

File No. PSUR/WHO/GBT/VIG/001/2022/8196358

Dated:

23/12/2022

NOTICE


Subject: Inspections/ Audits of Pharmacovigilance (PV) system of Importers and manufacturers of human Vaccine; -reg.

As per the 5th Schedule of NDCT Rules, 2019, the importer or Manufacturer of any new drug for sale and distribution shall have a Pharmacovigilance system in place for collecting, processing and forwarding the ADR reports to the Central Licensing Authority emerging from the use of the new drug imported or manufactured or marketed by the applicant in the country. The Pharmacovigilance system shall be managed by qualified and trained personnel and the Officer-In-Charge of collection and processing of data shall be a trained Pharmacist or Medical Officer in collection and analysis of Adverse Drug Reaction Reports (ADR).

Accordingly, you are required to maintain qualified trained personnel and Officer-In-Charge of collection, processing of data and furnishing of PSUR as per fifth schedule of NDCT Rules, 2019 as the same may be subject to inspection at any time for verification of compliance.

In this regard you are requested to furnish the following documents to this directorate at the earliest.

1. Summary of established pharmacovigilance system.
2. Name, email ID of Pharmacovigilance officer –in-charge (PvOI), Name address, contact, Email ID of the premises where PV system is established.
3. Self- Inspection report (if any)


(Dr. V. G. Somani)
Drugs Controller General (India)

To;

1. All the Manufacturers and importers of Human vaccines

Copy to;

1. QMS division, CDSCO(HQ)