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Leading the international development, implementation
and maintenance of harmonised GMP standards and
quality systems of inspectorates in the field of medicinal
products

Press release: PIC/S meetings in Geneva (Switzerland)

From 8 to 10 April 2019, the following meetings took place in Geneva (Switzerland): PIC/S Committee and PIC/S Executive Bureau.

HEADLINES

- **PIC/S Inspection Reliance Initiative: successful examples of desk-top assessments in support to PIC/S GMP Inspection Reliance Guidance.**
- **Updates on future revisions to PIC/S GMP Guide: Annexes 1 (sterile), 2 (biologicals and ATMP), 13 (IMP) and 16 (certification by an AP & batch release).**
- **New working group established to develop a PIC/S Aide Memoire on Tissues and Cellular Therapy Products Inspections (excluding ATMP).**
- **Progress in amendment of PIC Scheme.**
- **PIC/S 2019 Seminar to be hosted by Japan / MHLW & PMDA in Toyama and updates on PIC/S Inspectorates' Academy and future training activities.**
- **Completion of pre-accession of Saudi Arabia / SFDA and new PIC/S pre-accession application received from Bangladesh / DGDA.**
- **Bilateral meetings with China / NMPA and ICH.**

PIC/S COMMITTEE MEETING

The PIC/S Committee met on 9-10 April 2019, under the chairmanship of Mr Boon Meow Hoe (Singapore Health Sciences Authority / HSA). The meeting was attended by 45 out of 52 PIC/S Participating Authorities (= Members) as well as by a number of Applicants, Pre-Applicants, Associated Partners and Guests. The latter including Delegations from China / NMPA and Philippines / PFDA.



PIC/S Committee meeting in Geneva

IMPLEMENTATION OF PIC/S GMP INSPECTION RELIANCE GUIDANCE

The PIC/S Guidance on GMP Inspection Reliance (PI 048-1), based on a draft by the International Coalition of Medicines Regulatory Authorities (ICMRA), entered into force on 1 June 2018 (for more information see Press Release of May 2018).

This Guidance provides a **framework** (PIC/S GMP Inspection Reliance Initiative) under which a Member of PIC/S can take informed decisions on the GMP compliance of a manufacturing facility **based on the inspection report or GMP certificate** of another Member, subject to national law or legally binding agreements such as Regional Integration or Mutual Recognition Agreements.

This voluntary framework allows for Members to waive by way of a **desk-top assessment** a GMP inspection because an acceptable level of compliance has been confirmed by another Member. The PIC/S network, which currently includes 52 Members worldwide, provides a unique platform for this reliance process. This is because PIC/S has very stringent rules regarding membership and expects new Members to have an **equivalent** GMP Regulatory Compliance Programme, notably GMP inspection and Quality System, in place. The equivalency is ensured as each Member is assessed for equivalence prior to being admitted to PIC/S. The PIC/S Joint Reassessment Programme (JRP) also ensures that existing Members fulfil and maintain the same requirements through reassessment for equivalence on a regular basis.

Further to the entry into force of PI 048-1, Members have been invited to collect statistics on desk-top assessments as from **1 January 2019** based on a template including metrics. The purpose of these statistics is to document the efforts made by Members to rely on existing inspection reports rather than duplicate foreign GMP inspections. Results will be collected at the end of 2019.

In order to apply PI 048-1 some Members will need to adapt their inspection strategy to a **risk-based** strategy. In this perspective, the Committee was updated on **successful examples** of processes used by some of its Members in identifying instances where an onsite inspection of an overseas facility is not necessary. In particular, Australia / TGA and Health Canada presented on their active desk-top assessment procedures and implementation as well as on current statistics.

TGA reported that currently ~ 92% of GMP approvals for products registered or listed in Australia utilise their GMP Clearance desk top program, which has become an integral part of Australia’s regulatory framework. To date, there are ~207 manufacturing sites that are subject to TGA inspections and ~2700 overseas manufacturing sites that rely on evidence from recognized regulators. TGA also provided statistics over the last few years on the number of GMP Clearance applications received. For the fiscal year 2017/2018, this amounted to 5327 GMP clearance applications.

