PHARMACEUTICAL INSPECTION CONVENTION

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 13/2022
16 May 2022

PIC/S WORK PLAN FOR 2022

Approved by the PIC/S Committee by written procedure, successfully completed on 13 May 2022

1. PIC/S Sub-Committees have been elected for a 2-year term starting on 1 January 2022 and ending on 31 December 2023. The present Work Plan has been prepared by the newly-elected Sub-Committees. As the year has already started, objectives which cannot be completed by the end of 2022, will be rescheduled in 2023.

2. With the planned resumption of face-to-face meetings and events in 2022, the exact dates of a number of PIC/S activities or events have not been determined yet. Once they have been agreed, the dates will be published on the PIC/S website (see https://picscheme.org/en/activities). Subject to the evolution of the COVID-19 pandemic as well as other events such as the war in Ukraine, the dates or the format of PIC/S meetings and events may also need to be adapted.

3. In 2022, the PIC/S Committee will meet face-to-face in Dublin (Ireland) on 3 October 2022 in connection with PIC/S' 50th Anniversary, which will be hosted by Ireland / HPRA the following day (4 October 2022). Attendance to the anniversary will be restricted to invited guests. The anniversary will be the occasion to celebrate 50 years of PIC/S as well as promote and highlight PIC/S' contribution to GMDP. The anniversary will be followed by the 2022 PIC/S Annual Seminar, hosted by HPRA / Ireland, from 5 to 7 October 2022. The seminar's topic will be on "Inspecting the Pharmaceutical Quality System (PQS)".

4. The PIC/S Executive Bureau (EB) will meet virtually as well as face-to-face. A face-to-face meeting is scheduled to take place in Dublin (Ireland) on 2 October 2022 in connection with the CO's meeting the following day.

COMPLIANCE

5. Due to the pandemic and other events, all assessments and reassessment visits have been put on hold in 2020-21. Only a few processes have been able to unfold virtually during the pandemic such as the pre-accession process of China / NMPA, the accession of Bulgaria/ BDA and Saudi Arabia / SFDA or the reassessment of New Zealand / Medsafe. The objective for 2022 is to restart all assessments and reassessments and to reschedule all visits, subject to priorities and the availability of resources.

6. The following Competent Authorities having applied for accession or pre-accession will be assessed / continued to be assessed in 2022 (dates are tentative and may change):

In alphabetical order

Name	Status	Step	By (estimate)
Armenia / SCDMTE	Applicant	Documentation review	Q2 (TBC)
Azerbaijan / AEC	Pre-applicant	Pre-accession assessment	Q2
Bulgaria / BDA	Applicant	On-site assessment visit	Q2-Q3
China / NMPA	Pre-Applicant	Pre-accession assessment	On-going
Jordan / JFDA	Applicant	Documentation review	Q2-Q3
		On-site assessment visit	TBC
Saudi Arabia / SFDA	Applicant	Documentation review	Q2-Q3
		On-site assessment visit	TBC

7. Due to travel restrictions to Russia, the application by the Competent Authorities of Russia, i.e. Minpromtorg, Roszdravnadzor, FSI “SID & GP”, and FSBI "SCEMD”, will be frozen until further notice.

8. The following PA will be reassessed under the PIC/S Joint Reassessment Programme (JRP):

In alphabetical order

Name	Step	Tentative date
Chinese Taipei / TFDA	Nomination of Team	Q2 (TBC)
	Documentation review	Q3-Q4 (TBC)
	On-site reassessment visit	TBC
Indonesia / NADFC	Nomination of Rapporteur	Q2
	Documentation review	Q3-Q4 (TBC)
	On-site reassessment visit	TBC
New Zealand / Medsafe	Desktop assessment	Q2
South Africa / SAHPRA	Documentation review	Q2-Q3 (TBC)
	On-site reassessment visit	Q4 2022- Q1 2023 (TBC)

Note 1: The term “documentation review” refers to the proposed method of evaluation of the Audit checklist (PS/W 1/2005) where a number of indicators can be evaluated remotely. Other indicators can only be reviewed during the on-site reassessment visit, which takes place in the jurisdiction of reassessed Participating Authority. The term “desktop assessment” refers to the possibility to reassess a Participating Authority remotely with no on-site visit.

Note 2: Dates are tentative and may change subject to priorities and availability of resources.

9. All assessment and reassessment activities will be co-ordinated and monitored by the Sub-Committee on Compliance (SCC). While waiting for these activities to unfold, the SCC will focus on completing the revision of guidelines and procedures related to the Accession and Joint Reassessment Programme (JRP).

