

59 new drug applications pending review at CDSCO

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Singapore: While there are 59 new drug application cases pending for approval in the Central Drugs Standard Organisation (CDSCO), the cases of approval for new drugs are close to 10 in number. Similarly, there are 04 cases of notified diagnostic kits that are pending for registration approval.

The details released by the regulator mention that the status of these cases, pending for the last four months, is under review currently.

The marketing authorization proposals of veterinary vaccines that are pending approval stand at 19 whereas there are 06 cases of human vaccines in various disease areas that are being reviewed.

The medical devices that are pending registration are 59 in number and those which require re-registration stand at 25.

The cases where query letters have been issued and reply has not yet been received from the applicant i.e. those applications which are pending at the applicants level are not included in the pending lists issued by the CDSCO.