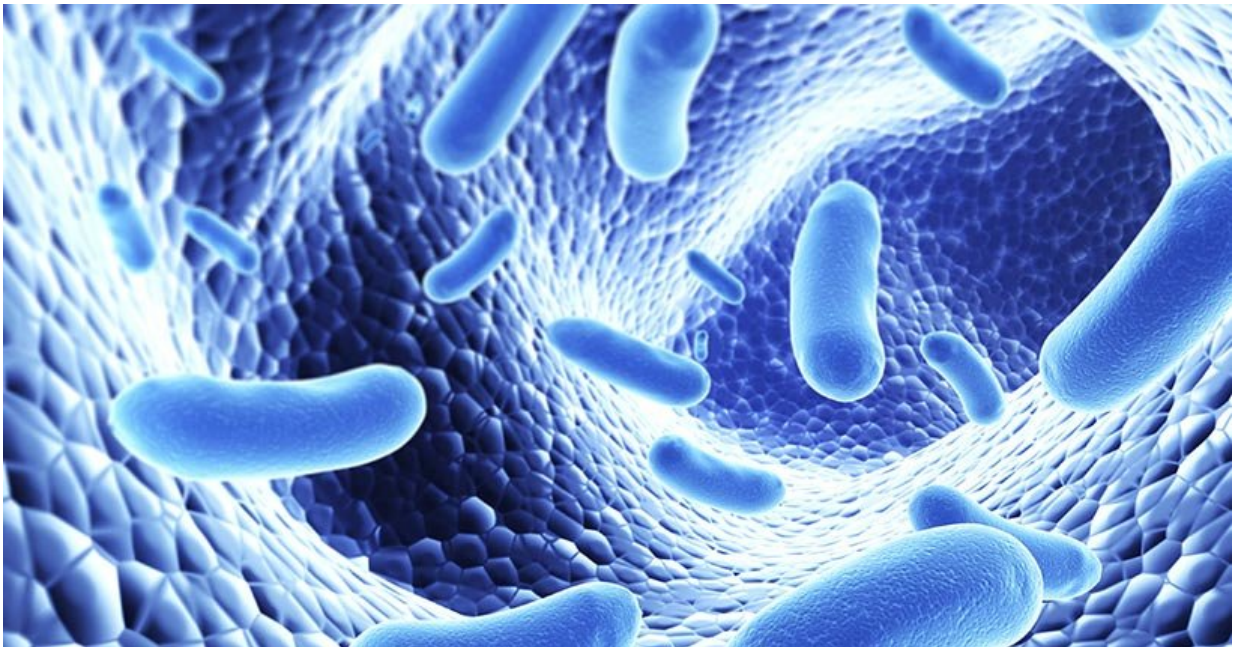


Tackling the rising sale of unapproved antibiotics in India

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Credit: Newcastle University

Indian government needs to do more to tackle rising sale of unapproved antibiotics, according to an analysis by researchers at Newcastle University and Queen Mary University of London.

In India, the sale of [antibiotics](#) requiring the tightest control and regulation is rising the fastest, warn the researchers. The correspondence published in *The Lancet Global Health* highlights serious hurdles for

controlling [antimicrobial resistance](#) in the country.

In June 2017, the World Health Organization (WHO) adopted a new classification for antibiotics, to combat rising antimicrobial resistance and preserve the effectiveness of antibiotics that are a 'last resort'.

The new model comprised three categories: 'Key Access' antibiotics that should be widely available, 'Watch Group' that includes critically important antimicrobials which should only be used for certain infections, and 'Reserve Group' antibiotics for severe circumstances when all alternatives have failed.

Ensuring rational medicine prescribing and use

Professor Allyson Pollock, Director of the Institute of Health and Society at Newcastle University, said: "In India, rational use of antibiotics is imperative to limit antimicrobial resistance. It is of concern that [sales](#) of irrational and unsafe combinations are increasing and many have never been approved by the government. There are many calls from within the country for a new medicines Act and effective implementation of regulation to ensure rational medicine prescribing and use."

Dr Patricia McGettigan from Queen Mary University of London said: "In India, total sales of antibiotics are increasing, and for the antibiotics that require the most careful control and regulation, their sales are increasing at the fastest rate. The increases are driven by sales of fixed dose formulations, many of them indiscriminately combining two antibiotics together. Even worse, most of these formulations were never approved by India's national drugs regulator so their sale is illegal. The government has done nothing effective to stop the sales."

India is a major [drug](#) producer with some of the highest sales of

antibiotics globally and the highest levels of antimicrobial resistance. Contributing factors include failures of India's drug regulatory system which have been identified in government reports, the sale of antibiotics without prescription, and the use of fixed-dose combination (FDC) antibiotics - formulations composed of two or more drugs in a single pill.

Scale of the problem

The team analysed antibiotic sales in India between 2007 and 2012, and found that total antibiotic sales increased by 26 per cent, with the increase mainly due to the growth in sales of FDCs, which rose by 38 per cent. By 2011–12, FDCs comprised a third of total sales in India.

When taking into account the new WHO categories, sales of FDCs with Key Access antibiotics had risen by 20 per cent in five years, but those with Watch Group or Reserve Group antibiotics had risen more steeply, by 73 per cent and 174 per cent, respectively.

Of 118 different formulations of FDCs being sold, only 43 were approved by India's national regulator, the Central Drugs Standard Control Organization (CDSCO), even though the sale of unapproved new medicines is illegal in India. Only five of the formulations were approved in the UK or US.

Looking at single drug formulations (SDFs) which are composed of a single drug on its own, the majority (58 per cent) of the 2011-12 sales were either Watch Group or Reserve Group antibiotics. Over five years, sales of Key Access antibiotics had risen by 13 per cent, Watch Group by 24 per cent, and Reserve Group by 69 per cent. Unlike FDCs, most of the 86 SDFs on the market in India were approved by the national regulator and were also approved in the UK and US.

Good use of antibiotics

The researchers say that the changes needed to achieve the WHO vision of good use of antibiotics include banning the sale of unapproved FDC antibiotics and enforcing existing regulations to prevent unapproved and illegal drugs reaching the market.

Improved access to health care to reduce non-prescription sales is also needed, alongside research to understand why doctors complicate problems by prescribing unapproved antibiotics.

Provided by Newcastle University

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