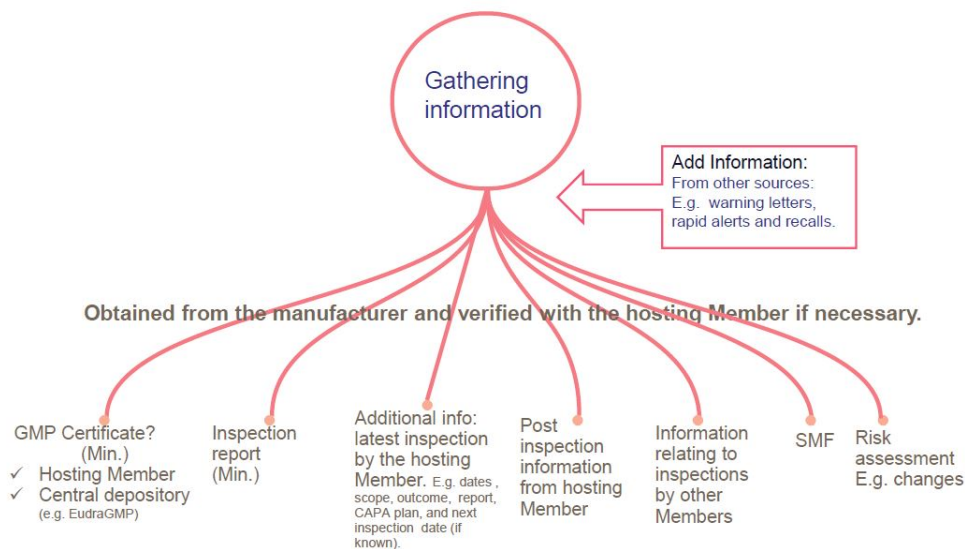
Health Canada referred to statistics covering the past few years on assessments of GMP evidence for foreign sites through their desktop assessment process (off-site reviews). For the fiscal year 2018/2019 this included exchange of Certificates of Compliance (500+) under a mutual recognition agreement (MRA) or through desk-top assessments (600+) by reviewing GMP compliance information from a foreign regulator or consultant audit.

Experience and figures shared, including those from Singapore / HSA, demonstrate how hugely successful such reliance programmes are and how they allow Members to **allocate inspection resources** more appropriately through better leveraging of resources and information where possible. Such examples also show the benefits of **mutual reliance** which can be further strengthened between Members.

The sharing of inspection information between Members is key to the success of the PIC/S GMP Inspection Reliance Initiative. In most cases, the availability of a GMP certificate or an inspection report will provide sufficient information regarding compliance to enable another Member to make an informed regulatory decision to waive their inspection. PI 048-1 also notes that additional risk-indicating information may be requested **from the manufacturer** to aid assessment.

The PIC Scheme itself (PIC/S 1/95 (Rev. 5)) provides that upon written request of a Member the following information can be shared under the Scheme on a voluntary basis: GMP compliance inspection report (for the format, see PI 013), corrective actions, correspondence, follow-up, etc.

Assessment of site compliance



The interest of **Industry** in PI 048-1 and its implementation is key, in particular as it is up to manufacturers to **proactively share reports** if they wish to avoid duplicate inspections. The PIC/S Sub-Committee on Strategic Development, chaired by Susan Laska (US FDA), will be discussing an offer made by ISPE's Global Pharmaceutical Manufacturing Leadership Forum (GPMLF) to PIC/S and to ICMRA to monitor regulatory inspections in connection with the PIC/S GMP Inspection Reliance Initiative.

The Committee discussed the sharing of **compliance management information** for borderline cases in support of PI 048-1. Such cases involve sharing of information on manufacturers who have a low level of compliance but who have not yet reached a state of non-compliance that requires strong regulatory action.

LATEST DEVELOPMENTS IN THE FIELD OF GM(D)P

The PIC/S Committee was updated on progress in the revision of **Annex 1** (Manufacture of Sterile Medicinal Products) to the PIC/S-EU GMP Guide, by the PIC/S-EMA Working Group, in which WHO is also represented. The WG is newly chaired by France / ANSM since February 2019. Further to the review of more than 6,300 comments resulting from the PIC/S-EU-WHO public consultation carried out in 2018, the Working Group is in the process of finalising a revised draft. The revision will be the focus of the PIC/S 2019 Seminar which will be hosted by Japan / MHLW & PMDA (see below for more details).

The PIC/S Working Group established with WHO on the Revision of **Annex 2** of the PIC/S GMP Guide, chaired by Australia / TGA, has drafted a new annex, **Annex 2A** for Manufacture of Advanced Therapy Medicinal Products (ATMP) for Human Use. This new Annex takes into account the EU Guidelines on ATMP while addressing at the same time concerns of PIC/S PAs, as expressed to the European Commission (EC) during the drafting process of the EU Guidelines. **Annex 2B** for the Manufacture of Biological Medicinal Substances and Products for Human Use will be the revised version of EU Annex 2 for biologics (excluding ATMPs).

The Committee decided to carry-out a **targeted stakeholder consultation** on the development of revised Annex 2.

Interview of the Chair of the Working Group on revision of Annex 2 Francesco Cicirello (Australia / TGA)



Q. What is the strategy which has been developed by the Working Group to harmonise where possible with the EU Guidelines on ATMP while addressing the concerns raised by PIC/S PAs which led to international divergence in this field?

A. The options for such a strategy were to either revise Annex 2, create a separate Annex for ATMP, or both. The WG considered a number of factors, including the published feedback from stakeholders during the European consultation, the feedback from PIC/S Members on aspects viewed to be of importance to protection of patient safety and the results of an internal survey on the use and the interpretation of Annex 2 amongst PIC/S Members.