10. Jointly with the European Commission (EC) and the Joint Audit Programme (JAP) of EEA Heads of Medicines Agencies (HMA), PIC/S will also co-organise a training for JAP-JRP auditors. Closed links will be maintained with the EC, which is developing a programme (EU4Health 2021-2027) covering the (re-)assessment process of EU MS Competent Authorities.

11. Subject to the availability of resources, the SCC will consider proposals for (i) the introduction of an annual reporting system (in order to monitor the continued compliance of PAs with PIC/S requirements); and (ii) the establishment of a list of experienced auditors to assist and advise new rapporteurs and auditors.

12. Contacts will be established (or maintained) with non-Member Competent Authorities, which have signalled an interest in the PIC/S pre-accession process or membership. It will also consider ways on engaging Pre-Applicant Authorities once the process has been completed.

TRAINING AND EXPERT DISCUSSIONS

13. PIC/S will continue to provide training to GMDP inspectors and organise expert discussions on various GMDP topics. The main training event in 2022 will be the annual seminar hosted by Ireland / HPRA in Dublin on 5-7 October 2022. The seminar topic is on "Inspecting the Pharmaceutical Quality System (PQS)".

14. A number of other training events will be organised in 2022 (see paragraphs 17ff). When recorded, training events such as the annual seminar or Expert Circle meetings will also be made available on the PIC/S Inspectorates' Academy (PIA).

15. The implementation and development of PIA, in particular of e-learning modules, will remain a key focus and priority of the Sub-Committee on Training (SCT), which is in charge of monitoring PIA. A number of e-learning modules are currently in preparation such as on QRM / Q9, soft skills, Q12 and JRP-JAP auditor training. A number of curricula for the training and qualification of PIC/S inspectors are also being developed. To meet deadlines, all this will require substantial efforts, notably in the field of human resources. Moreover, the funding and financing of PIA will remain critical to ensure its planned development in line with the PIA Business Case and the PIA Multiannual Budget Plan, both of which will need to be updated.

16. The Sub-Committee on Expert Circles (SCEC) will continue to monitor the activities of the various PIC/S Expert Circles and Working Groups operating under its responsibility.

17. The Expert Circle on Quality Risk Management (QRM) will organise two training events: the first will be hosted by UK / MHRA on 2 March 2022 and consists of a webinar on QRM; the second will held face-to-face in São Paulo and hosted by Brazil / ANVISA from 29 November to 1 December 2022. It will consist of 2-day QRM training (with remote participation) followed by 1-day face-to-face Expert Circle meeting on 2 December 2022. The Expert Circle will continue to work on developing the pilot e-module on QRM for PIA. The Co-ordinating Committee will also continue to revise the PIC/S Aide Memoire on QRM in parallel with the revision of ICH Q9.

18. Subject to the availability of a host, the Expert Circle on Good Distribution Practice (GDP) intends to meet in the course of 2022 or in 2023 at the latest. It will present a revised mandate to the Committee and continue to co-operate with the Working Group on Veterinary Medicinal Product (VMP) on GDP for VMP (see paragraph 36). It also plans to discuss concept papers on GDP-specific issues, which could result in new guidance documents.

19. Subject to the availability of a host, the Expert Circle on Human Blood, Tissues, Cells and ATMP will also try to meet in 2022 and if not, in 2023. It will work jointly with the Working Group on Annex 2 on preparing a training event on the inspection of ATMPs based on the new Annex 2A of the PIC/S GMP Guide. This event is planned to take place in 2023 and will be hosted by Austria / AGES. The Co-ordinating Committee will also work on drafting three PIA training curricula for inspectors specialised in the inspection of (i) ATMPs; (ii) blood

establishments, hospital blood banks and plasma warehouses*; (iii) and tissues & cells establishments*.

* in co-operation with the EU Commission Expert Sub-Group on Inspections in the Blood, Tissues and Cells Sectors (IES)

20. Two new Expert Circles will be established in 2022: one on Clinical Practices (GCP) and one on Good Pharmacovigilance Practices (GVP). The related Co-ordinating Committees will be appointed. Meetings of these new Expert Circles are not foreseen to take place immediately.

21. The Expert Circle on Active Pharmaceutical Ingredients (API) will need to be re-activated and a new Chair elected by the Co-ordinating Committee. Its priority in 2022 will be to finalise the development of an API Curriculum for PIA.

22. The Expert Circle on Controlling Cross Contamination in Shared Facilities (CCCISF) met in December 2021 virtually and the next meeting is not planned to take place in 2022.

23. The Working Group on Veterinary Medicinal Product (VMP) will mainly work on the revision of Annexes 4 & 5 of the EU-PIC/S GMP Guide as well as veterinary specific guidance documents, see paragraph 36.

24. Subject to the availability of human resources, the Joint Visits Programme (JVP) will be restarted while opportunities for joint training events with Partner Organisations (in particular EMA and WHO) and other organisations will continue to be further explored.

