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Is time to access novel cancer therapies in Asia accelerating? A preliminary investigation

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OBJECTIVES

Cancer burden in Asia is high and recent initiatives in Asian markets aim to accelerate patient access to novel cancer therapies.

In this pilot study, regulatory and reimbursement timescales in China, Taiwan, South Korea, and Japan in two major oncology indications were assessed to understand how policy reforms impact patient access.

METHODS

FDA-approved therapies for relapsed/refractory multiple myeloma (RRMM) and non-small cell lung cancer (NSCLC) were identified; 6 approved pre-2015, 8 in 2015-16, and 2 in 2018 were selected.

Time from FDA to local market-specific regulatory approval, and subsequent time to local reimbursement (automatic, fixed timeframe for Japan) were calculated from national stakeholders' websites to March 31, 2020.

RESULTS

Time from FDA to local regulatory approval was consistently shorter for therapies approved in 2015 or later (compared with pre-2015), most noticeably for Japan.

Additionally, time from local regulatory approval to reimbursement had shortened for China and South Korea.

Of the 8 2015-16 FDA approvals, the proportion with secured local regulatory approval varied (China: 50%, Japan: 88%, South Korea and Taiwan: 100%), along with median time from FDA to local regulatory approval (median 8, 10, 13, and 29 months in Taiwan, Japan, South Korea, and China, respectively).

For these 8 FDA approvals, the proportion with positive reimbursement decisions also differed (China: 25%, Taiwan: 63%, South Korea and Japan: 88%).

Both 2018 FDA-approved therapies had secured local regulatory approval in Japan and China in shorter timeframes (median 4 and 12 months after FDA approvals, respectively); neither were yet in the Chinese NRDL. In Taiwan and South Korea, one of the two medicines obtained local regulatory approval; neither were yet reimbursed.

CONCLUSIONS

There are early signs of change in the timescales for access to cancer therapies in Asia.

These findings should be explored in a larger study to better understand the impact of policy reforms on patient access.

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