

New cancer drugs approved faster in U.S. than Europe

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New oncology therapies generally are approved more quickly in the



United States than in Europe, according to a study published online June 10 in *JAMA Network Open*.

Mark P. Lythgoe, M.B.B.S., from Imperial College London, and colleagues analyzed differences in approval timings and review speed between new cancer therapy approvals by the U.S. Food and Drug Administration and the European Medicines Agency (EMA). Analysis included 89 new oncology therapies approved by both the FDA and the EMA from 2010 to 2019.

The researchers found that the FDA approved 85 oncology therapies (95 percent) before European authorization and four therapies after. In Europe, the median delay in market authorization for new oncology therapies was 241 days. For the FDA, the median review time was 200 days, compared to 426 days for the EMA. More new licensing applications were submitted to the FDA first versus the EMA (64 versus 21). Prior to pivotal study publication, the FDA approved 35 oncology therapies, compared to eight approved by the EMA.

"The past decade has seen record numbers of new oncology therapy authorizations in the U.S. and Europe," the authors write. "It is critical that medicine regulators undertake rigorous scientific review of all new therapies to ensure efficacy, safety, and <u>public confidence</u> in cancer medicines."

Several authors disclosed financial ties to pharmaceutical companies.

More information: <u>Abstract/Full Text</u> <u>Editorial</u>

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