the marketplace for safety reasons in any of the jurisdictions after approval.

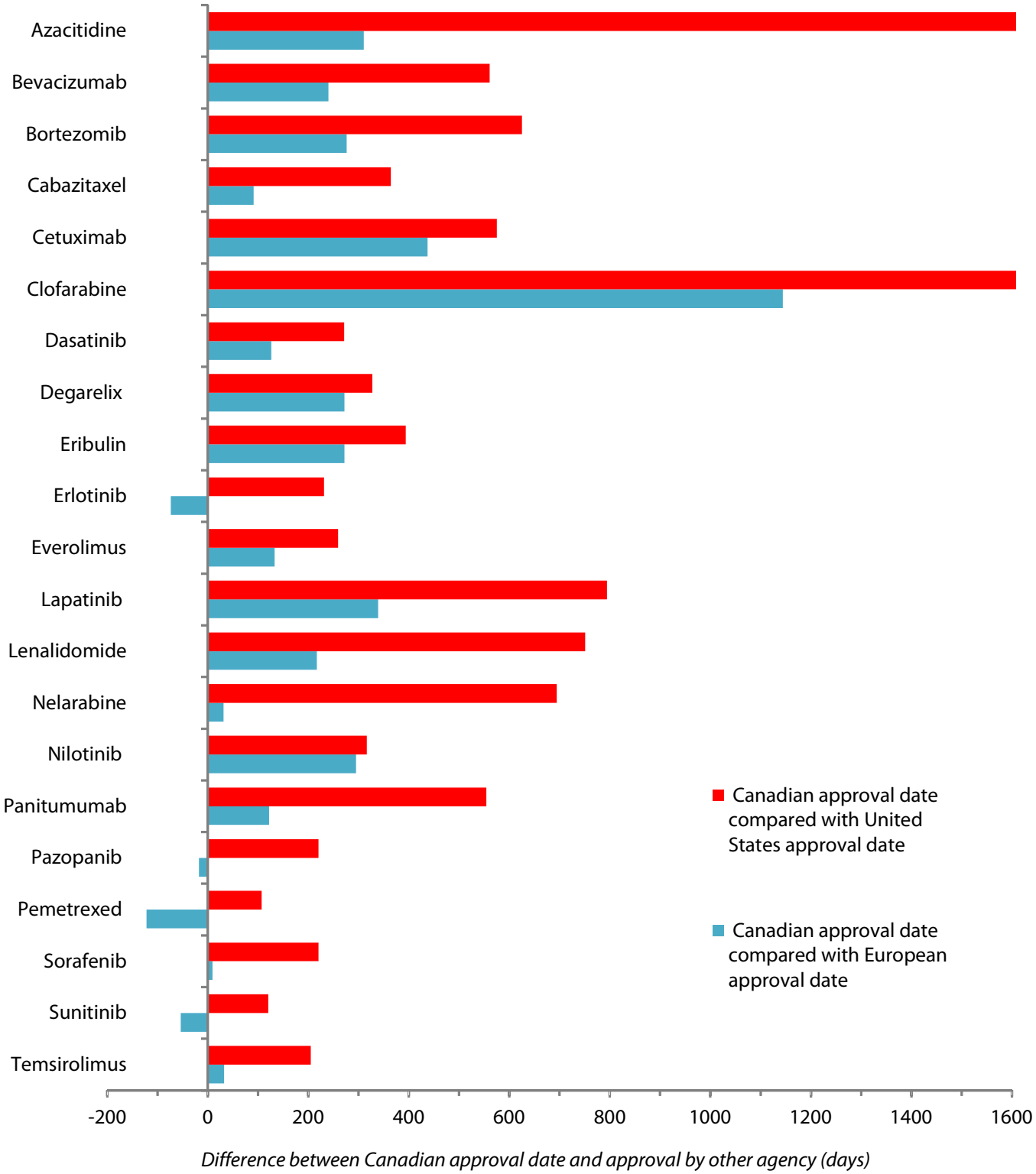
Discussion

Even allowing for the inclusion of drugs approved in Canada in 2011, considerably fewer new oncology products were approved in this country in the last decade than in the US. Moreover, the review times for oncology drugs approved in Canada since 2005 are longer than in the United States by a substantial period and show no evidence of improving in the most recent years. For over 40% of the drugs reviewed in Canada, it took 180 days longer (or more) to complete the review than it did for the same drugs in the US. The analysis is necessarily limited by the fact that no account was taken of time when the regulatory clock stopped. The objective of the analysis was to evaluate the overall time from submission to approval and differences between the timing of marketing authorization in the three jurisdictions.

