

F. No. X-11026/71/2019-VD
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Veterinary Division)


FDA Bhawan, Kotla Road,
New Delhi-110002, India,
Dated:

02 DEC 2019

Notice

Various stakeholders of the Veterinary Products have raised concern regarding the clarification with respect to Pharmacovigilance reporting for veterinary products in India.

In this regard it is stated that as per the conditions for grant of approval/permission in Form 45 and Form 46 of the Drugs and Cosmetics Act, 1940 and rules thereunder, the applicant shall submit Periodic Safety Update Reports every six months for the first two years. For subsequent two years, the Periodic Safety Update Reports shall be submitted annually.


(Dr. K. Bangarurajan)
Joint Drugs Controller (India)