Agenda Item …

PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 1/2021
8 March 2021

PIC/S WORK PLAN FOR 2021

Approved by the PIC/S Committee by written procedure, successfully completed on 5 March 2021

1. The present Work Plan has been prepared for the year 2021 in line with the goals and priorities defined in the PIC/S Road Map for the period 2018-2020 (see PS/W 23/2016). Some of the goals could not be achieved in 2020 due the COVID pandemic and has thus been rescheduled for 2021.

2. Due to COVID-related uncertainties regarding travelling, dates mentioned in this Note are all indicative (unless a precise date is given). For further details on PIC/S activities, see www.picscheme.org. For PIC/S policy on the organisation of events in 2021 (and beyond), see PS/W 2/2021.

3. In 2021, the PIC/S Committee (CO) will meet twice as follows:

Date	Place	Organised / hosted by
Q2 2021 (20-21 April 2021)	Virtually, by VC	PIC/S Secretariat
Q4	Virtually, by VC (unless agreed otherwise)	PIC/S Secretariat

4. Since the virtual PIC/S Committee meetings will be shorter than the face-to-face meetings, written consultations will be organised by the Secretariat on all issues, which cannot be addressed during the virtual meetings.

5. The PIC/S Executive Bureau (EB) will meet virtually as often as necessary in-between Committee meetings. These meetings will also be supported by written consultations.

COMPLIANCE

6. On 1 January 2021, Brazil's (ANVISA) joined PIC/S to become the 54th Participating Authority (PA).

7. The following Competent Authorities having applied for accession or pre-accession will be assessed (dates are tentative and may change as the pandemic situation evolves):

In alphabetical order

Name	Status	Step	By (estimate)
Armenia / SCDMTE	Applicant	Documentation review	Q1/Q2
		On-site assessment visit	Q3/Q4
Azerbaijan / AEC	Pre-applicant	Pre-accession assessment	Q3 2022
Bangladesh / DGDA	Pre-Applicant	Pre-accession assessment	Q1
Bulgaria / BDA	Applicant	Documentation review	Q1
		On-site assessment visit	Q3/Q4
Jordan / JFDA	Applicant	Nomination of Rapporteur	Q1/Q2
Pakistan / DRAP	Pre-Applicant	Closure of Pre-accession	Q4 2020
Russia / Minpromtorg, Roszdravnadzor, FSI "SID & GP") and FSBI "SCEMD"	Applicant	Nomination of Rapporteur	Q1/Q2
		Document review	Q3/Q4
		On-site assessment visit	2022
Saudi Arabia / SFDA	Applicant	Documentation review	Q1/Q2
		On-site assessment visit	Q3/Q4

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	Documentation review	Q3/Q4
	On-site assessment visit	2022
Indonesia / NADFC	Documentation review	Q2/Q3
	On-site assessment visit	2022
New Zealand / Medsafe	Desktop assessment	Q1
South Africa / SAHPRA	Documentation review	[under discussion]
	On-site assessment visit	[under discussion]

Note that the documentation review refers to the proposed method of evaluation of the Audit checklist (PS/W 1/2005) where indicators could be evaluated remotely. The on-site visit is planned when travels are safe to resume. The term "Desktop assessment" refers to the Joint Reassessment Programme (PS/W 9/2000) where no on-site visit is planned.

9. All assessment and reassessment activities will be co-ordinated and monitored by the Sub-Committee on Compliance (SCC). The SCC will start planning the reassessment of the PIC/S PA, which are next line for re-assessment.

10. The SCC will prepare a proposal for the introduction of an annual reporting system (in order to monitor the continued compliance of PAs with PIC/S requirements).

11. The SCC will consider the implementation of desktop reassessment process.

12. The Working Groups established under the SCC will continue their work in relation with the revision of the Accession and Joint Reassessment Programme (JRP) guidelines

13. The SCC will establish a list of experienced auditors who would be available to assist and advise Rapporteurs and auditors.

14. The SCC will continue to collaborate in the joint PIC/S and EMA Auditors training.

15. The SCC will encourage PAs to participate in the above training session and in the assessment and reassessment activities.

16. Close 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.

17. Priority will also be given by the PIC/S Executive Bureau to conclude the discussions with China / NMPA on its possible membership application.

TRAINING AND EXPERTS DISCUSSIONS

18. PIC/S will provide training to GMDP inspectors and organise experts' discussions on various GMDP topics. The main event will be the virtual annual PIC/S Seminar organised by Korea (Republic of) / MFDS.

19. A number of training events, which were cancelled in 2020, will need to be rescheduled, in 2021, if possible. This is notably the case of the cancelled meeting of the Expert Circle on Good Distribution Practice (GDP), which was supposed to be hosted by Ukraine / SMDC in Kiev, and the New Inspectors Training Course, which was supposed to be organised by Ireland / HPRA in Dublin.

