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Review Article

An Intellectual approach of PIC/S Guide to Good Manufacturing Practice for Medicinal Products

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ABSTRACT

In a retrospective approach on the link between PIC/S guide to GMP is to meet the quality and standards in manufacturing the pharmaceutical products. The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a scheme promising to informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human. It is open to any Authority having a comparable GMP inspection system. The main instrument for harmonisation has been the PIC/S GMP Guide. The PIC/S provide an active and constructive cooperation in the field of GMP and related areas. The purpose of PIC/S is to facilitate, networking between participating authorities, maintenance of mutual confidence, exchange of information and experience, mutual training of GMP inspectors.

Keywords: Good Manufacturing Practice, GMP inspection, role, mission, significance, organization structure, members, GMP guide and Pharmaceutical Inspectorates.

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INTRODUCTION

The pharmaceutical arena is widely spread, profitable sector and the global market is expected to grow 5 - 8% annually through 2014. To manufacture and market the pharmaceutical products, the manufacturer must follow the approval guidelines of the respective country's regulatory authority and after getting the approval the manufacturer is entitled to manufacture and market the drugs.[1]In 1995, PIC/S was established as a provision to streamline with long back established Pharmaceutical Inspection Convention. 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 Cooperation Scheme. PIC/S has brought understanding among health authorities and governments and led to joint execution of activities of PIC and PIC scheme.

MEMBERS OF PIC AND PIC/S:

Initialy 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. Presently, 49 regulatory authorities are members and partners of PIC/S.[2]

ORGANISATIONAL STRUCTURE:

As the PIC Scheme is an arrangement between Regulatory Authorities, it is very flexible, dynamic and proactive. A Committee of the Participating Authorities' representatives (PIC/S Committee) supervises the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by 7 Sub-Committees (e.g. on the training of inspectors, on GMDP harmonisation, etc.), by an Executive Bureau, which steers the Organisation in-between meetings, and by a small Secretariat, which mainly assists the Committee, the Sub-Committees, the Bureau and Participating Authorities in their duties.[3]

GOVERNANCE

The decision-making ("legislative") body is the PIC/S Committee, which is an assembly of the representatives of all Participating Authorities. The PIC/S Committee has 7 Sub-Committees and numerous working groups. The executive body is the PIC/S Executive Bureau, which comprises the Chairperson, the Deputy Chairperson, the immediate former Chairperson, the 7 Chairs of Sub-Committees and the Secretary. The PIC/S Secretariat assists both the PIC/S Committee and the PIC/S Executive Bureau in their tasks.[4]

OBJECTIVE

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.[2]

MISSION

The mission of the PIC/S is "to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products".

In practical terms, this means that if a country joins PIC/S they will recognize GMP inspections and assessments done by other PIC/S member countries[5]

PHARMACEUTICAL INSPECTION CONVENTION AND PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S):

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly known as PIC/S) develop international standards between countries and pharmaceutical inspection authorities, to provide a harmonised and constructive co-operation in the field of GMP[6].

MAIN BENEFITS FOR MEMBERS OF PICS:

- Training opportunities: PIC/S provides a forum for the training of GMP inspectors thus allowing the latter to benefit from increased training opportunities by attending PIC/S Seminars and Expert Circles and by participating in the PIC/S Joint Visits Programme.
- International GMP harmonisation: By taking part in the meetings of the PIC/S Committee, PIC/S Participating Authorities are involved in the development and harmonisation of international GMP guides and guidelines. The PIC/S Committee also actively promotes the uniform interpretation of GMP and Quality Systems for GMP Inspectorates.

