Press Release

18th December 2017

Oviya MedSafe announces One Day Intensive Training & Certification Workshop for Pharmacovigilance Officers in Charge (PvOI) at Mumbai

The event will be held at Hotel Kohinoor Continental on Friday 12-Jan-2018

Oviya MedSafe, a global Pharmacovigilance consulting and Drug Safety services-providing organization based in India and the UK, has announced the conduct of a one-day intensive training & certification workshop exclusively for Pharmacovigilance Officers in Charge (PvOI) on **Friday 12th January 2018** at Hotel Kohinoor Continental, **Mumbai**.

The Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products was released by the Secretary, Ministry of Health and Family Welfare, Government of India, on 29-Sep-2017. It was developed by the National Coordination Centre of the Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission, in collaboration with the Central Drugs Standard Control Organization (CDSCO), in order to ensure smooth functioning of pharmacovigilance activities by the pharmaceutical industry, with an aim to establish and ensure an effective pharmacovigilance system at their site according to the recent amendment in the Drugs & Cosmetics Rules, 1945, Schedule Y vide Gazette Notification G.S.R. 287(E) published on 08-Mar-2016. This document, which is set to be effective from January 2018, mandates that one qualified and trained personnel should be authorized by the company management as PvOI with responsibilities for dealing with pharmacovigilance activities at the MAH's organization. This PvOI should be a medical officer or a pharmacist trained in the collection and analysis of ADR (Adverse Drug Reaction) reports.

The scope of the guidance document includes all drugs, biologics, radiopharmaceuticals and phytopharmaceutical products but excludes veterinary products and medical devices. For the purpose of this guidance document, the term MAH refers to the manufacturer or the importer of the drug who has a valid manufacturing or import license. Since each MAH has to identify a PvOI within a short time frame, a dire need for capacity-building has arisen. The role of the PvOI requires the PvOI nominee to have a 360-degree perspective of pharmacovigilance from the MAH's point of view, ranging from ensuring written procedures for the pharmacovigilance operations, the pharmacovigilance quality management system (QMS) and the ongoing internal training needs in pharmacovigilance. The PvOI is expected to reside in India and respond to queries of regulatory authorities whenever required. More importantly, the PvOI needs to exercise sufficient authority over the pharmacovigilance system in the MAH in order to promote, maintain and improve compliance. Therefore, it is mandatory for PvOI candidates to be well-versed in basic concepts of pharmacovigilance and the core activities to be performed by a MAH for compliance with the norms outlined by this Guidance Document.

While speaking to the media, **Dr J Vijay Venkatraman**, Managing Director & CEO of Oviya MedSafe, said “Oviya MedSafe has been active in the Indian pharmacovigilance compliance space since 2013 and therefore, we are already aware that the

pharmacovigilance expertise levels in Indian MAHs vary right from being regulatorily self-sufficient (typically in companies that market their products in regulated markets) to literally non-existent (often in companies that hold manufacturing licenses but seldom market their products even domestically). Nevertheless, the requirements for a PvOI, among all other pharmacovigilance obligations detailed in this document, will be applicable across all organizations that qualify to be MAHs. While Oviya MedSafe has an enviable track record of working with several clients to help them comply with their global pharmacovigilance obligations (including Indian) as an outsourced partner, we also realize that we should take ownership for building the capacities of our clients' staff, especially the PvOI nominees so that they could perform their roles in line with the expectations of them. Oviya MedSafe has decided to conduct this capacity-building activity for Indian MAHs with the wider motive of benefiting as many Indian MAHs as possible. In this context, we decided to announce our plan of conducting one-day intensive pharmacovigilance training & certification workshops exclusively for PvOIs. We have ensured that it would involve certification for the successful trainees so that their training in the collection & analysis of ADR reports, which is mandatory for PvOIs according to this Guidance Document, would be validated."

Given this background, Oviya MedSafe is happy to announce that the first such one-day intensive training & certification workshop for PvOIs of MAHs will be conducted at Hotel Kohinoor Continental, Mumbai on Friday 12-Jan-2018 from 9 AM to 5 PM. The workshop will be open only to official PvOI nominees of Indian MAHs and their nominated back-up persons. The registration fee per participant has been fixed as INR 5000 + applicable taxes only, in order to encourage as many micro, small and medium-sized MAHs as possible to get their PvOIs trained and certified by Oviya MedSafe.

"We plan to conduct this workshop at other locations in India in quick succession to this grand beginning at Mumbai", Dr Vijay concluded.

For registration and/or more information, please contact Oviya MedSafe at +91-82207-63222 and info@oviyamedsafe.com .

****