With this in mind and acknowledging that the EC GMP Guidelines for ATMP had significantly evolved since the initial consultation and had also included a number of PIC/S recommendations, reflected on the harmonisation of GMP requirements for ATMP between PIC/S Members. The WG recognized the needs to fulfil PIC/S mission to improve harmonisation on GMP. The WG considered this occasion as a unique opportunity to improve on existing GMP ATMP guidelines available across different jurisdictions bringing together the multifaceted experience of the inspectors participating in the WG utilizing language from all PIC/S Members and associated Partner Organisations.

The WG thought that using a compilation format for the Annex 2 related to ATMP (i.e. a format that would confirm explicitly that any language in the Annex was replacing, adding or removing requirements in the PIC/S GMP Guide) could bring together the best of two worlds, as it could also be easily consolidated in a “one stop shop guide” for ATMPs. This format permits receiving language deemed useful from other existing guidelines for ATMP, including the ones from the EC, US FDA, Australian, Japanese and Korean, while maintaining the code of GMP for ATMPs within the PIC/S GMP Guide. The Working Group agreed on having two Annexes, Annex 2A Manufacture of ATMP for human use and Annex 2B Manufacture of biological medicinal substances and products for human use. Annex 2B would be aligned to the EU Annex 2 as issued by the EC. The WG had a number of informal discussions with stakeholders, both from industry and regulators and is looking forward to consult further with stakeholders on how GMP expectations are presented.

Q. What are the key features of the future draft Annexes 2A and 2B in development?

A. Draft Annex 2A is mainly based on the existing PIC/S Annex 2 having removed language that was not related to ATMPs. The WG carried out an analysis of the EU consultation responses and considered the information in light of patient safety, experience in regulatory oversight in other jurisdictions, with particular attention at what in the view of WG participants worked well and determined which part of the EC guidelines to utilise. The WG incorporated also original language proposed by the WG. It has addressed the original PIC/S concerns with regards to the language and structure to the EU Guidelines in particular with regards to processing environment classification, patient safety and not having a standalone code. It has also addressed, improving on existing guidelines, some of the industry concerns and gaps as identified by PIC/S Members, such as diffuse manufacturing, use of out of specifications products in certain compelling circumstances and use of unlicensed laboratories.

Q. What are the next steps in the development and adoption process for these drafts?

A. Recognizing that PIC/S Members are not positioned to fully know what are the industry needs and concerns without openly consulting with them, and considering the time that has lapsed since the EC has published the GMP Guide on ATMP, it is in the best interest of PIC/S, the patients and the industry to proceed as soon as possible with a consultation of stakeholders on development of draft Annexes 2A and 2B. This consultation will take the form of a targeted consultation, which was agreed by the Committee at its meeting in Geneva, and will include specific questions on the design and on topics with potential sensitivity, where in particular feedback will be requested from stakeholders. It will take place after the internal consultation of PIC/S PA ends on 24 May 2019. The WG will promptly consider the internal feedback received and is looking forward to engaging with industry stakeholders in the drafting of Annex 2 as soon as possible after that.

The Committee was updated on the outcome of step 1 of the adoption process (internal consultation of PIC/S PA) of the draft revision of **Annex 13** (Investigational Medicinal Products - IMPs) as well as of the outcome of step 1 of the draft adaptation for PIC/S purposes of **Annex 16** (Certification by an Authorised Person & Batch Release), prepared by the PIC/S Sub-Committee on GM(D)P Harmonisation, chaired by Paul Gustafson (Health Canada).

One major difficulty in the adaptation of **Annex 16** was that neither the PIC Scheme nor the PIC/S GMP Guide deal with import or import controls. As a result, there was some discussion on whether to allow for the voluntary implementation for import-related activities. The Committee decided that the question of whether to include or exclude release aspects associated with importation should be further addressed by PIC/S experts of non-EEA PA in order to clarify this issue prior to proceeding with step 2 (Consultation of non-EEA PA of their national industry association(s)).

The Committee was informed of the status of feedback received further to the 3-month focused stakeholders' consultation which ended on 28 February 2019 on the draft **PIC/S guidance on Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments (PI 041-1 (Draft 3))**, developed by the PIC/S Working Group on Data Integrity, co-led by Australia / TGA and UK / MHRA. This focused consultation sought substantive comments from trade and professional associations on specific questions, which selected associations (ECA Foundation, IFPMA, ISPE and PDA) have compiled. In parallel to this stakeholder consultation, PIC/S Members were invited to apply (PI 041-1 (Draft 3)) on a trial basis for a new implementation trial period. The Working Group will be reviewing feedback received with a view to finalise PI 041-1 for its adoption by the Committee.

PIC/S PAs also discussed and agreed on how and where other internal guidance documents in development in this field by the Working Group such as a **PIC/S Aide-Memoire on Inspection of Data Management and Integrity** as well as **system-specific guidances** should be published once adopted by the Committee, in line with the need for their access to be restricted to PIC/S Members-only.

A new Working Group for the development of a **PIC/S Aide Memoire on Tissues and Cellular Therapy Products Inspections** was established. This future Aide Memoire is intended for inspection of minimally manipulated human tissues and cells for human applications (ATMPs will not be within its scope).