- Attending PIC/S activities, participants benefit from personal contacts with other agencies, whether they are part of PIC/S or not. This networking often simplifies contacts and the exchange of GMP related information. In addition, PIC/S is one of the few international GMP fora for networking and confidence building amongst Regulatory Inspectors where experts (GMP Inspectors, specialist GMP Inspectors and Chief Inspectors) can meet, discuss issues of mutual concern and share experiences and information. In other fora, participation is either at the level of Heads of Agencies (e.g. WHO) or at the level of experts in a particular field (ICH).
- PIC/S ensures that all Members comply with PIC/S standards at all times (assessment of new applicants and reassessment of existing Member Inspectorates). Preparing for the accession to the Scheme (or reassessment) forces improvements in the GMP inspection system and procedures.
- PIC/S allows for a more effective use of inspection resources through the voluntary sharing of GMP inspections reports. Membership is also a cost-saving measure for the inspection authorities confronted with an increase of inspections, notably in the field of Active Pharmaceutical Ingredients (APIs).
- Through PIC/S Membership, Regulatory Authorities automatically benefit from being part of the PIC/S Rapid Alert and Recall System arising from quality defects of batches of medicinal products, which have been distributed on the market. The PIC/S Alert and Recall System is part of a wider system, which includes the Alert and Recall System of EU/EEA/MRA partners.
- Facilitating the conclusion of other Agreements: 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 the recently concluded initial negotiation on ASEAN MRA on GMP Inspection, PIC/S Membership accession was accepted as one of the essential criteria for MRA.

INDIRECT BENEFITS FOR INDUSTRY

There are also indirect benefits to industry when their relevant Regulatory Authority becomes a Member of PIC/S. These benefits may include the following:

- Reduced duplication of inspections
- Cost savings
- Export facilitation
- Enhanced market access

Although PIC/S is not a trade agreement, Membership in PIC/S may facilitate the export of pharmaceuticals. Some non-PIC/S Authorities 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.[7]

IMPORTANCE OF PIC/S COMPLIANCE:

A company manufacturing and supplying pharmaceuticals to multiple countries would be subjected to audits from the regulatory bodies of each country. For those countries who are members of PIC/S, an audit by another PIC/S member country will be accepted without the need for a further audit.

Let's look at an example:

Company X ships product to Australia, Singapore and Malaysia. They have been audited by the Australian regulatory body, the Therapeutic Goods Administration (TGA) and have been granted a GMP license. As Australia, Singapore and Malaysia are all members of PIC/S, Singapore and Malaysia will accept CompanyX's products without their regulatory bodies performing an audit on Company X. Once one PIC/S member country has confirmed that a manufacturer meets GMP requirements then all other PIC/S member countries will usually accept the GMP certification without performing and inspection and assessment themselves.

So, being assessed as PIC/S GMP compliant will significantly reduce your compliance burden and costs if you are supplying product to multiple countries.[5]

SIGNIFICANCE ABOUT THE US JOINING WITH PIC/S

With nearly 40 countries being members of PIC/S, most of the Western world, and more than 75% the pharmaceutical spend, is represented. From January 1st 2011, the US FDA became members of PIC/S. This means that companies currently exporting or wanting to export products to the USA will be able to do so without a specific FDA GMP audit (well, that's the theory anyway). If a manufacturing site has successfully passed a GMP audit from another PIC/S member country, then the FDA should accept that without further investigation.

So which PIC/S authority should you choose to receive your GMP certification from? Here are some of the considerations:

- Some authorities don't conduct many foreign audits, so it's worthwhile asking first.
- Some are very expensive – request a quote
- Some are held in higher esteem by the public than others, so having their GMP certification will be better for you commercially.[5]

GOAL:

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.[2]

The main functions of PIC/S are:

- To provide a forum for the training of GMPinspectors.
- To facilitate the exchange of informationbetween member authorities.
- To develop guidance documents on GMP.
- To promote uniform interpretation ofGMP.
- To encourage international harmonization of GMP.
- To develop and promote Quality Systems forGMP Inspectorate.
- To ensure that all Members comply with PIC/S standards (assessment of new applicants andreassessment of older inspectorates).
- To provide a forum for networking and confidencebuilding amongst inspectors.[8]

ROLE OF PIC/S:

The Pharmaceutical Inspection Co-operation Scheme (hereinafter referred to as "Scheme") is hereby established as an Association under the Swiss Code of Civil Law (Art. 60 ff). For registration purpose, the Scheme shall be referred to as "Pharmaceutical Inspection Co-operation Scheme - Association de Droit Suisse".

For the purpose of this Scheme "medicinal product" means:

(a) any pharmaceutical, medicine or similar product intended for human or veterinary use which is subject to control by health legislation in the manufacturing country or in the importing country, and

(b) any active pharmaceutical ingredient (API) or excipient which the manufacturer uses in the manufacture of a product referred to in subparagraph (a) above.