20. The next Expert Circle on Controlling Cross Contamination in Shared Facilities (CCCISF) will be hosted by WHO in Copenhagen (Denmark) in Q3/Q4 2021.Travel restrictions as well as social distancing measures will be taking into account PIC/S' policy (PS/W 2/2021).

21. A possible, virtual training will be organised by the Expert Circle on Human Blood, Tissues, Cells and ATMP jointly with a professional organisation. This training will focus on the new Annex 2A of the PIC/S GMP Guide. It will also include updates on issues related to the inspection of blood, tissues and cells. The new goals and mandate of the Expert Circle will also be submitted to the PIC/S Committee for adoption.

22. The Expert Circle on Quality Risk Management (QRM) will develop a three-day QRM training event for GMP Inspectors, with a view to possibly running it in Q3 or Q4 2021 (virtually or in person, depending on COVID-19 travel restrictions at that time), but may need to be pushed out to 2022. It also plans to complete its work on developing the contents of the e-module on QRM for PIA, in accordance with the plan that was agreed in 2020. For the Expert Circle's work on guidance documents, see paragraph 42 below.

23. The Expert Circle on Active Pharmaceutical Ingredients (API) will focus on the development of an API Curriculum for PIA.

24. The Working Group on Veterinary Medicinal Product (VMP) will mainly work on veterinary specific guidance documents, see paragraphs 43-45 below.

25. The Working Group on Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP) will continue its discussions on whether to establish two separate Expert Circles: one on GCP and one on GVP. If the proposal is endorsed by the WG, it will be submitted to the SCEC and then to the PIC/S Committee for endorsement.

26. When recorded, training events will also be made available on the PIC/S Inspectorates' Academy (PIA). The implementation, development and promotion of PIA, in particular of e-learning modules, will remain a key focus and priority of the Sub-Committee on Training (SCT) as well as the Sub-Committee on Expert Circles (SCEC).

27. Both Sub-Committees intend to further improve their joint efforts in order to ensure that training priorities, identified by PIC/S PA during the 2019 training survey, are fed into the training activities of PIC/S Expert Circles as well as the annual training seminar.

28. Expert Circles and relevant Working Groups will also become more actively involved in the development and design of training curricula, training materials and their continuous updating under PIA in their respective fields of competence, including how to best share knowledge and deliver ongoing training to inspectors.

29. The SCEC will revise the guidelines on Expert Circles in order to respond to the need to review the organisation of Expert Circles and allow for increased flexibility in the composition of their respective Co-ordinating Committees.

30. Opportunities for joint training events with Partner Organisations (in particular EMA and WHO) and other organisations (e.g. ICH and ICMRA) will continue to be explored. In particular, the Working Group on Training Materials for Q12 will organise a webinar for better defining GMP inspector's expectations regarding this guideline in the field of training. Similarly, JRP/JAP auditor training with the EMA will be prioritised.

31. In line with the 2020 PIC/S seminar outcomes and after a call for volunteers, PIC/S will collaborate with the ICMRA WG on "distant assessment" to define common guidelines and possibly, training material.

HARMONISATION OF GM(D)P

32. 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 2021, the following revisions will be continued:

GMP Guide	Topic	IWG- PIC/S	PIC/S
Chap 1	Pharmaceutical Quality System	X	
Chap 4 & Annex 11	Documentation & Computerised Systems	X	
Annex 1	Sterile Medicinal Products	X*	
Annex 2	Biological medicinal substances & products for human use		X*
Annexes 4 & 5	Veterinary medicinal products (VMP) and biologicals	X [#]	

* With WHO

33. The above-mentioned revisions are monitored by the Sub-Committee on GM(D)P Harmonisation (SCH), which will also work on the transposition, for PIC/S purposes, of the revised EU Annex 16 (Certification by a QP & Batch Release). The SCH has completed the transposition of the revised EU Annex 13 on Investigational Medicinal Products (IMP). Both the EU and PIC/S Annex 13 will enter into force at the same time, probably in the second half

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

of 2021. The SCH will also continue to monitor EU Annex 21 (importation of medicinal products) through the participation of Swissmedic in the Drafting Group.

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

Reference	Topic	SC
PE 005-3 PI 008-3 PI 019 PI 020	Revision of PIC/S GMP Guide for Blood Establishments (PE 005-3); PIC/S Guide to Inspections of Source Plasma Establishment and Plasma Warehouses (PI 008-3); 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 041 PI 049 PI 050	PIC/S Guidance good practices for data management and integrity in regulated GMP/GDP environments; Aide Memoire on Inspection of Data Management and Integrity; Aide Memoire on PIC/S Data Integrity System-Specific Guidance: Chromeleon 7 Chromatography Data Systems and Server/Client Systems	SCH
PI 054-1	Recommendation on How to Evaluate / Demonstrate the Effectiveness of a Pharmaceutical Quality System in relation to Risk-based Change Management	SCH

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

36. The Working Group on Annex 1 – Manufacture of Sterile Products will conclude revisions in consideration to stakeholder feedback following the second consultation on this annex.