The Committee noted that the Working Group on the revision of the PIC/S Guidances for Blood, led by Switzerland / Swissmedic, has prepared a draft revision of **PIC/S Good Practice Guidelines for Blood Establishments and Hospital Blood Banks** (PE 005-4 (Draft 1)). The draft revision is based on the Good Practice Guidelines (GPG) for blood establishments drafted by the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM) and the European Commission. It is currently under step 1 of the adoption process (consultation of PIC/S Members). It was also noted that a revision of the **PIC/S Guide to Inspections of Source Plasma Establishment and Plasma Warehouses** (PI 008-3) is in preparation by this Working Group and that PI 008 will not be merged with PE 005, as initially foreseen.

A draft **PIC/S Aide-Memoire on Inspection of Health Based Exposure Limit (HBEL) Assessments and use in Quality Risk Management** was advanced by the UK / MHRA Chair of the Expert Circle on Cross-Contamination in Shared Facilities (CCCISF). Its aim is to support the PIC/S Guideline on Setting Health Based Exposure Limits for Use in Risk Identification in the Manufacture of Different Medicinal Products in Shared Facilities (PI 046-1), which entered into force on 1 July 2018. This new draft Aide Memoire will shortly be submitted to step 1 of the adoption process (consultation of PIC/S PA). In complement to this Aide Memoire, **a transposition of the EMA Questions and Answers** on implementation of risk-based prevention of cross-contamination in production and 'Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' is being considered.

A draft revision of the **PIC/S SOP on Inspection Report Format** (PI 013-3) has been advanced for step 1 of the adoption process (consultation of PIC/S PA). A revision is necessary in order to better align with the Guidance on Classification of Deficiencies (PI 040-1) which entered into force on 1 January 2019. The changes are viewed to be minimal in nature and harmonisation with the EU will be maintained.

The PIC/S Expert Circle on GDP, chaired by UK / MHRA, will finalise the draft **PIC/S Aide-Memoire on Inspection of Manufacturers and Wholesale Distributors for Compliance with GDP** and **draft Q&A for the PIC/S GDP Guide**, which were discussed at its last meeting on 16-18 October 2018 in Madrid (Spain).

The Committee was updated on PIC/S involvement in ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Expert Working Groups, in particular **Q13** (Continuous Manufacturing of Drug Substances and Drug Products) and **E19** (Optimisation of Safety Data Collection) as well as on any recent developments by ICH in the field of GM(D)P which may impact on PIC/S such as **Q12** (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management).

PROGRESS IN THE AMENDMENT OF THE SCHEME

The Committee discussed progress made in the drafting of a future revision of the PIC Scheme (PICS 1/95 (Rev 5)), which gives PIC/S' legal basis as a non-profit association under Swiss law and governs its organisation and functioning (see [Press Release of October 2018](#) for more details on the purpose of the revision).

A revised draft on the proposed revision of the PIC Scheme was discussed by the Committee taking into account comments received from PIC/S Members further to the first draft discussed at the last Committee meeting in September 2018 in Chicago (USA). The adoption of the revised Scheme is planned for the next Committee meeting in November 2019 in Toyama (Japan).

**PIC/S SEMINAR 2019
AND UPDATES IN THE FIELD OF TRAINING**



The Committee was updated on the programme of the **2019 PIC/S Annual Seminar** on "Quality Assurance of Sterile Medicinal Products - PIC/S GMP Guide Annex 1" which will be hosted by Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medicinal Devices Agency (PMDA) in Toyama (Japan) from **13-15 November 2019**. To view the promotional video [click here](#).

The Seminar will focus on **Quality Assurance of Sterile Medicinal Products - PIC/S GMP Guide Annex 1** and will consist of interactive discussions, presentations and workshops. It will be an ideal opportunity for both novice and experienced inspectors to enhance their inspection skills through knowledge sharing and discussion. This Seminar is intended to provide a further understanding of PIC/S GMP Guide Annex 1 based on issues discussed during its ongoing revision and through a case study of sterility assurance. The Seminar will also allow participants to acquire skills on how to make risk based decisions during GMP inspections. Workshops will be supported by the use of videos of practical manufacturing operations in order to stimulate active discussions.

Registrations to the PIC/S Seminar 2019 are now **open [here](#)** (for Medicines Regulatory Authorities only).

The Committee also discussed preparations for the **2020 PIC/S Annual Seminar** which will be hosted by Thailand / Thai FDA in Bangkok (Thailand) in November 2020 and will focus on "How to be a good GMP Inspector" and/or "How Best Practices and Skills could be built into a GMP Inspectorate Unit".

A proposal by Ireland / HPRA to host the **2021 PIC/S Annual Seminar** in Ireland was welcomed by the Committee. As **PIC/S 50th Anniversary** will also take place in 2021, options are being discussed by the Executive Bureau for a combined special event to mark this milestone in conjunction with the 2021 Seminar.