1. Purpose of the scheme:

The purpose of the PIC Scheme is, with due regard to public health,

- to pursue and strengthen the co-operation established between the Participating Authorities in the field of inspection related to the manufacture (or distribution) of medicinal products and associated activities with a view to maintaining the mutual confidence and promoting quality assurance of inspections,
- to provide the framework for the sharing of information and experience on a voluntary basis,
- to co-ordinate mutual training for inspectors and for other technical experts in related fields,
- to continue common efforts towards the improvement and harmonisation of technical standards and procedures regarding the inspection of the manufacture (or distribution) of medicinal products and the testing of medicinal products by official control laboratories,
- to continue common efforts for the development, harmonisation and maintenance of Good Manufacturing and Distribution Practice (GMDP), and
- to extend the co-operation to other competent authorities having the national arrangements necessary to apply equivalent standards and procedures with a view to contributing to global harmonisation.[9]

Before a regulatory authority can become a member of the PIC Scheme, a detailed assessment is undertaken to determine whether the authority has the arrangements and competence necessary to apply an inspection system comparable to that of current PIC/S members. This assessment involves an examination of the authority's inspection and licensing system, quality system, legislative requirements, inspector training, etc, and is followed by a visit by a PIC/S delegation to observe inspectors carrying out actual GMP inspections.[10]

THE PIC/S GUIDE TO GMP FOR MEDICINAL PRODUCTS:

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme develop international standards between countries and pharmaceutical inspection authorities, to

provide a harmonised and constructive co-operation in the field of GMP.

The Agency is a recognised partner of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, jointly referred to as PIC/S. PIC/S are two international instruments between countries and pharmaceutical inspection authorities. They aim to lead the international development, implementation and maintenance of harmonised good-manufacturing-practice (GMP) standards and quality systems of inspectorates in the field of medicines.

Achievements

- Developing and promoting harmonised GMP standards and guidance documents.
- Training national regulatory authorities, particularly inspectors;
- Assessing and re-assessing inspectorates;
- Facilitating co-operation and networking for national regulatory authorities and international organisations.

Role of Agency while working with PIC/S

- Training GMP inspectors;
- Developing harmonised guidance documents;
- Sending a representative to PIC/S meetings.

PIC/S also has a representative participating in the Agency's GMP/Good Distribution Practice Inspectors Working Group.

The Agency also assists with assessment of the equivalence of authorities, inspection activities and the sharing of information on inspections.[12]

Categories of the PIC/S Guide:

The PIC/S Guide to GMP for medicinal products applies to all medicines (unless exempt under provisions in the Act). Interpretations of the PIC/S guide to GMP for medicinal gas manufacturers have been agreed by the TGA and the Australia New Zealand Industrial Gas Association.

The Guide is divided into two parts and a number of annexes.

- Guide to Good Manufacturing Practice for Medicinal Products - Introduction
- Guide to Good Manufacturing Practice for Medicinal Products - Part I
  Part I covers GMP principles for the manufacture of medicinal products
- Guide to Good Manufacturing Practice for Medicinal Products - Part II
  Part II covers GMP for active substances used as starting materials
- Guide to Good Manufacturing Practice for Medicinal Products - Annexes
  The annexes provide detail on specific areas of activity
- Technical interpretation of PIC/S GMP guide Annex 1 - Manufacture of sterile medicinal products[6]

Guide to Good Manufacturing Practice for Medicinal Products - Introduction

- Introduction
- Adoption and entry into force
- Revision history

Guide to Good Manufacturing Practice for Medicinal Products - Part I

- Quality management
- Personnel
- Premises and equipment
- Documentation
- Production
- Quality control
- Contract manufacture and analysis
- Complaints and product recall
- Self-inspection

Guide to Good Manufacturing Practice for Medicinal Products - Part II

Contents

- Introduction
- Quality management
- Personnel
- Buildings and facilities
- Process equipment
- Documentation and records
- Materials management
- Production and in-process controls
- Packaging and identification labelling of APIs and intermediates
- Storage and distribution
- Laboratory controls
- Validation
- Change control
- Rejection and re-use of materials
- Complaints and recalls
- Contract manufacturers (including laboratories)
- Agents, brokers, traders, distributors, repackers and relabellers
- Specific guidance for APIs manufactured by cell culture / fermentation
- APIs for use in clinical trials