Submission dates in Canada were within 90 days of those in Europe and the United States for about a third and half, respectively, of the 21 oncology drugs approved by all three agencies. However, due to the longer review times, Canadian approval dates were more than 180 days after those in Europe and the United States for 48% and 90% of the drugs, respectively. These results raise the question as to why the international collaboration reported by Health Canada (2011b) is not leading to review times in Canada that are more comparable with the United States and Europe. Health Canada's response to the Auditor General's recent recommendation that the agency "should ensure that it meets service standards for the review of all drug submission types" (70% of new drug submissions meet the target) provides an answer—Health Canada only began to pilot the use of foreign reviews in late 2011 (Auditor General of Canada, 2011).

Both the United States and Canada have regulations to facilitate timely access to new medications of potential clinical significance, but the FDA has more than one way in which applications can be expedited (Rawson, 2005) and there is a proposal for yet another method (Pecquet, 2012). Health Canada has a priority review system in which the criteria are close to those for a priority review in the United States, although to obtain this status, the manufacturer must submit an application to the agency. The drugs in this analysis are indicated for common cancers for which the numbers of new cases per year over the past 20 years have shown little reduction and that continue to have significant mortality rates (CCS, 2012). However, only a third of the drugs approved in Canada received a priority review compared with 80% of the drugs that were expedited in the United States. Reports that outline the information submitted to Health Canada and the review and decision process (Summary Basis of Decision [SBD] reports) are available for 23 of the 24 drugs approved in this country. These show that applications for priority status were

Figure 2: Comparison of Canadian approval dates with US and European approval dates for the 21 drugs approved by all three agencies



Sources: Roberts et al, 2011; Health Canada, 2010; Health Canada, 2011a

also made for everolimus and nelarabine but were denied, and none was made for the remainder (Health Canada, 2012). While the grounds for acceptance of a priority review application are available in the SBD reports (most commonly a potential benefit over existing therapy for a condition not adequately managed), those for rejection are not.

Considerably fewer oncology drugs were approved in this country in the last decade than in the United States. Further, slower review times in Canada led to delays in access to those that were approved.

Regardless of the reasons for expedition of the reviews of some products, the fact remains that expedited products in the United States had a median review time of six months, whereas the Canadian priority review drugs had a median approval time of close to a year. Greater transparency in the Canadian system might allow a better understanding of the reasons why the priority review times were longer than in the United States (Health Canada, 2011b; Lexchin and Mintzes, 2004). For instance, Health Canada could be required to monitor approvals in the United States and Europe and, if a drug is not approved in Canada within a set number of days (eg., 90 days) of the later of the American or European approval dates, to report to Parliament on the situation with regard to the drug in this country.

Another concern is that marketing approval by a drug regulatory agency allows a product to be sold, but it does not guarantee patient access to it. Many new oncology drugs are expensive (CCS, 2009) and, without private or government insurance, many patients may be unable to afford them. Information on private and government insurance coverage is incomplete; only five provinces (British Columbia, Alberta, Saskatchewan, Ontario, and Nova Scotia) have their oncology drug formularies on line, raising further issues about the lack of transparency in the Canadian health system. Drugcoverage.ca (2012) provides information on government coverage and indicates whether a drug may be covered by private insurance schemes, but since manufacturers pay to have the information on the web site, the comprehensiveness, accuracy, and timeliness of the information are unknown. Nevertheless, the web site indicates that just three (13%) of the 24 drugs approved in Canada (bortezomib, dasatinib, and sunitinib) by the end of 2011 were covered to some degree by government insurance in all 10 provinces by the end of March 2012. Seven (29%) other drugs had government coverage in some provinces (pemetrexed [8 provinces], nilotinib [7], panitumumab [7], lapatanib [6], cetuximab [5], pazopanib [6] and temsirolimus [6]) raising issues of inequity (CCS, 2009; Stanbrook et al., 2011). Most importantly, for a country that prides itself on having a universal health care system, almost 60% (14) of the drugs had no government coverage in any province at the end of 2011.