Finland / FIMEA volunteered to host the **2022 PIC/S Annual Seminar**.

The PIC/S Committee was updated by the Sub-Committee on Training (SCT) Chairman, Jacques Morénas (France / ANSM), on the current status of a new survey on **future training priorities** which aims to update, clarify and identify future training priorities for PIC/S - taking also into account priorities identified by EMA / HMA (EEA Heads of Medicines Agencies) - in order to respond to training needs, in particular via the PIC/S Inspectorates' Academy (PIA).



The **PIC/S Inspectorates' Academy (PIA)** is a **Global Capacity Building and Training Initiative** developed by PIC/S Members aiming at delivering inspection excellence through harmonized training in the field of Good Manufacturing Practices (GMP) to ensure that high quality standards for medicinal products are met worldwide in the interest of public health. It provides for:

- Training to improve **inspection expertise** in the manufacturing of medicines and of their distribution
- **for regulators by regulators**, developed on the basis of **PIC/S recognised GMP training experience and expertise** since 1971
- supported by **52 PIC/S Participating Authorities** from all continents
- for more than **2,000 inspectors** worldwide
- offering currently more than **500 training materials** and **250 training videos**
- **Webinars, on-line learning tools, forum** in development
- Library of relevant **GMP references**, and much more.

This Training Initiative, for which a presentation brochure will be published by PIC/S, aims at harmonising and standardising GMP training at an international level through a recognised qualification system. It is being implemented in various stages.

Stage 1 focused on the development of a PIA website and incorporation of PIC/S training materials, for which a view of the user interface is provided below. The PIA website regroups all PIC/S training materials as they are produced.

PIC/S Seminar 2017 on Quality Control Laboratories: How to Inspect, Taipei (Chinese Taipei)

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A02 | QC In-Process Control

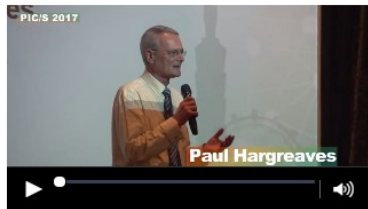
A02 | QC In-Process Control

★★★★★ Total: 1 Average: 5/5

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Speakers

Paul Hargreaves (UK / MHRA)

[Email](#)



Stage 2 is currently under development and comprises the identification of training needs, the development of an international training curriculum as well as the development of e-learning modules responding to specific needs, including possible co-operation with stakeholders.

The Committee was updated by the SCT Chairman on a workplan to develop Stage 2 and notably on work currently being carried out on draft definitions, future possible structure of PIA, future steps in development of training and draft curriculums such as for new inspector for non-sterile manufacture and for new inspector for API manufacture.

Other steps to be developed in co-ordination with interested PIC/S Members concern the future learning management system and e-learning for which several PIC/S Members have already expressed interest and volunteered to share their experience in this field.

Ireland / HPRA is considering reformatting the **PIC/S - HPRA New Inspector Training Courses** which may also include preparatory steps for trainee inspectors, made available via the PIA.

The Committee discussed a draft revision of the **PIC/S Joint Visits Programme (JVP)** guidance documents. Under this training programme, 3 inspectors from 3 different countries are teamed up to observe GMP inspections in each country with a view to comparing inspection procedures and techniques and to harmonise GMP interpretation. The aim of the revision is to clarify and improve the operation of the JVP and merge the current relevant guidance documents. At the end of 2018, there were approximately 19 active PIC/S Joint Visit Groups involving around 57 inspectors. More groups are planned to be established in 2019, particularly in the field of ATMP as well as further to interest expressed in the field of GCP for veterinary clinical products.

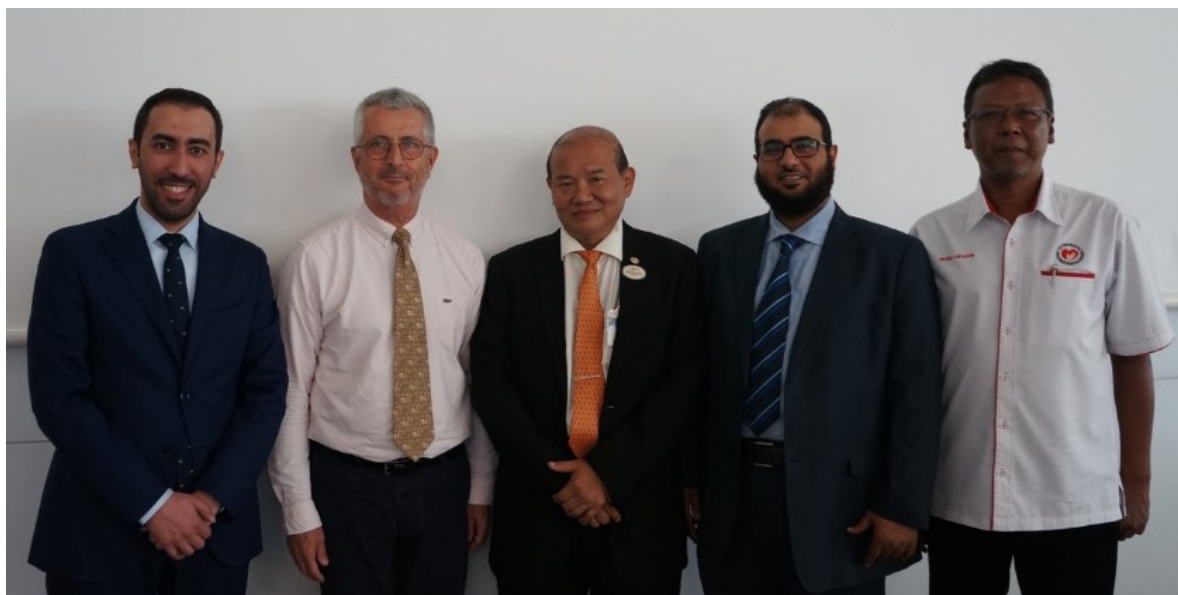
Japan / PMDA reported on the outcome of the PMDA / Japan - Asia Training Center (ATC) GMP Inspection Seminar 2018 on mock-inspections based on risk for biological APIs, which took place in Tochigi (Japan) from 26-30 November 2018, with the support of PIC/S.