Guide to Good Manufacturing Practice for Medicinal Products – Annexes

Contents

- Manufacture of sterile medicinal products
- Manufacture of biological medicinal products for human use
- Manufacture of veterinary medicinal products other than immunological
- Manufacture of immunological veterinary medical products [This Annex is not adopted by Australia]
- Manufacture of medicinal gases
- Manufacture of herbal medicinal products
- Sampling of starting and packaging materials
- Manufacture of liquids, creams and ointments
- Manufacture of pressurized metered dose aerosol preparations for inhalation
- Computerized systems
- Use of ionizing radiation in the manufacture of medicinal products
- Manufacture of investigational medicinal products
- Manufacture of products derived from human blood or human plasma [This Annex is not adopted by Australia]
- Qualification and validation
- Qualified person and batch release [This Annex is not adopted by the PIC/S and Australia]
- Parametric release
- GMP guide for active pharmaceutical ingredients [This Annex no longer exists]
- Reference and retention samples
- Quality risk management
- Glossary

Technical interpretation of PIC/S GMP guide Annex 1 - Manufacture of sterile medicinal products

PIC/S has published a recommendation for the technical interpretation of Annex 1 on the Manufacture of Sterile Medicinal Products.

This recommendation summarizes the interpretations an inspector adopts during an inspection of the manufacture of sterile medicinal products. It reflects the most important changes introduced in the revised Annex 1, but is not intended to address all changes in the revision.

This recommendation came into effect on 1 January 2010.

Contents

- Document history
- Purpose and scope
- Basics
- Definitions and abbreviations
- New texts and their interpretation
- Revision history[6]

NEW REVISION OF PIC/S GMP GUIDE (PIC/S PE 009-13):

On 1st of January 2017, revision 13 of the PIC/S Code of GMP for medicinal products (PIC/S PE 009-13) entered into force. Four Chapters of PIC/S PE 009-13 were revised to align with the current EU GMP code and ICH Q10. This was conducted "*with some minor differences in terms of language*". The PIC/S website indicates that the PIC/S PE 009-13 revision was managed by the PIC/S Sub-Committee on the Harmonisation of GM(D)P, led by Paul Gustafson (Canada/RORB).

Main Changes: The title of Chapter 1 of PIC/S PE 009-13 has now been changed to "Pharmaceutical Quality Systems" and the title of Chapter 7 has now become "Outsources Activities". These two Chapters, along with Chapter 2 Personnel have been revised to reflect the current version of ICH Q10 and the lifecycle stages.

Chapter 2 Personnel has a new section on consultants that states: "Consultants should have adequate education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records should be maintained stating the name, address, qualifications, and type of service provided by these consultants."

In Chapter 6 Quality Control, "all sections have been reviewed and amended". A new section on "Technical transfer of testing methods" for analytical methods has been added.

The scope of Chapter 7 Outsources Activities has been expanded and not just focused on contract manufacture and analysis.

New revision available on:

The revised GMP Guide (PIC/S PE 009-13) is in force from January 1st and can be downloaded from the PIC/S website.[14]

CONCLUSION

The present review of PIC/S promotes a harmonisation among GMP standards and guidance documentsfor medicinal products.WHO-GMP standards are more Stringent than PIC/S-GMP standards but PIC/S has its own benefits, it helps the membered authority by to trade the medicinal products in the other member countries by removing the barrier as they all will be following the same PIC/S GMP standards.

