

19 September 2019

Half of Cancer Drug Approvals Rely on Results of Potentially Biased Clinical Trials

New research raises questions about credibility of evidence supporting approvals of new medicines

AMSTERDAM—A new paper published today in [The BMJ](#) raises serious questions about the credibility and strength of the evidence that the European Medicines Agency (EMA) uses to approve new cancer medicines.

Researchers found that, between 2014 and 2016, half (16 of 32) of EMA's cancer drug approvals relied on trials that were deemed to be at high risk of bias in their design, conduct or analysis. EMA's Committee for Medicinal Products for Human Use (CHMP) identified other concerns for seven of the 16 cancer drugs that had at least one Randomised Controlled Trials (RCT) at low risk of bias.

The paper by top researchers at some of the world's leading Universities, including London School of Economics (LSE), King's College London, University of Bristol, and Queen's University, is the latest in a growing body studies and articles that point to the often dubious added-therapeutic and economic value of many new cancer drugs being brought to the market.

Lead author of the study, Dr Huseyin Naci, Assistant Professor of Health Policy at LSE, said:

"The validity of the available evidence on new cancer drugs is a pre-requisite for shared decision-making in clinical practice. Currently, patients and clinicians have limited information to gauge the validity of the clinical studies that form the basis of cancer drug approvals. We recommend devising and testing novel strategies for collating and communicating information about the validity of clinical studies in the future."

Dr Christopher Booth, Professor of Oncology at Queen's University at Kingston, and the senior author the study, said:

"There are fundamental concerns in the current era of cancer drug development. This study adds another layer of complexity for patients and clinicians by identifying bias which may influence the analysis and interpretation of RCTs. The oncology community needs to reconsider how we test new cancer agents and strive to identify therapies that are associated with meaningful gains in survival and quality of life."

Jaume Vidal, Senior Policy Advisor at Health Action International, who partly funded the study, called for regulatory authorities, particularly the EMA, to take notice and act on the findings:

"This paper highlights short-comings within the regulatory system. It also adds to previous evidence showing many newly marketed medicines bring negligible or non-existent improvements to survival rates and quality of life for patients, while becoming ever-more unaffordable to already stretched health systems. Regulators must take on the findings to help ensure new medicines on the market are there for the benefit of the patient and society and not pharmaceutical companies and shareholders"

Cancer drugs make-up the single largest category of new medicine approvals in Europe, making action to tackle bias in clinical trials absolutely essential.

- END -

NOTES TO EDITORS

- **Paper title:** *Design characteristics, risk of bias, and reporting of randomised controlled trials supporting European Medicines Agency approvals of cancer drugs, 2014-2016: Cross-sectional analysis*
- **Public link to paper:** <https://www.bmj.com/content/366/bmj.l5221>
- **Public link to accompanying editorial:** <https://www.bmj.com/content/366/bmj.l5399>

For interview requests and further information, please contact:

Alex Lawrence | Communications Manager | Health Action International
T: +31 20 412 4523 | M: +31 6 1832 1612 | alex@haiweb.org

[Health Action International](#) is an independent non-profit organisation. We advance policies that enable access to medicines & rational medicine use through research & advocacy. At Health Action International, we're driven by our vision of a world with safe, effective, affordable and quality-assured medicines for everyone, everywhere. To make this a reality, our staff and global network conduct research and advocacy to advance policies that enable access to medicines and rational medicines use for all people around the world.