BANGLADESH / DGDA APPLIES FOR PRE-ACCESSION

Bangladesh's Directorate General of Drug Administration (DGDA) applied for PIC/S pre-accession on 26 February 2019. A Rapporteur was appointed by the Committee.

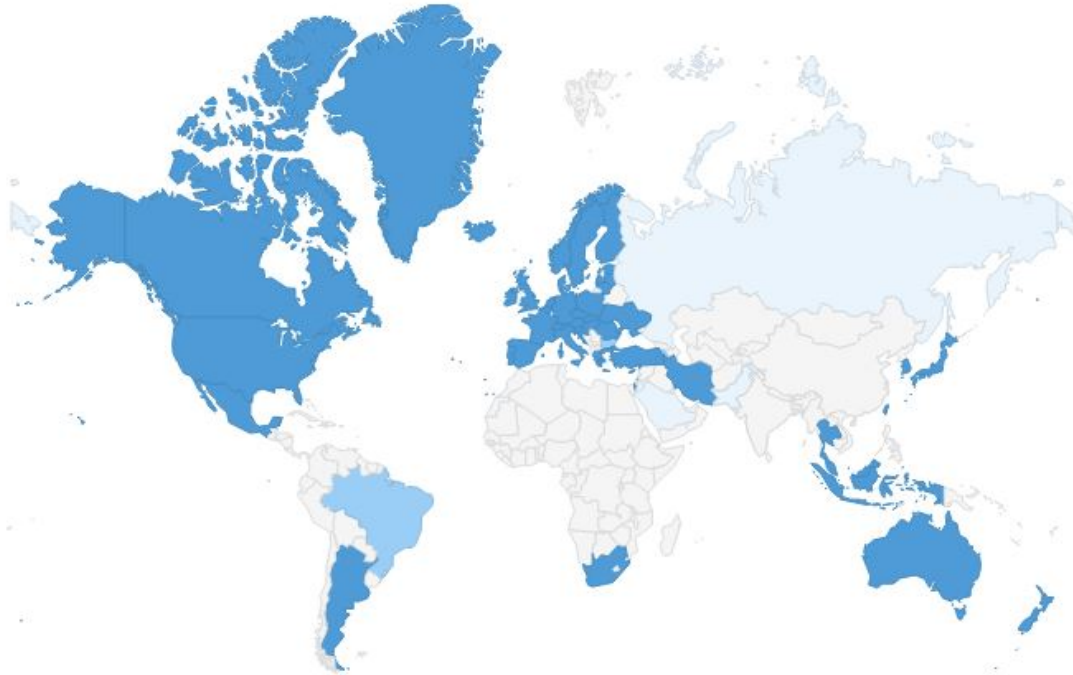
SAUDI ARABIA / SFDA COMPLETES PRE-ACCESSION

The **Saudi Food and Drug Authority (SFDA)** completed its PIC/S pre-accession procedure lodged on 31 July 2017. The Committee endorsed a recommendation by the Rapporteur that Saudi Arabia / SFDA is now ready to apply for PIC/S membership.



From left to right: Mr. Mohammed A. AL-Ageel (Saudi Arabia / SFDA); the PIC/S Rapporteur, Mr. Jacques Morénas (France / ANSM); the PIC/S Chairman, Mr. Boon Meow Hoe (Singapore / HSA); Mr. Mohammed A. Dahhas (Saudi Arabia / SFDA); the PIC/S Co-Rapporteur, Mr. Muhammad Lukmani Bin Ibrahim (Malaysia / NPRA).