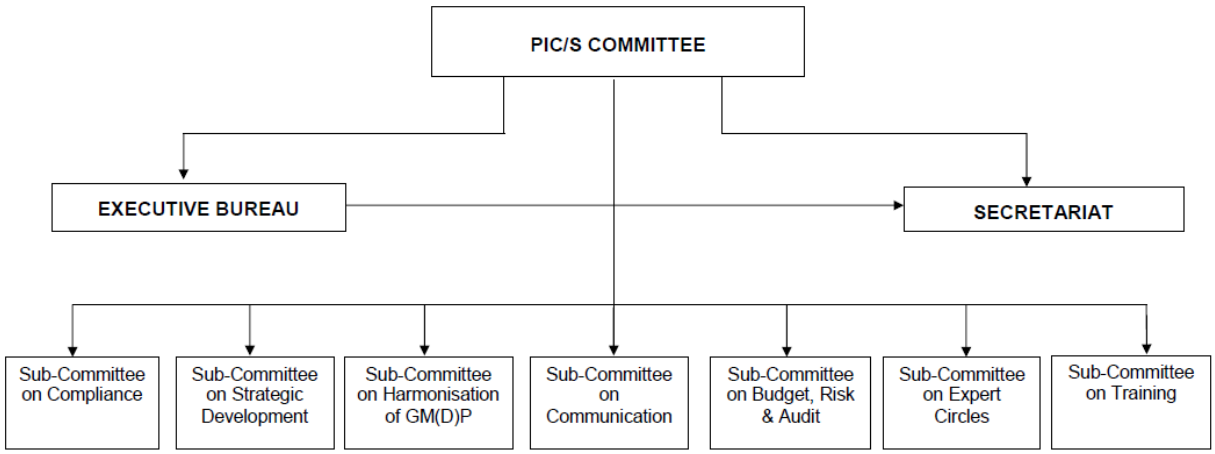

Fig.1: Overview of PIC/S Committee [3]

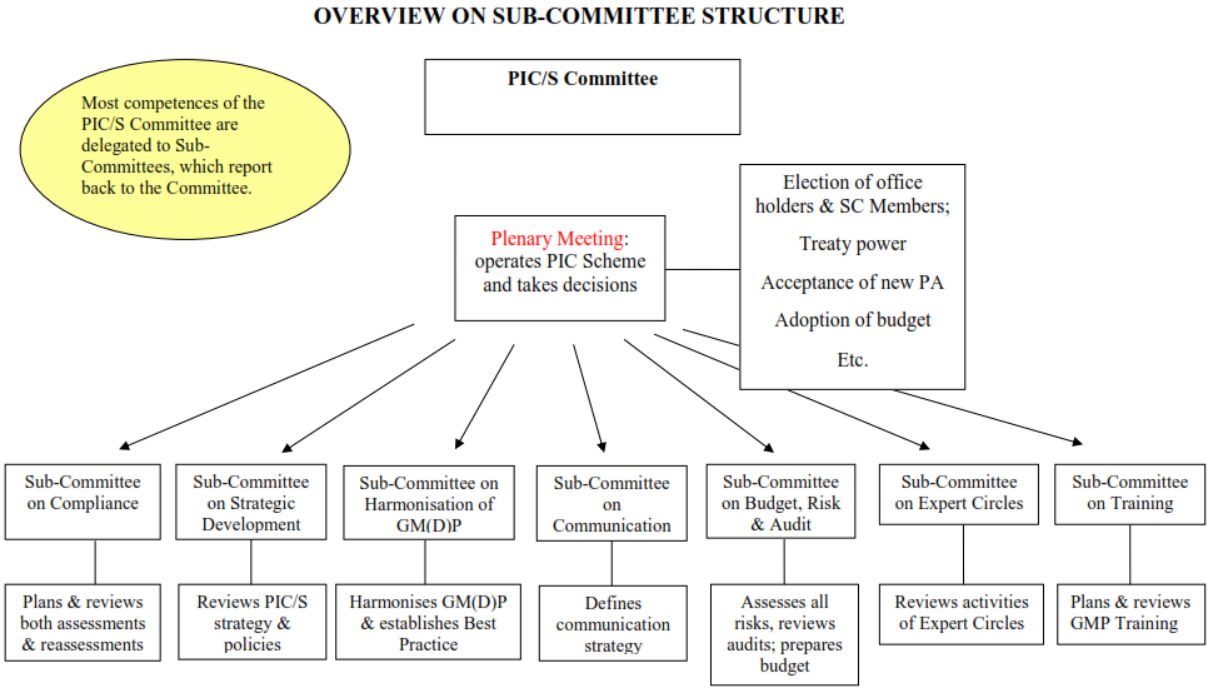

Fig.1: Organisational Chart of PIC/S[4]

