



# Clinical Trials of Antibiotics on Children

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Central Licensing Authority i.e. Drugs Controller General (India) has given approval for conduct of various clinical trials of Antibiotics on children under one year of age. During the last three years, such clinical trials approved were mainly related to trials in Multi Drug Resistant Tuberculosis (MDRTB) and Tuberculosis Meningitis in children. The details of the clinical trials are registered in Clinical Trial Registry of India (CTRI), which is publicly available ([www.ctri.nic.in](http://www.ctri.nic.in)).

Antibiotic use is a major driver of resistance. Neonates are more prone to infections and vulnerable to ineffective treatment. Sepsis remains a leading cause of mortality and morbidity, especially during the first five days of life and in low and middle-income countries (LMIC).

Antibiotics are included in Schedule H and H1 to the Drugs & Cosmetics Rules, 1945, and, therefore, cannot be sold in retail except on and in accordance with the prescription of a Registered Medical Practitioner.

Indian Council of Medical Research (ICMR) has launched a programme on Antimicrobial Stewardship, Prevention of Infection and Control (ASPIC) in 2012. Functional infection control programmes not only cut down the rates of nosocomial infections, but also reduce the volume of antibiotic consumption and are a critical part of any comprehensive strategy to contain antimicrobial resistance (AMR). Further, a red line campaign has been launched to regulate over the counter sale of Schedule H antibiotics. The campaign is aimed at discouraging unnecessary prescription and over-the-counter sale of antibiotics causing drug resistance for several critical diseases including TB, malaria, urinary tract infection and even HIV.

The Ministry of Health & Family Welfare has also launched a programme named 'National Programme on Containment of Antimicrobial Resistance' to address the problem of growing AMR.

The Minister of State (Health and Family Welfare), Sh Faggan Singh Kulaste stated this in a written reply in the Rajya Sabha here today.

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