Unregulated 'innovation': India's medicine problem

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If India is the pharmacy of the world, it's not doing a good job of providing safe products. A large number of children in the Gambia have recently died after ingesting cough syrup made in India. And in 2019, 11

children in India's Jammu region died the same way. The cough medicine contained diethylene glycol, an industrial solvent.

Counterfeit and sub-standard medicines are only one of several problems India and the rest of the world face because of the country's weak drug regulations.

A pressing problem is an explosion in the consumption of antibiotics in India where overuse and misuse are major contributors to the development of antibiotic resistance. India has one of the highest antibiotic resistance rates, estimated to be growing by 5%-10% annually. About 1.3 million people died in 2019 as a direct result of antibiotic resistance.

Particularly worrying is the large number of antibiotics being consumed in the form of fixed-dose combinations (FDCs). These products comprise two or more drugs in a fixed ratio of doses and are available in a single dosage form.

FDCs are effective for some diseases, such as tuberculosis and HIV treatments. But many antibiotic FDCs sold in India are of unknown effectiveness and have not been approved by India's central drug regulator, the Central Drugs Standard Control Organisation.

Unapproved and potentially inappropriate FDCs are a peculiar feature of the Indian landscape. The companies claim that FDCs are innovative, that combining different medicines in one pill is more convenient for patients and ensures compliance.

However, without clinical trials to show their safety and effectiveness, the risks and benefits of these innovative FDCs are unknown. This unregulated "innovation" is an immense problem because of its potential to accelerate antibiotic resistance.

The World Health Organization is so concerned about the problem that it has classified antibiotics according to their impact on antibiotic resistance and listed antibiotic FDCs that it advises doctors not to prescribe.

The Indian government has a national action plan on antibiotic resistance and has introduced several government initiatives to tackle sales of FDCs that have not been approved by the central regulator. It also has a national list of essential medicines to promote rational prescribing and prioritize medicines for use. These initiatives go back decades. However, the problem of unapproved and unsafe medicines persists.

Most medicines consumed in India are bought in the private sector. Our latest research into the sales of antibiotics (those taken orally, intravenously or in the form of injection) in the private sector in India in 2020, showed that a third are in the form of FDCs. We found that these sales are driven in large part by drugs the WHO has listed as not recommended and are not on the country's essential medicines list. Focusing prescribing on well-evidenced FDCs, such as those listed on the essential medicines list, would strengthen antibiotic stewardship in India.

We also found that 278 of 395 (about 70%) antibiotic FDC formulations marketed in India in 2020 had either no record of approval by the central regulator or were banned. These findings demonstrate the need for a radical overhaul of drug regulation in India.

Complex laws

A big part of the problem is the complexity of the much-amended drug laws that date back to 1940 and split responsibilities between the federal and state governments.

The center has the responsibility for overseeing the safety and effectiveness of new drugs while the states grant licenses to manufacturers. However, the states have been granting licenses to manufacturers for FDCs that have not had the necessary prior approval of the central regulator.

Unless India introduces laws to ensure that all FDCs are approved centrally having met the requirements of safety and effectiveness, ensures that unapproved drugs are taken off the market, and prosecutes manufacturers who break the law, the problems of unapproved and unsafe medicines and growing antibiotic resistance will not be solved. Urgent legislation and strict enforcement of the rules are needed to ensure that there is global confidence in India's drug manufacturers.

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