Fig.2 PIC/S Committee Meeting[11]

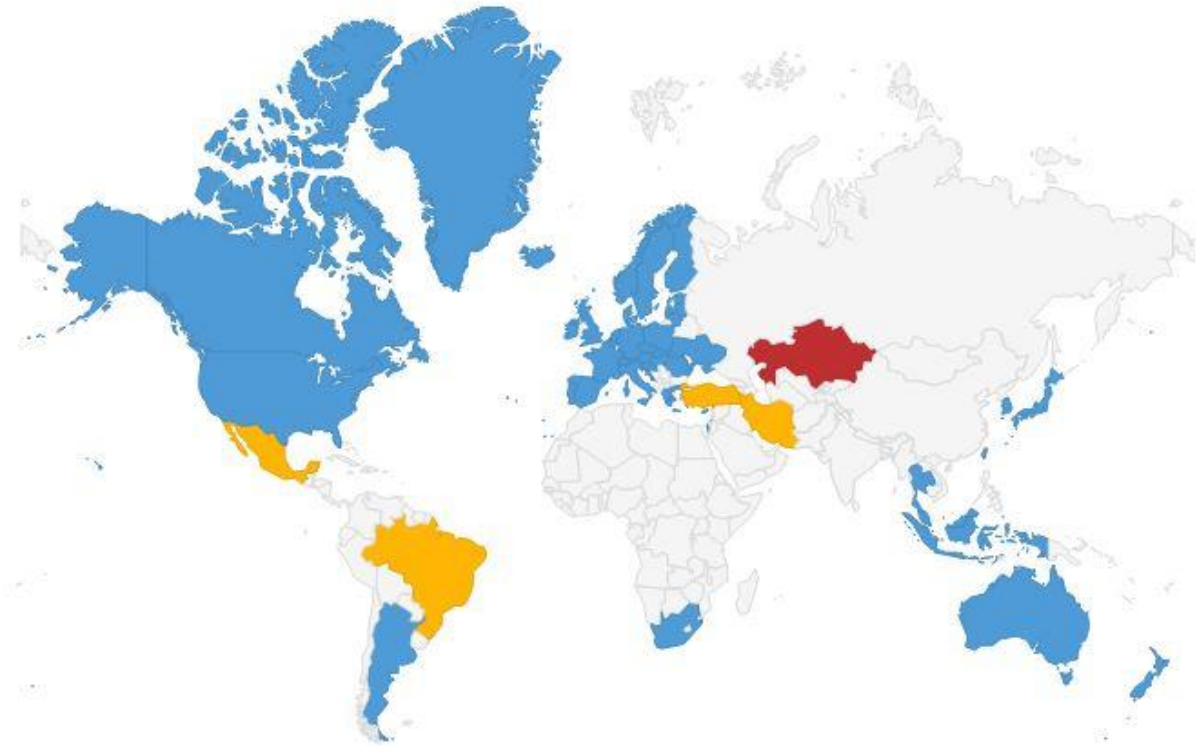

Fig.2. PIC/S MEMBERSHIP APPLICATIONS[11]

Table-1: Differences between PIC Scheme and PIC[2]

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

Table-2:PIC/S Participating Authorities [13]

Name of the Country	Regulatory Logo	Regulatory Authority
Argentina		National Institute of Drugs *Instituto Nacional de Medicamentos* (INAME)
Australia	Australian Government Department of Health Therapeutic Goods Administration	Therapeutic Goods Administration **(**TGA**)**
Austria	AGES	Austrian Agency for Health and Food Safety (AGES) *Österreichische Agenturfür Gesundheit und Ernährungssicherheit*(AGES)
Belgium	FAGG AFMPS	Federal Agency for Medicines and Health Products *Agence Fédérale des Médicaments et des Produits de Santé (AFMPS)* *Federaal Agentschapvoor Geneesmiddelen en Gezondheidsproducten (FAGG)*
Canada	Health Canada Santé Canada	Health Canada *Regulatory Operations and Regions Branch (RORB)* *Direction générale des opérations réglementaires et des régions (DGORR)*
Chinese Taipei	FDA 食品藥物管理署 Food and Drug Administration	**T**aiwan **F**ood and **D**rug **A**dministration (**TFDA**)
Croatia	HALMED Agency for Medicinal Products and Medical Devices of Croatia	Agency for Medicinal Products and Medical Devices of Croatia *Agencijazalijekoveimedicinskeproizvode* (HALMED)
Cyprus		**Ph**armaceutical **S**ervices (**CyPHS**)

