Benefit of expedited regulatory approval for oncology drugs eliminated by slow reimbursement reviews and price negotiations

Description

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Nigel S B Rawson and David J Stewart

ABSTRACT

Summary: In an examination of 92 oncology drugs that received regulatory approval from Health Canada with a Notice of Compliance with conditions (NOC/c) since the policy was introduced in 1998 through to December 1, 2021, the authors concluded the “NOC/c policy has been successful in providing expedited access to promising therapies.” We investigated the time required by Canada’s Drug Agency (CDA) to complete reimbursement reviews and the pan-Canadian Pharmaceutical Alliance (pCPA) to perform price negotiations with manufacturers for 66 of the 92 drugs that were likely to have been eligible for review and negotiation. Twelve of the 66 drugs had no submission to CDA; potential reasons were identified for six. In the other 54 drugs, 37 (68.5%) had a positive CDA review and 17 (31.5%) a negative review. Only seven reviews (13.0%) took less than CDA’s claimed “typical timeline” of 180 days or less, while almost three-quarters were within its 270-day target. The pCPA’s targets of 40 business days (60 calendar days) for deciding whether to negotiate and 90 business days (130 calendar days) for completion of negotiations were achieved for only 37% of the recommendations and 41% of the negotiations. The resulting delays led to the time between NOC/c and final pCPA outcome being close to two years for over 50% of the drugs and almost three years for a quarter of them. This delay is compounded by government drug plans taking further lengthy time periods to decide whether to fund the drugs. The potential benefit to patient access of an expedited regulatory review resulting in an NOC/c is eliminated when unnecessarily extensive delays occur in reimbursement review and price negotiation processes established by government drug plans.

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