Regulating new drugs in India needs to be improved

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The results and conclusions of the study by Koya and colleagues on antibiotic consumption in India in 2019[1] have important implications for policy makers in the country, which I hope they will heed. I would though like to draw attention to some of the statements in the paper (which are not linked to the results or conclusions), and to new rules introduced in 2019, in the interests of clarity, accuracy and understanding.

The authors rightly point out that drug regulatory responsibilities in the country are divided between the national regulator, the Central Drugs Standards Control Organization (CDSCO), and the states. In the introduction, they state that "[t]his means each Indian state can provide market approval even without CDSCO approval", and in the discussion section, they state "More than 90% of macrolides and 61% of cephalosporins are sold in the market without the approval of the central agency. These products are permitted by the state government agencies that have limited technical capacity to decide on the merit of approval."[1]

Unfortunately, these statements are problematic and might cause confusion, for three reasons. First, the state regulators do not give market approvals or permissions, but they issue licences for manufacture, distribution, and sale.[2] It is the function of CDSCO to give prior permission for marketing, before a state can give a manufacturing licence.[3,4] Second, the need for CDSCO's approval applies to 'new drugs' as defined in the legislation. The third reason is perhaps the most important, or at least has been. Until March 2019, demonstrating safety and effectiveness was legally required for central approval, and thus for 'new drugs'; it was not legally required for state licences. The authors quite rightly note the limited technical capacity of the states, but that is beside the point here, because they have never had the legal duty to assess safety and effectiveness before granting licences. It is well known that states have granted numerous licences for 'new drugs' without the prior approval of CDSCO and therefore without evaluation of safety and effectiveness. As well as posing a threat to public health, this is unlawful, and was so since 1961. These details were fully explained in a legal analysis which was published in 2015 as supporting information to a paper referenced by the authors.[5] However, the New Drugs and Clinical Trials Rules 2019 introduced new rules to govern central approval and declared the previous rules–including the safety and effectiveness requirement–to be no longer applicable. As a result, the threshold standard for new drug approvals is now unspecified and unclear, which is both extremely worrying and unsatisfactory.

The authors also write in the discussion section, referencing the report of the Kokate Committee which was dated April 16, 2015, that "[i]n 2015, the national government had banned 16 unapproved systemic antibiotics FDCs that accounted for 14% of antibiotic FDC sales following the Kokate Committee recommendations." The government bans which followed the recommendations of the Kokate Committee were issued on March 10, 2016,[6] after a further report of the committee dated Feb 10, 2016.[7] It might also have been illuminating if the source data for the number banned and market share had been referenced. (In the event, the bans in March 2016 were immediately suspended by the Delhi High Court, and in December 2017 the Supreme Court remitted the matter for further assessment by a committee of the Drugs Technical Advisory Board,[8] which reported in July 2018[9] and which was followed by fresh government bans in September 2018.[10])

Contributors

PR conceptualised and wrote the paper.

Declaration of interests

None.

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