HARMONISATION OF GM(D)P

25. The PIC/S GMP Guide will be further revised in close co-operation with the EMA's Inspectors Working Group (IWG) on GMDP. PIC/S normally participates through experts in IWG Drafting Groups in line with the EMA-PIC/S Joint Consultation Procedure. In 2022, the following revisions will be continued / finalised:

GMP Guide	Topic
Chap 1	Pharmaceutical Quality System
Chap 4 & Annex 11	Documentation & Computerised Systems
Annex 1	Sterile Medicinal Products
Annexes 4 & 5	Veterinary medicinal products (VMP) and biologicals

26. The above-mentioned revisions are monitored by the Sub-Committee on GM(D)P Harmonisation (SCH), together with the EMA Inspectors Working Party (IWG) on GMDP.

27. The joint PIC/S-EMA Working Group on Annex 1 – Manufacture of Sterile Products will conclude its work following the foreseen entry into force of the revised Annex 1 by Q2/Q3 2022. The next step may consist in establishing an Expert Circle on Sterile Products with the aim to deliver training to inspectors on Annex 1. If established, this Expert Circle will operate under the responsibility of the SCEC.

28. Following the publication of the concept papers on veterinary specific GMP guidelines, the PIC/S Working Group on Veterinary Medicinal Product (VMP) will temporarily merge with the EMA Drafting Group in order to start with the revision of Annex 4 (Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products) and Annex 5 (Manufacture of Immunological Veterinary Medicinal Products).

29. The SCH will also continue to monitor EU Annex 21 (importation of medicinal products) through the participation of Swissmedic in the Drafting Group. Once finalised, the Committee, based on a recommendation of the SCH, will need to decide whether to adapt this Annex for PIC/S purpose.

30. PIC/S GMDP-related guidance documents will be further revised (or developed) as follows:

Reference	Topic	SC
PI 019 PI 020	PIC/S Site Master File for Source Plasma Establishments (PI 019); PIC/S Site Master File for Plasma Warehouses (PI 020).	SCH
PE 010-4	PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (to add annex on guidance on Total Parenteral Nutrition (TPN))	SCH
PI 006-3	Revision of PIC/S Recommendations on Validation Master Plan; Installation and Operational Qualification; Non-Sterile Process Validation; and Cleaning Validation	SCH
PI 007	Recommendation on Validation of Aseptic Processes	SCH
PI 011	PIC/S Guidance on Good Practices for Computerised Systems in Regulated GxP Environments	SCEC
PI 013	PIC/S Inspection Report	SCH
PI 023-2	Aide Memoire on Inspection of Quality Control Laboratories	SCH
PI 025	Aide Memoire on Medicinal Gases	SCH
PI 030-1	Aide-Memoire on the Inspection of APIs [#]	SCH
PI 043-2	PIC/S Aide Memoire on Controlling Cross-Contamination in Shared Facilities	SCH
PI 050	Aide Memoire on PIC/S Data Integrity System-Specific Guidance: Chromeleon 7 Chromatography Data Systems and Server/Client Systems	SCH

31. The Working Group on Controlling Cross-Contamination in Shared Facilities will continue with the update and revision of the PIC/S Aide Memoire on Controlling Cross-Contamination in Shared Facilities (PI 043).

32. The Working Group on Data Integrity will discuss whether to finalise PI 050 “Aide Memoire on PIC/S Data Integrity System-Specific Guidance: Chromeleon 7 Chromatography Data Systems and Server/Client Systems”.

33. The Working Group on Revision to Blood Guidance Documents will revise the PIC/S Site Master File for Source Plasma Establishments (PI 019) and PIC/S Site Master File for Plasma Warehouses (PI 020).

34. The Working Group on Aide Memoire on Tissues and Cellular Therapy Products Inspection will develop the inspection Aide Memoire for this product class.

35. A focused stakeholder consultation (Step 2) will be organised for the revised version of PI 006-3 “Recommendations on Qualification and Validation”, developed by the Working Group on PI 006-3.

[#] The role of the SCH will be for collaborative support once a draft is available.

36. The Working Group on Veterinary Medicinal Product (VMP) also plans to start developing new veterinary specific guidance in co-operation with EMA (cf. EMA GMDP IWG work plan 2021-2023):

- GMP for Veterinary ATMPs;
- GMP for Autogenous Veterinary Vaccines;
- GDP for API use as starting material for VMP*;
- GDP for VMP*.

* Already in force in the EU / to be transposed for PIC/S purpose

37. Taking in account the recent VICH initiative on mirroring ICH Q7 in a VICH guideline on GMP for the manufacturing of APIs for medicines for veterinary use, the WG on VMP will follow with attention the work done by the existing VICH Quality Expert Working Group that will be responsible for developing this guideline. The goal will be to observe and, if possible, influence discussions in order to contribute to a better international harmonisation for the manufacturing of APIs for medicines for veterinary use.

