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Government of India

Directorate General of Health Service

Central Drugs Standard Control Organization

(Pharmacovigilance Division)

FDA Bhavan, Kotla Rd. New Delhi- 110002.

Date: 27-09-2018

NOTICE

Sub: -- Draft Pharmacovigilance System Inspection Guideline ; -reg.

All stake holders' attentions are hereby invited to the requirements specified in Schedule-Y of Drugs and Cosmetics Rules 1945, envisaging the GSR notification No. 287(E) dated 08th March 2016. This gazetted notification emphasises that all Market Authorization Holders (MAH) i.e the companies holding Licences to manufacture and / or import of "Drugs" for an ultimate motive of marketing medicinal products in India , shall have an established Pharmacovigilance System for collection, processing and reporting of Adverse Drugs reactions (ADR) to the concerned Licencing authorities.

Reference is also invited to Section 28.2 of Schedule-M which mandates that companies holding manufacturing licences are supposed to submit forthwith the reports of serious adverse drug reactions resulting from the use of their drug products along with comments and documents to the concerned licensing authority. Similarly, it is also mandatory in Schedule-D (II) section 2.18 that the Importers of "Drugs" shall submit the detailed PMS study Report for their marketed drug products at the time of renewal application submission.

Therefore this office is currently in the process of examining the current status of PV-systems in companies who are manufacturing and / or importing Drug Products including pharmaceuticals, Phyto-pharmaceuticals, Human Vaccine, Blood products, rDNA technology derived drugs, stem cell therapeutics in the Indian market. Accordingly a comprehensive PV-Guideline has been drafted which will be finalized after deliberations with the stakeholders of such products. Accordingly a meeting of the stake holders was organized on the 24th September 2018 at 2.30 PM in the Conference hall, 5th floor FSSAI, FDA Bhavan, Kotla Road, New Delhi-110002. The meeting was attended by the representatives of Indian Drugs and Pharmaceutical association Forum, Pharmacovigilance Programme of India (IPC), Indian Society for Clinical Research, AEFI secretariat and many pharmaceutical companies. The subject guideline was completely presented, discussed in details with all participants during the meeting.

Now, with the approval of the competent authority, the said guideline is being placed on the official website for public view and further consideration. The stake holders' valuable comments, suggestion are hereby requested for further improvement and finally rolling out a fully functional document. All such feed-back will be acceptable till 31st October, 2018. Contact us at the E-mail: dci@nic.in and pharma.covig@cdsco.nic.in

27/9/2018

(Somnath Basu)

Assistant Drugs Controller (I)