



Revise antibiotics safety data, pharma cos told

CDSCO collects data

S Eswara Reddy, Drugs Controller General of India, said, under the Pharmacovigilance programme of India, the CDSCO collects adverse drug reactions reported from across 250 adverse drug reactions monitoring centres, majority of them located in various medical colleges

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THE Central Drugs Standard Control Organisation (CDSCO) has issued directions to manufacturers to revise safety data for various antibiotics based on the data from the Pharmacovigilance programme on India. Under the programme, the organisation collects adverse drug reactions reported from adverse drug reactions monitoring centres in the country, said S Eswara Reddy, Drugs Controller General of India, on Monday.

Speaking at the 29th convocation of Sri Ramachandra Institute of Higher Education and Research (SRIHER) here, Eswara Reddy said, "Under the Pharmacovigilance programme of India, the CDSCO collects adverse drug reactions reported from across 250 ad-



Dr S Eswara Reddy presenting gold medal and degree to a student at convocation of Sri Ramachandra Institute Of Higher Education And Research | MARTIN LOUIS

verse drug reactions monitoring centres, majority of these are located in various medical colleges. Due to a large patient pool, the CDSCO is able to generate robust and quality data which is further analysed for signals."

"Recently, we have issued directions to manufacturers to

revise safety data for various antibiotics based on the signals from the pharmacovigilance programme," Eswara Reddy said. Speaking about the regulations, he said, "Separate rules for regulation of medical devices have been put in place. The New Drugs and Clinical Trial Rules, 2019, which have

been notified very recently, will promote academic medical research, ensure time bound approvals for clinical trials among other features, etc. We are also looking to regulate the internet pharmacies in the coming future."

"Under new clinical trial rules announced, for clinical trials, approval will be given within 30 days," said Eswara Reddy. He also gave away 22 gold medals to meritorious students. Chancellor V R Venkataachalam conferred the degrees and distributed certificates to 452 graduates including Ph.D, Super Specialties, Post Graduate, MBBS, BDS and BPT. Pro Chancellor R V Sengutuvan presented certificates to students.

Vice Chancellor P V Vijayaraghavan said, from 2019-2020 academic year, SRIHER will offer new courses.