Czech Republic	SÚKL	State Institute for Drug Control *Státní Ústav pro Kontrolu Léčiv* (SÚKL)
Czech Republic		Institute for State Control of Veterinary Biologicals and Medicines (ISCVBM)
Denmark	LÆGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY	Danish Medicines Agency (DKMA)
Estonia	REPUBLIC OF ESTONIA AGENCY OF MEDICINES	State Agency of Medicines (SAM)
Finland	fimea Lääkealan turvallisuus- ja kehittämiskeskus Säkerhets- och utvecklingscentret för läkemedelsområdet Finnish Medicines Agency	**Fi**nnish **Me**dicines **A**gency **(**FIMEA**)**
France	ansm Agence nationale de sécurité du médicament et des produits de santé	French National Agency for Medicines and Health Products Safety Agencenationale de sécurité du médicament et des produits de santé (ANSM)
France	anses	Agency for Food, Environmental & Occupational Health Safety Agencenationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)
Germany	Bundesministerium für Gesundheit ZLG	Federal Ministry of Health * *Bundesministeriumfür Gesundheit* (BMG) Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices * Zentralstelle der LänderfürGesundheitsschutzbeiArzneimitteln und Medizinprodukten (ZLG)

Greece		Greek National Organisation for Medicines *Εθνικός Οργανισμός Φαρμάκων* (EOF)
Hong Kong SAR		Pharmacy and **P**oisons **B**oard of **H**ong **K**ong (**PPBHK**)
Hungary		National Institute of Pharmacy and Nutrition (NIPN)
Iceland		Icelandic Medicines Agency (IMA)
Indonesia		National Agency for Drug and Food Control (NADFC) *(BadanPengawasObatdanMakananRepublik Indonesia)*
Ireland		Health Products Regulatory Authority (HPRA)
Israel		Institute for Standardization and Control of Pharmaceuticals (ISCP)
Italy		Italian Medicines Agency *Agenzia Italiana del Farmaco* (AIFA)
Japan	 	Ministry of Health, Labour and Welfare (MHLW) Pharmaceuticals and Medical Devices Agency (PMDA)

Korea (Republic of)	Ministry of Food and Drug Safety	**M**inistry of **F**ood and **D**rug **S**afety (MFDS**)**
Latvia	State Agency of Medicines of the Republic of Latvia	State Agency of Medicines *Zāļu valsts aģentūra* (ZVA)
Liechtenstein	LANDESVERWALTUNG FÜRSTENTUM LIECHTENSTEIN	Office of Healthcare *Amtfür Gesundheit* (AG)
Lithuania	VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA	State Medicines Control Agency (SMCA)
Malaysia	NPRA MALAYSIA NATIONAL PHARMACEUTICAL REGULATORY AGENCY	National Pharmaceutical Regulatory Agency (NPRA)
Malta	AWTORITÀ DWAR IL-MEDIĊINI	Medicines Authority Malta (MAM)
Netherlands	Health Care Inspectorate Ministry of Health, Welfare and Sport	Dutch Health Care Inspectorate* *Inspectievoor de Gezondheidszorg* (IGZ)
New Zealand	MEDSAFE NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY A BUSINESS UNIT OF THE MINISTRY OF HEALTH www.medsafe.govt.nz	Medicines and Medical Devices Safety Authority (Medsafe)
Norway	Statens legemiddelverk Norwegian Medicines Agency	Norwegian Medicines Agency (NOMA)
Poland	GŁÓWNY INSPEKTORAT FARMACEUTYCZNY	Chief Pharmaceutical Inspectorate (CPI)
Portugal		National Authority of Medicines and Health Products, IP *AutoridadeNacional do Medicamento e*

