

F. No. X11026/114/15-BD
Directorate General of Health Services
O/o Drugs Controller General (I)
(Biological Division)
FDA Bhawan, Kotla Road, New Delhi

Dated: 04 OCT 2016

Sub: Drug safety label change of Rabies Vaccine (Human) marketed in India - regarding.

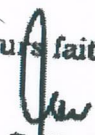
Ref: PvPI- Signal review Panel recommendations for the drug safety label change of Anti-Rabies Vaccine marketed in India.

Sir,

With reference to the subject cited above, it is to inform that Signal Review Panel (SRP) of Pharmacovigilance Programme of India (PvPI) concluded that there is a strong relationship between anti-rabies vaccine and Erythema Multiforme, based on spontaneously received Adverse Drug Reactions (ADRs) data and published literature. Hence, the SRP has recommended that Erythema Multiforme needs to be inserted in the drug safety label of Anti-Rabies vaccine, manufactured and imported in India.

Accordingly, all the manufacturers and importers of rabies vaccine are hereby directed to ensure that Erythema Multiforme is inserted in the drug safety label of the subject vaccine and also submit the revised Prescribing Information/Package Insert to this Directorate for further review and approval of the same.

Yours faithfully,


(Dr. G. N. Singh)
Drugs Controller General (India)

- To,
1. M/s. Bharat Biotech International Ltd, Genome Valley, Turka-pally (V), Shameerpet Mandal, Ranga Reddy District, Hyderabad
 2. M/s. Biomed Pvt. Ltd, C-96, B.S. Road, Industrial Ropad, Ghaziabad-201009
 3. M/s. Cadila Healthcare Ltd, Sarkhej/Bawala, NH No. 8-A, Moraiya, Sanand, Ahmedabad Gujarat.
 4. M/s. Chiron Behring, Plot No. 3502, Post Box No. 136, GIDC, Estate, Ankleshwar, Bharuch, Gujarat.
 5. M/s. Human Biological Institute, Rakshapuram, Gaachibowli, Hyderabad-500032
 6. M/s. Human Biological Institute, Kozhipannai, Pudumund, P.O. Udhagamandalam- 643 007
 7. M/s Human Biologicals Institute, Sy. No. 281-284 and 321, Karakapatla Village, Mulugu Mandal, Medak Dist - 502 281, Telangana State
 8. M/s. Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune- 411028
 9. M/s Pusan Bioresearch Enterprises, Unit 007, TAL: Turbhe (Thane-Zone 7) India
 10. M/s Kiran Agencies, B-3D, Prem Estate, Mazgaon, Mumbai - 400010
 11. M/s. Sun Pharmaceutical Ind. Ltd., Room No. 210, 2nd Floor, Acme Plaza, Opp. SangamCin. Andheri-Kurla Road, Andheri (E), Mumbai - 400059, India.
 12. M/s Sanofi Pasteur India Private Limited, 54/A Sir MathuradasVasanji Road, Andheri East, Mumbai- 400093
 13. M/s. Prosper Channel Life Science India Pvt. Ltd., B-244, Sector-7, Palam Extn. New Delhi-110045, India

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