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LETTERS

APPROVAL OF CANCER DRUGS

EMA and FDA decisions based on flawed evidence to approve new cancer drugs negatively affect Latin American patients

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A recent editorial[1] by Mintzes and colleagues warns about using flawed clinical trials to approve new cancer drugs in Europe[2] and the US.[3] The implications go further, however: during the past decade, several Latin American countries have adopted regulations that abbreviate the approval process of new drugs in the case of earlier approval by the European Medicines Agency (EMA) or the US Food and Drug Administration (FDA).

Between 2012 and 2017 the Mexican regulator approved, through an accelerated procedure, 310 new drugs already authorised by the FDA, EMA, and Australian, Canadian, and Swiss regulators.[4] In 2011 Ecuador launched a standardisation process of marketing authorisation. Current regulation establishes standardisation with the FDA, EMA, and several other national regulators. In 2016 Argentina authorised 15 new drugs through a similar process; only four showed some added therapeutic value.[5]

Furthermore, the EMA and FDA implemented regulations to shorten the marketing authorisation process of certain drugs. Under these programmes, drugs are authorised on the basis of phase II trials, single arm trials, and surrogate end points.[6] Consequently, whenever a drug is authorised by the EMA or FDA through an accelerated process, it can be quickly registered in several Latin American countries. Studies have shown that most cancer drugs that initially show positive results on surrogate outcomes later have disappointing results on overall survival.[7 3] Latin American regulators are seldom able to react, for example by revoking the authorisation when new evidence emerges. This leads to other problems that can result in financial risks to their healthcare systems, such as lawsuits and increased pressure to reimburse the drug or include it on public procurement lists.

We join the call to raise the bar for the approval of new cancer drugs.[1 8] The EMA, FDA, and other international regulatory authorities must think globally to protect patients worldwide.

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Full response at: www.bmj.com/content/366/bmj.l5399/rr-0.

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