ONGOING PIC/S MEMBERSHIP APPLICATIONS



Overview of PIC/S 52 Members as of 1 May 2019 (dark blue); 4 Applicants (medium blue) and 5 (Pre-) Applicants (pale blue)

Applicants (4)

Armenia / SCDMTE
Brazil / ANVISA
Bulgaria / BDA
Italy (Vet) / DGSAF

Pre-Applicants (5)

Bangladesh / DGDA
Jordan / JFDA
Pakistan / DRAP
Russian Federation / Minpromtorg
Russia and FSI "SID&GP"
Saudi Arabia / SFDA

(in alphabetical order, starting with Applicants and then Pre-Applicants).

- An update was given on the status of assessment of the membership application of **Armenia / SCDMTE**;
- **Brazil / ANVISA** reported on the updating of its membership application which it committed to provide during the 1 year clock stop which has ended on 17 April 2019. The PIC/S on-site assessment is scheduled to take place in October 2019;
- The planning of an on-site visit and the possible combination with a Canadian MRA assessment was discussed for the membership application of **Bulgaria / BDA** which will be facilitated through a partial assessment taking into account the audit performed within the EMA Joint Audit Programme, in line with the PIC/S-EEA HMA Letter of Agreement;
- The Committee was updated on the on-site visit which took place on 14-18 January 2019 to observe an inspection on sterile and biological products which was part of the membership application of **Italy (Vet) / DGSAF**, facilitated by a partial assessment, taking into account the audit performed within the EMA Joint Audit Programme, in line with the PIC/S-EEA HMA Letter of Agreement. The assessment report will be provided at the next Committee meeting;

- A Rapporteur was appointed for the pre-accession application of **Bangladesh / DGDA**;
- An update was given on the status of the pre-accession assessment of **Pakistan / DRAP**;
- A new Rapporteur was appointed for the pre-accession application of **Jordan / JFDA**;
- The Rapporteur reported on progress made in the updating of the pre-accession documentation by the **Russian Federation / Minpromtorg Russia and FSI SID&GP** with the Federal Service for Surveillance in Healthcare (Roszdravnadzor);
- The **Philippines / PFDA**, which attended as a guest, reported on the positive outcome of the ASEAN MRA GMP Panel of Experts (PoE) onsite assessment which was completed on 6 April 2019 and on their intent to submit a new PIC/S membership application.

BILATERAL MEETINGS WITH CHINA / NMPA AND ICH

A new bilateral meeting between a Delegation from the PIC/S Executive Bureau and a Delegation from **China's National Medical Products Administration / NMPA** took place on 8 April 2019. The outcome was mutually very constructive in helping to address some issues raised by NMPA in connection with a possible future PIC/S application.



From left to right: Dr. Cui Hao (China / NMPA); Mr. Liu Jingqi (China / NMPA); PIC/S Chairman, Mr. Boon Meow Hoe (Singapore / HSA); Mr. Wang Xiangyu (China / NMPA).



The PIC/S meetings in Geneva also provided the opportunity for a bilateral side-meeting between Delegations from the PIC/S Executive Bureau and the **ICH Management Committee**, allowing to discuss a number of matters of common interest.

From left to right: PIC/S Deputy Chairperson, Ms. Anne Hayes (Ireland / HPRA); ICH representative, Dr. Theresa Mullin (US FDA); ICH Assembly Chair, Ms. Lenita Lindström-Gommers (European Commission); PIC/S Chairman, Mr. Boon Meow Hoe (Singapore / HSA); PIC/S Chair of Sub-Committee on Strategic Development, Ms. Susan Laska (US FDA).

OTHER NEWS

The PIC/S Committee:

- adopted the **PIC/S 2018 Annual Report**, which will be published under “Publications”;
- was updated on the outcome of discussions within the **PIC/S Executive Bureau** meeting on the morning of 9 April 2019, which preceded the Committee meeting;
- was updated on progress made by the **Working Group on Unique Facility Identifiers (UFI)**, led by US FDA and on progress by the **Working Group on Inspector Travel Safety**, led by UK / MHRA;
- adopted a mandate for the **Working Group on Confidential Informants**, which will be co-led by US FDA and UK / MHRA;
- was updated on recent GMP-related developments by **EDQM, EMA, UNICEF** and **WHO** as PIC/S Associated Partner Organisations as well as was updated on current developments with regard to the implementation of the **EU - US Mutual Recognition Agreement (MRA)** ;
- was updated by the PIC/S - ASEAN Liaison Authority, Singapore / HSA, on recent activities within **ASEAN**, in particular, a proposal, already endorsed in principle by the PIC/S Committee, for a non-binding exchange of letters between PIC/S and the ASEAN Pharmaceutical Product Working Group (PPWG) which has been formally approved by the PPWG. This exchange of letters with ASEAN will allow for co-operation between PIC/S and the ASEAN PPWG in GMP matters. The Committee also discussed an issue raised by a PIC/S Member in connection with development in ASEAN of a new ASEAN GMP Guide for Traditional Medicines;
- endorsed a proposal for an informal exchange of letters as a basis for future co-operation with the **World Organisation for Animal Health (OIE)**;
- was informed by the PIC/S Representative in ICH on the outcome of a meeting with the Co-Chairs of the **International Pharmaceutical Regulators Programme (IPRP)**;
- was updated on the development of a checklist to determine the use and **implementation of PIC/S guidance documents** and endorsed the conduct of a survey which will be outsourced;
- appointed the Members of the **Working Group on Quality Defects Procedures** in charge of transposing for PIC/S purposes the revised EMA procedures on (i) Managing Reports of Suspected Quality Defects in Medicinal Products; and (ii) Handling Rapid Alerts Arising from Quality Defects;
- appointed the Members of the **Working Group on Veterinary Medicinal Products (VMP)** which will be led by France / ANSES;
- approved PIC/S’ **2018 Accounts** and was provided an update on the status of the **PIC/S Working Group on Third-Party Funding**;
- was updated on further development of the **Guideline and Interpretation of the Audit Checklist** by the PIC/S Sub-Committee on Compliance, in co-operation with the EU Joint Audit Programme Compliance Group;
- discussed the **new PIC/S Pre-Accession Guidelines** developed by the Working Group on drafting Pre-Accession Guidelines, chaired by France / ANSM, for which adoption will take place by written procedure;