Conclusion

Considerably fewer oncology drugs were approved in this country in the last decade than in the United States. Further, slower review times (irrespective of whether the review was expedited) in Canada led to delays in access to those that were approved. For over 40% of the drugs, Canadian marketing approval was more than 18 months after that in the United States. This finding, combined with the fact that only three of 24 new oncology drugs approved in Canada between 2003 and 2011 have some degree of government insurance coverage in all provinces, raises concern for Canadian cancer patients. It also raises questions as to why review times are longer in Canada than in the US or Europe and whether the drug evaluation system in this country is beneficial or detrimental to Canadians with cancer. This concern may resolve itself with Health Canada's use of foreign reviews, starting with its pilot program in 2011 (Auditor General of Canada, 2011), but progress must be monitored, as must the availability to all Canadians, irrespective of where they live, of medications that have been approved by Health Canada.

Methodology

Data on the review times of the initial submissions of 35 new

oncology drugs approved in the United States or the European Community between 2003 and 2010 came from Roberts et al. (2011), who obtained the information from publicly available databases on the web sites of the relevant regulatory agencies: the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). Two drugs used in cancer patients to counteract adverse effects of oncology therapy were excluded, leaving 33 in this analysis. The information from Roberts et al. (2011) was correlated with data from the web sites of the FDA and EMA to check for updates.

For drugs approved in the United States, the FDA review time was calculated as the difference in days between the submission date of the first New Drug Application or Biologics License Application and the date of the FDA's final marketing approval. In the European Community, two steps are necessary before a drug can be marketed. First, a positive opinion for marketing authorization from the EMA's Committee for Medicinal Products for Human Use (CHMP) is required and, second, the CHMP's opinion must be formally adopted by the European Commission. While the number of days between the date of the first Marketing Authorization Application (MAA) to the EMA and the date of the CHMP's positive opinion is the technical review period, the number of days between the MAA and the adoption of the CHMP's opinion by the European Commission (EC approval time) is the appropriate measure with which to compare the time taken to review and approve a drug in other countries.

In Canada, a medication can only be marketed after Health Canada has reviewed the manufacturer's submission and given the drug a Notice of Compliance (NOC) (Rawson, 2003). The date of the NOC is available from a publicly accessible database on Health Canada's web site (Health Canada, 2010). The date of the submission is available from the relevant Health Canada annual performance report. These reports were accessible on the agency's web site until 2007, after which they could only be obtained by request (Health Canada, 2011a); information for 2008-2010 was procured via a data request. For each drug approved in Canada, the Health Canada review time was calculated as the number of days between the submission and NOC dates.

Since Canada has previously been shown to have slower review times in general (Rawson, 2000, 2003; Rawson and Kaitin, 2000, 2003; Rawson et al., 1998; Rovere and Skinner, 2012), the Health Canada web site was searched for any approvals of the 33 oncology drugs in 2011. The same search was performed on the EMA web site. Data for drugs found were included in the analysis.

The calculation of the approval times for all three agencies made no attempt to measure and separate out any period in which the regulatory clock was stopped, for example, while the agency was waiting for the manufacturer to respond to a request for further information. There were two reasons for this approach: (1) information on clock-stopping was not available for all of the agencies and, (2) more importantly, the objective was to compare overall review times between submission and marketing approval.

The numbers of oncology drugs approved in the United States, Europe, and Canada were evaluated and overall review times compared using the median number of days (the number of days within which half the drugs were approved) and the range of review times as the principal summary statistics, although the average number of days is also reported for comparison. In addition, median review times were recalculated for the United States and Europe when limited only to those drugs approved in Canada. A comparison of the oncology drugs given an "expedited review" in Canada or the United States was also performed. Canada has only one process to expedite the review of a new drug known as "priority status," whereas the United States has three (priority, accelerated, and fast track reviews (Rawson, 2005)), all of which were considered simply as one category (expedited) for the purpose of this study.

For the drugs approved by all three agencies by the end of 2011, review times were compared and the relationship between Canadian submission and approval dates and those in the United States and Europe for these products was assessed.

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