

Report on

“PIC/S AND ITS ROLE”

(Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme)



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce & Industry, Govt., of India)

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Introduction:

PIC/S is a combination term used for the execution of activities of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme. PIC/S was established to harmonize, educate, and update aspects relating to Good Manufacturing Practice among member countries. PIC/S is also a body that even harmonized relation among regulatory authorities and governments. The present article helps in understanding the origin, purpose, objective, role and functions of PIC/S.

Origin and Purpose:

In 1995, PIC/S was established as a provision to streamline with long back established Pharmaceutical Inspection Convention of 1970 with some flexibility. Initially, European Commission is the body permitted to sign agreements with countries outside Europe. Since, European Commission is not a member of Pharmaceutical Inspection Convention of 1970, there was some incompatibility among European Law and PIC. This incompatibility did not allow EU countries that were members of PIC to have agreement with countries that are seeking to join PIC. This led to formation of a PIC Scheme that is a less formal, more flexible, with no legal status that in turn brings understanding between health authorities. Thus PIC/S is a parallel scheme of both Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme. PIC/S has brought understanding among health authorities and governments and led to joint execution of activities of PIC and PIC scheme.

History, Members of PIC and PIC/S:

Pharmaceutical Inspection Convention was established in 1970 by European Foreign Trade Association under the title “The Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products”. Initial ten members of EFTA i.e. Austria, Denmark, Finland, Iceland, Liechtenstein, Norway, Portugal, Sweden, Switzerland and

United Kingdom were later members of PIC. Membership of PIC was subsequently expanded to include Hungary, Ireland, Romania, Germany, Italy, Belgium, France and Australia. It was later the PIC scheme established in 1995 that in turn led to PIC/S. Presently, 39 regulatory authorities are members and partners of PIC/S (Annexure A).

Objective of PIC and PIC/S:

The main objective is to harmonize Good Manufacturing Practice requirements, bring about uniform-mutual recognition inspections, educate and exchange information, among different countries and attain mutual confidence of drug regulatory authorities. The key issues like duplication of inspections, licensing procedures, expenditure and licensing can be overcome by one time procedures.

Role of PIC/S:

The role of PIC scheme is to safe guard public health by providing good quality medicines by bringing a harmonization in Good Manufacturing Practice among countries. To achieve this harmonization, regular awareness along with training, sharing information and experience, implementing procedures to be followed relating to manufacture and quality control of medicinal products so that equivalent standards among countries can be implemented.

To meet the objective, PIC/S has to thoroughly assess the status of regulatory process of a drug regulatory authority of a country and make necessary changes if necessary in the protocols of manufacturing and quality control of drugs so as to harmonize Good Manufacturing Practice among the member countries.

Administrative Structure of PIC/S:

PIC/S is constituted with a permanent committee and executes meetings with representative of participating authorities. The meetings are held at least twice a year by the committee. The PIC/S committee is assisted by a secretariat in coordinating, documenting and implementing the objectives of PIC/S.

Functions of PIC/S Committee:

To meet the objectives of PIC/S in terms of harmonisation of GMP, the committee makes recommendations, update and improve GMP, promote cooperation relating to quality assurance of inspections and quality systems of inspectorate, educate the authorities by means of training and exchange of information and helps in bringing out new guidelines relating to manufacturing and quality control of medicinal products. The committee also assesses the system being practiced by a country for medicinal products in terms of manufacture, quality control along with protocols followed for corresponding regulatory inspections/inspectors and decides suggestions and changes necessary for the country to become a member of PIC/S.

Advantages with PIC/S:

PIC/S brings about an international harmonization among countries with relating to Good Manufacturing Practice, quality maintenance systems of medicinal products. In addition to this, implementation of high standards of quality along with mutual understanding among members is achieved. PIC/S brings about a single network system relating to GMP of medicinal products and helps member regulatory authorities in sharing, facilitating, recalling, concluding aspects relating to manufacture, quality and inspection systems among inspectorates, pharmaceutical industries. Aspects relating to duplication of inspections and other regulatory become cost effective. PIC/S also brings about single window export facilitation to enhance marketing of the medicinal products. As a whole, PIC/S brings about uniform licensing decisions among member countries. Several countries like Colombia that is a non-PIC/S authority do accept GMP certification from PIC/S member countries for import of the medicinal product which is a benefit.