38. An Aide-Memoire on Inspection of Manufacturers and Wholesale Distributors for Compliance with GDP and Q&A for the PIC/S GDP Guide will be finalised by 2022[#].

39. The Working Group on Annex 2, in co-operation with Austria / AGES, will start with the organisation of training on PIC/S Annex 2A (Manufacture of advanced therapy medicinal products for human use). The training in itself will be provided in 2023.

40. The Sub-Committee will also follow up on some outstanding work, in particular:

- Completing the project on the PIC/S Library; and
- Circulating and evaluating the outcome of a survey to measure the use/implementation of PIC/S guidance documents (whether they are used and useful).

STRATEGIC DEVELOPMENT AND CO-OPERATION

41. The Sub-Committee on Strategic Development (SCSD) will continue to monitor the activities of the five Working Groups, operating under the SCSD, which are:

- Working Group on Unique Facility Identifiers (UFI);
- Working Group on Remote Assessment;
- Working Group on Inspector Travel Safety;
- Working Group on Confidential Informants;
- Working Group on Inspection Reliance.

42. The Working Group on UFI will work on the implementation of its proposal, endorsed by the PIC/S Committee, which is for PIC/S Participating Authorities to collect, verify and use WGS84 geographic coordinates (geocodes) in a specific format in order to aide in the identification of global pharmaceutical manufacturing facilities, for both national and third country inspections. The WG on UFI will gather information on the proposed implementation through a survey.

[#] The role of the SCH will be for collaborative support.

43. The Working Group on Remote Assessment, established in October 2021, will work on harmonising the terminology on remote assessment, inspector's qualifications, and best practices on remote assessment.

44. The Working Group on Inspection Reliance has been established in order to identify barriers that prevent PAs to rely on already existing inspection reports, based on the PIC/S Inspection Reliance Initiative (see PIC/S Guidance on GMP Inspection Reliance: PI 048-1). The Working Group is collecting yearly statistics on the number of GMP inspections waived by Participating Authorities on the basis of a desktop assessment of an existing GMP inspection report or certificate. In 2022, it will revise the template on yearly inspection reliance statistics in order to add specific questions on existing barriers to inspection reliance.

45. The Working Group on Confidential Informants, which has been dormant since the outbreak of the pandemic in 2020, will be reactivated. The Working Group on Inspector Travel Safety will have to elect a new Chair before resuming its activities.

46. Co-operation with Partner Organisations (EC, EMA, EDQM, OIE, UNICEF and WHO) will be further pursued and improved interaction considered in order to avoid the duplication of activities, notably in the field of GMDP training and the drafting of guidance documents.

47. Possibilities to co-operate with other organisations will be further explored, in particular with the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

48. The SCSD will monitor the finalisation of the Memorandum of Understanding (MoU) with the European Commission (EC), which will serve as a basis for future co-operation. Regulatory collaboration will be strengthened with ICMRA, notably through PIC/S' participation in the ICMRA project on PQ-KMS (Pharmaceutical Quality – Knowledge Management System).

49. The SCSD will finalise the draft PIC/S policy on non-political, non-discriminatory organisation, which will be submitted to the Committee for adoption. It will review the classification of PIC/S documents and further discuss the launching of a voluntary pilot on compliance management related to the sharing of information regarding borderline compliance, i.e. cases, where a GMP certificate has been issued but the manufacturer does not fully comply with GMP.

50. Relations with selected Non-Members, having expressed an interest to join PIC/S, will be fostered. Establishing a good working relationship is essential for Competent Medicines Regulatory Authorities to apply for PIC/S membership.

COMMUNICATION AND FINANCES

51. The general objective of the Sub-Committee on Communication (SC COM) will be to improve communication, both internally and externally, notably on social media. A promotional video for PIC/S will be developed as well as tools to measure the utilisation and implementation of PIC/S guidance documents. A call will be made to restart the PIC/S List of Planned Foreign Inspections, which has been put on hold during the COVID-19 pandemic. Ways to enhance the use of the list will be considered in co-ordination with the Working Group on Inspection Reliance.

52. The goals of the Sub-Committee on Budget, Audit & Risk (SCB) will be:

(i) to review the 2021 PIC/S financial accounts and the related financial report by the External Auditor;
(ii) to monitor the 2022 PIC/S finances;
(iii) to separate out PIA finances from PIC/S finances and prepare two separate budgets for 2023: one for PIC/S and one for PIA; and
(iv) to review the multiannual budget plan (2022-24) and propose solutions to cover future financial needs of PIC/S.

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