	infarmed Autoridade Nacional do Medicamento e Produtos de Saúde I.P.	*Produtos de Saúde IP* (INFARMED IP)
Romania	National Medicines Agency NMA	National Agency for Medicines and Medical Devices (NAMMD)
Singapore	HSA Health Sciences Authority	**H**ealth **S**ciences **A**uthority **(**HSA**)**
Slovak Republic	ŠÚKL ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV	**S**tate **I**nstitute for **D**rug **C**ontrol **(**SIDC**)**
Slovenia	jazmp Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	Agency for Medicinal Products and Medical Devices *Javna agencijaRepublikeSlovenijeza zdravila in medicinske pripomočke* (JAZMP)
South Africa	mcc MEDICINES CONTROL COUNCIL	Medicines Control Council (MCC)
Spain	agencia española de medicamentos y productos sanitarios	Spanish Agency of Medicines and Medical Devices * *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS)
Sweden	LÄKEMEDELSVERKET MEDICAL PRODUCTS AGENCY	**M**edical **P**roducts **A**gency **(**MPA**)**
Switzerland	swissmedic	Swiss Agency for Therapeutic Products (**Swissmedic**)
Thailand	Thai FDA	Food and Drug Administration (Thai FDA)

Ukraine		State Service of Ukraine on Medicines and Drugs Control (SMDC)
United Kingdom	MHRA Regulating Medicines and Medical Devices	Medicines & Healthcare Products Regulatory Agency (MHRA)
United Kingdom	Veterinary Medicines Directorate	Veterinary Medicines Directorate (VMD)
U.S.A	FDA	U.S. Food and Drug Administration (US FDA)

Table-3: PartnersToPICS[2]

Name of the Country	**Regulatory Logo**	**Regulatory Authority**
France	edqm European Directorate for the Quality of Medicines & HealthCare / Direction européenne de la qualité du médicament & soins de santé; COUNCIL OF EUROPE CONSEIL DE L'EUROPE	European Directorate for the Quality of Medicines & HealthCare
United Kingdom	EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH	European Medicines Agency
Denmark		United Nations International Children's Emergency Fund
Switzerland		World Health Organization

REFERENCES

1. Pasumarthy N. V. Gopal et al. Contingent analysis and evaluation of pharmaceutical product recall procedure of USA and India. World J Pharm Sci 2014; 2(12): 1728-1735.
2. Pharmexcil.org. http://pharmexcil.org/uploadfile/ufiles/pxl-edigest/docs/1PICs.pdf(Accessed 20 April 2017)
3. PIC Scheme, Organisational Structure. https://www.picscheme.org/en/organisational-structure#subpage_76(Accessed 20 April 2017)
4. PIC Scheme, Governance. https://www.picscheme.org/en/governance(Accessed 20 April 2017)
5. Pharmout, Why PIC/S compliance is so important. https://www.pharmout.net/pfizer-and-merck-were-the-acquisitions-worth-it/(Accessed 20 April 2017)
6. Therapeutic Goods Administration, Manufacturing principles for medicinal products.https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products(Accessed 20 April 2017)
7. PIC Scheme, Benefits. https://www.picscheme.org/en/benefits(Accessed 21 April 2017)
8. Daniel Brunner. Pharmaceutical Inspection Co-operation Scheme (PIC/S). QualAssur J 2004;8:207-211.
9. Pharmaceutical Inspection Co-Operation SchemeGuidelines. https://www.picscheme.org/layout/document.php?id=132.(Accessed 20 April 2017)
10. PIC Scheme, Accession to PIC/S. https://www.picscheme.org/en/accessions(Accessed 21 April 2017)
11. PIC Scheme,Press release: PIC/S Meetings in Geneva (Switzerland).https://www.picscheme.org/newsletter/newsletters.php?newsletter_id=58bd2bd6d28ae(Accessed 24 April 2017)
12. European Medicines Agency, The Pharmaceutical Inspection Co-operation Scheme. http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000470.jsp&mid=WC0b01ac05801f0a08(Accessed 24 April 2017)
13. PIC Scheme, Members. https://www.picscheme.org/en/members(Accessed 24 April 2017)
14. Pharmout, New revision of PIC/S GMP Guide (PIC/S PE 009-13) now live. https://www.pharmout.net/new-revision-of-pics-pe-009-13/(Accessed 24 April 2017)