Difference between PIC Scheme and PIC:

	PIC Scheme	PIC
1	Scheme	Convention
2	An informal arrangement	A formal treaty
3	Has no legal status	Has legal status
4	Between Health authorities	Between countries
5	Exchange of information	Mutual recognition of inspections

List of PIC/S Guide Lines:

PIC/S provides guide lines for industry, inspectorates and inspectors as mentioned below:

Guidance to Industry:

- PE 009-9 : Good Manufacturing Practice for Medicinal Products (Part I, II, Annexes)
- PI 010-4 : Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects

Guidance to Inspectorate:

PIC Convention

PIC/S Scheme

Participating Authorities & Partners

- PI 002-3 : Quality System Requirement for Pharmaceutical Inspectorate
- PI 013-3 : Standard Operating Procedure PIC/S Inspection Report Format

Guidance to Inspectors:

- PI 009-3 : Aide-Memoire Inspection of Utilities
- PI 021-2 : Aide-Memoire on GMP Particularities for Clinical Trial Products
- PI 023-2 : Aide-Memoire on Inspection of Quality Control Laboratories
- PI 024-2 : Aide-Memoire on Inspection of Biotech
- PI 025-2 : Aide-Memoire on Medicinal Gases
- PI 028-1 : Aide-Memoire on Packaging
- PI 030-1 : Aide-Memoire on the Inspection of APIS
- PE 005-3 : PIC/S GMP Guide for Blood Establishments

- PE 010-3 : Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments
- PI 005-3 : Guidance on Parametric Release
- PI 006-3 : Validation Master Plan Installation and Operational Qualification Non-Sterile Process Cleaning Validation
- PI 007-6 : Validation of Aseptic Processes
- PI 008-3 : PIC/S Guide to Inspections of Source Plasma Establishments and Plasma Warehouses (Inspection Guide)
- PI 011-3 : Good Practices for Computerized Systems in Regulated GXP Environments
- PI 012-3 : Recommendation on Sterility Testing
- PI 014-3 : Isolators used for Aseptic processing and Sterility Testing
- PI 032-2 : Technical Interpretation of Revised Annex 1 to PIC/S GMP Guide

Conclusion:

Implementation of PIC/S has brought a harmony among PIC and PIC Scheme. It has brought a uniform understanding among member countries regarding Good Manufacturing Practices for medicinal products. PIC/S has brought an understanding among drug regulatory authorities in bringing high standard, uniform acceptable quality standard medicines that can be permitted into the member countries. As a whole, PIC/S has benefited the pharmaceutical manufacturers, inspectors, inspectorate and governments in saving time, cost for drug approval procedures and enhance the pharmaceutical market.

Annexure A

Members & Partners of PIC/S:

A. Participating Authorities:

- i. Argentinian National Institute of Drugs-Instituto Nacional de Medicamentos (INAME)
- ii. Australian Therapeutic Goods Administration (TGA)
- iii. Austrian Agency for Health and Food Safety
- iv. Belgian Federal Agency for Medicines and Health Products
- v. Canadian Health Products and Food Branch Inspectorate(HPFBI)
- vi. Cypriot Pharmaceutical Services (CyPHS)
- vii. Czech State Institute for Drug Control
- viii. Czech Institute for State Control of Veterinary Biologicals and Medicines (ISCVBM)
- ix. Danish Medicines Agency (DKMA)
- x. Estonian State Agency of Medicines (SAM)
- xi. Finnish Medicines Agency(FIMEA)
- xii. French Agency for Safety of Health Products
- xiii. French Agency for Food, Environmental & Occupational Health Safety
- xiv. German Federal Ministry of Health
- xv. German Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices
- xvi. Greek National Organisation for Medicines
- xvii. Hungarian National Institute of Pharmacy (NIP)
- xviii. Icelandic Medicines Control Agency (IMCA)
- xix. Irish Medicines Board (IMB)
- xx. Israeli Institute for Standardization and Control of Pharmaceuticals (ISCP)
- xxi. Italian Medicines Agency
- xxii. Latvian State Agency of Medicine
- xxiii. Liechtenstein's Office of Healthcare
- xxiv. Lithuanian State Medicines Control Agency (SMCA)
- xxv. Malaysian National Pharmaceutical Control Bureau (NPCB)
- xxvi. Maltese Medicines Authority (MAM)
- xxvii. Netherlands' Inspectorate of Health Care
- xxviii. Norwegian Medicines Agency (NOMA)
- xxix. Polish Main Pharmaceutical Inspectorate (MPI)
- xxx. Portuguese National Institute of Pharmacy and Drugs
- xxxi. Romanian National Medicines Agency (NMA)
- xxxii. Singapore's Health Sciences Authority (HAS)
- xxxiii. Slovak State Institute for Drug Control (SIDC)
- xxxiv. South African Medicines Control Council (MCC)
- xxxv. Spanish Agency of Drugs and Health Products

- xxxvi. Swedish Medical Products Agency (MPA)
- xxxvii. Swiss Agency for Therapeutic Products (Swissmedic)
- xxxviii. Ukrainian State Inspectorate for Quality Control of Medicines (SIQCM)
- xxxix. United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA)
- xl. U.S. Food and Drug Administration

B. Partners to PIC/S:

- i. European Directorate for the Quality of Medicines & Healthcare
- ii. European Medicines Agency
- iii. United Nations International Children's Emergency Fund
- iv. World Health Organisation