

Many fixed-dose drug combinations in India lack central regulatory approval

May 12 2015



Various pills. Credit: Wikipedia

Fixed-dose drug combinations (FDCs) which have not received central regulatory approval are sold in substantial numbers in India—despite concerns over the safety and efficacy of these combinations—according to new research led by Queen Mary University of London and published in *PLOS Medicine*.

FDCs include two or more [active pharmaceutical ingredients](#) combined in a single dosage form. They are used as effective treatments for many conditions, including Parkinson's disease, HIV, malaria and tuberculosis.

In 2012 however, a committee of the Parliament of India reported a very large number of FDCs had been licensed by state drug authorities

without approval by CDSCO (the Indian central drug licensing agency) - meaning they haven't been thoroughly examined or tested and could put patients' lives at risk.

Dr Patricia McGettigan, who led the study at Queen Mary University of London, comments: "In the interests of its patients, India needs to ban the sale and manufacturing of fixed-dose [drug combinations](#) not approved by the CDSCO - beginning with those which include drugs banned or unapproved internationally, and therefore most likely to be harmful.

"The wellbeing of patients is paramount. People taking these FDCs need to be reviewed and carefully switched to safe and appropriate alternatives."

This study provides specific evidence in support of the 2012 committee report. Using information from CDSCO on FDC formulations approved between 1961 and 2013, and FDC sales data between 2007 and 2012 from PharmaTrac (a database of drug sales in India), the researchers analysed approval status and sales volumes of FDCs in four therapeutic areas:

- Formulations containing a non-steroidal anti-inflammatory drug (NSAIDs, for pain relief)
- Formulations containing metformin (for diabetes)
- Formulations containing an anti-depressant or a benzodiazepine or both (for depression/anxiety)
- Formulations containing an anti-psychotic drug

Among these therapeutic areas, of 175 FDC formulations marketed in India between 2011 - 2012, the researchers found CDSCO approval for only 60 (34% per cent). Whilst almost all metformin FDC sales were from CDSCO-approved formulations, products with no record of

CDSCO approval accounted for over two-thirds of anti-depressant/benzodiazepine FDC sales (69%), almost half of anti-psychotic FDC sales (43%), and more than a quarter of NSAID FDC sales (28%).

Multiple formulations included drugs which are restricted, banned, or were never approved in other countries because of associations with serious adverse events including death.

Professor Allyson Pollock, Global Health expert and co-author at Queen Mary University of London, added: "The development of fixed-dose combination drugs is becoming increasingly important from a public health perspective and they are commonly used to manage some of the world's most infectious diseases. Benefits such as cost-effectiveness, simple distribution logistics and improved patient adherence all add to their importance.

"However - these benefits are completely negated when potentially dangerous and unregulated drug combinations are used and given to patients. India needs to build a rigorous foundation for putting safety, effectiveness, rationality and need at the heart of the country's drug regulatory system. Our research wholly supports the need for a complete overhaul of the new Drugs Bill and we urge the government of India to make this a priority."

More information: McGettigan P, Roderick P, Mahajan R, Kadam A, Pollock AM (2015) Use of Fixed Dose Combination (FDC) Drugs in India: Central Regulatory Approval and Sales of FDCs Containing Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Metformin, or Psychotropic Drugs. *PLoS Med* 12(5): e1001826. doi:10.1371/journal.pmed.1001826 . journals.plos.org/plosmedicine...journal.pmed.1001826

Provided by Queen Mary, University of London

Citation: Many fixed-dose drug combinations in India lack central regulatory approval (2015, May 12) retrieved 19 April 2024 from <https://medicalxpress.com/news/2015-05-fixed-dose-drug-combinations-india-lack.html>

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