- endorsed the reports of the **PIC/S re-assessments** of Ukraine / SMDC which took place on 22-26 October 2018 and of Argentina / INAME which took place on 5-9 November 2018;
- noted that the report for the **PIC/S re-assessment** of Switzerland / Swissmedic, which was combined with a MRA re-assessment by Health Canada and co-ordinated with the EMA JAP audit of Liechtenstein / AG, for which the on-site visit took place on 15-19 October 2018, will be will be tabled for the next Committee meeting in Toyama;
- appointed the Re-Assessment Team for the **PIC/S re-assessment** of Canada / ROEB in 2019 and discussed the planning also scheduled in 2019 of the **PIC/S re-assessment** of South Africa / SAHPRA;
- noted the need to appoint the Re-Assessment Teams for the **PIC/S re-assessments** of Indonesia / NADFC and New Zealand / Medsafe which will be taking place in 2020;
- was updated on **corrective actions or updates** by recently acceded PIC/S PA or PIC/S PA under Re-assessment;
- noted that the **Working Group on the revision of the Accession Guidelines (and related documents)**, chaired by France / ANSM, will be starting work and will include a representative of the EMA Compliance Group with a view to ensure harmonisation of PIC/S documents with revised JAP documents;
- noted that an **intermediate revision of the PIC/S Guidelines for Accession** (PS/W 14/2011 (Rev. 2)) entered into force on 1 January 2019 in order to align financial information with the revised PIC/S Financial Rules;
- noted that the **Working Group on the revision of PI 011-3** (Computerised Systems) has been put on hold while awaiting the revision of Annex 11 (Computerised Systems) of the PIC/S – EU GMP Guide;
- noted a status activity report by the **Working Group on GCP and GVP**, led by UK / MHRA;
- noted the sending of comments submitted by PIC/S on 17 December 2018 in response to the public consultation for the Draft **ICH guideline Q12** on technical and regulatory considerations for pharmaceutical product lifecycle management;
- noted that the **Guidance on Classification of Deficiencies (PI 040-1)** developed by the Working Group on Classification of Deficiencies, led by Australia / TGA, entered into force on 1 January 2019 and was published on the PIC/S website the same day. The definition of critical deficiency was amended after the meeting to match that currently used by PIC/S in its SOP on inspection report format (PI 013-3) and the EU;
- noted that a side-meeting between the PIC/S Sub-Committee on Training (SCT) Chairman and the Chair of the **ICH Sub-Committee on Training** took place in the margins of the Seminar in Chicago on 26 September 2018 in order to discuss opportunities for co-operation in the field of training between PIC/S and ICH;
- noted that a side-meeting between the PIC/S Sub-Committee on Training (SCT) Chairman and **WHO** is taking place in Geneva on 9 April 2019, in order to discuss opportunities for co-operation in the field of training between PIC/S and WHO;
- noted that the Committee is to reconvene in Toyama (Japan) on 11-12 November 2019 in conjunction with the 2019 Annual Seminar.

COMING UP...

- 19-21 June 2019: **PIC/S Expert Circle on Controlling Cross-Contamination in Shared Facilities (CCCISF) meeting**, in Taipei, hosted by Chinese Taipei / TFDA;
- 7-9 October 2019: **PIC/S Expert Circle on Active Pharmaceutical Ingredients (API) meeting**, in Madrid, hosted by Spain / AEMPS;
- 8-10 October 2019: **PIC/S Expert Circle on Blood, Tissues, Cells and ATMPs meeting**, in Jakarta, hosted by Indonesia / NADFC;
- 13-15 November 2019: **Annual PIC/S Seminar on “Quality Assurance of Sterile Medicinal Products – PIC/S GMP Guide Annex 1”**, in Toyama, hosted by Japan / MHLW & PMDA;
- Date to be defined: **PIC/S - HPRA New Inspector Training Course**, in Dublin, hosted by Ireland / HPRA.

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