

Experts urge India to join PIC/S to enhance recognition & sustain India's global leadership in pharma generics

Laxmi Yadav, Mumbai, Thursday, June 02, 2016, 08:00 Hrs [IST]

In its efforts to enhance recognition as provider of quality drugs and boost drug exports, a leading generics player like India needs to step up efforts to join the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) that currently has 48 medicine importing countries including US and European Union, said noted patent expert Dr Gopakumar G Nair.

India is only eligible to be an observer initially, till the regulatory system headed by DCGI under CDSCO and state FDAs qualifying to meet PIC standards. This will take a long time. Till such time India can be an observer in PIC/S, he added.

The prescribed standards of the PIC/S are good clinical practice (GCP), good pharmacovigilance practice (GPvP) and good manufacturing practice (GMP). The PIC/S membership has several benefits including reduced duplication of inspections, cost savings, export facilitation and enhanced market access.

The objective of PIC/S is global harmonization of health and regulatory inspection procedures by establishing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, to enhance mutual confidence.

The member countries of PICS import medicines from the manufacturing facilities of fellow member countries without duplication of inspections on the medicines and manufacturing facilities, helping exporters significantly save cost and time, said Dr Nair.

"Besides this, some non-PIC/S authorities e.g. Colombia accept GMP certificates from PIC/S participating authorities. This means that non-PIC/S authorities and organisations have a greater confidence in medicines manufactured in countries where the regulatory authority is a PIC/S participating authority. Consequently, the pharmaceutical industry located in these countries indirectly benefits from PIC/S membership," he added.

Membership in PIC/S may also facilitate the conclusion of other agreements, e.g. Mutual Recognition Agreements, between members at various levels (e.g. Australia-Canada MRA, EU-Switzerland MRA, etc.). During initial negotiation on ASEAN MRA on GMP Inspection, PIC/S membership accession was accepted as one of the essential criteria for MRA, he opined.

He further said that nearly two-thirds of India's exported drugs go to PICS member countries. With more and more countries seeking PIC/S compliance, it is need of the hour for India to join the forum to increase its drug export.

He added that quality issues raised by the US Food and Drug Administration (FDA) affected exports from several drug manufacturers of the country. Countries like Brazil and Russia have put their own plant audits for Indian exporters adding to the cost and time. Though Indian exporters comply with US FDA rules and regulations, a number of countries have begun placing their own plant audits. Given the situation, it has become necessity for Indian pharma to join PIC/S to avoid multiple inspections and save on time and money.

Taking serious note of benefits of PIC/S membership, Union commerce ministry has initiated steps to convince Indian drug makers to join the forum at the earliest.

Currently, small scale pharma industries which rely on domestic market are not willing to support India's initiative to join PIC/S as it will force them to enhance their manufacturing standards to meet global norms thereby putting financial burden on them.

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