37. The Working Group for Revision of Annex 2 will complete edits and advance publication of Annex 2A - Manufacture of advanced therapy medicinal products for human use and Annex 2B - Manufacture of biological medicinal substances and products for human use in consideration to stakeholder feedback following the consultation.

38. The Working Group on Data Integrity will review the comments received following the focused public consultation and finalise the “PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments” (PI 041-1). Additional guidance documents for inspectors on data integrity will also be finalised.

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

39. The Working Group on Revision to Blood Guidances 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).

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

41. The Working Group on PI 006-3 will finalise a version of PI 006-3 "Recommendations on Qualification and Validation" for Step 2 of the PIC/S adoption process.

42. The Expert Circle on Quality Risk Management (QRM) plans to complete work on revising the Aide Memoire on Assessment of Quality Risk Management Implementation (PI 038-1). Presentation of the revised version to the PIC/S SCEC and PIC/S SCH, and thereafter to the PIC/S Committee, are foreseen for August 2021, subject to unexpected disruptions relating to Covid-19. The expected timeline to reach Step 2 is projected for February 2022. The Expert Circle will also work on finalising the draft PIC/S Recommendation PI 054-1 on "How to Evaluate / Demonstrate the Effectiveness of a Pharmaceutical Quality System in relation to Risk-based Change Management", by reviewing the comments made during the 12-month consultation and updating the document, as required.

43. The Working Group on Veterinary Medicinal Product (VMP) will continue to work on veterinary specific GMP guidelines (Annex 4 on Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products and Annex 5 on Manufacture of Immunological Veterinary Medicinal Products) through the joint EMA-PICS drafting group.

44. The WG 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

45. Finally, 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 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.

46. 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 prioritised to be finalised during 2021[#].

47. The Sub-Committee will also continue with some of the priorities, established under the 2018-2020 Roadmap, in particular:

- Completing the project on the PIC/S Library;
- Strengthening PIC/S position in areas such as GDP, ATMP, VMPs, IMPS, etc.;
- Establishing instruments to measure the use/implementation of guidance documents (whether they are used and useful).

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

STRATEGIC DEVELOPMENT AND CO-OPERATION

48. In 2021, the Sub-Committee on Strategic Development (SCSD) will continue to give priority to the implementation and further development of its Inspection Reliance Initiative, which is based on the PIC/S Guidance on GMP Inspection Reliance (PI 048-1).

49. Although the implementation of the guidance is voluntary, PIC/S has agreed to monitor its use in practice, notably by collecting statistics on the number of GMP inspections waived on the basis of a desktop assessment of an existing GMP inspection report or certificate. The statistics were collected for the first time in early 2020 for the year 2019. They will be collected again in early 2021, based on data from 2020. The SCSD will review the outcome of the survey based on a revised questionnaire.

50. The SCSD will launch 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.

51. In addition to this, the SCSD – in co-operation with the SC COM – will consider means to encourage the use of the PIC/S List of Planned Foreign Inspections, which is an essential tool to reduce the number of same scope inspections. A survey will be carried out on the use of the list – in particular how many PA consult the PIC/S list before scheduling inspections and/or reaching out to other PA to determine whether joint inspections are possible. The possibility of collecting data on either joint inspections or the sharing of inspection data will also be considered.

52. The following four Working Groups, operating under the SCSD, will continue their work:

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

53. As the year before, PIC/S will further co-operate with its Partner Organisations, i.e. EMA, EDQM, OIE, UNICEF and WHO, and consider possible ways of better interacting with them in order to avoid the duplication of activities, notably in the field of GMDP and training.

54. Possibilities to co-operate with other organisations will be further explored such as the European Commission, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or the ASEAN Product Working Group (PWG) on Traditional Medicine and Health Products (TMHP).

55. Continued attention will be paid to establish relations with Non-Members of PIC/S, which are considered of “strategic” importance, i.e. countries which are large exporters of APIs or generic drugs such as India. Establishing a good working relationship is essential for Competent Medicines Regulatory Authorities to apply for PIC/S membership.

56. The SCSD will review the classification of PIC/S documents based on a Note by the Secretariat, which needs to be revised before being added to the Compilation of PIC/S Documents.

COMMUNICATION AND FINANCES

57. The general objective of the Sub-Committee on Communication (SC COM) will be to improve communication, both internally and externally. It will support initiatives that facilitate communication between PAs (e.g. ICH SOP, 'borderline cases' pilot for inspection reliance) and with Heads of Agencies to get increased support. 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 presence on professional social media will also be established and the effects of this on PIC/S' external profile will be monitored.

58. In addition, following a recent revision of its mandate, the SC COM will co-ordinate all activities related to the ICH.

59. The goals of the Sub-Committee on Budget, Audit & Risk (SCB) in 2021 will be to review the External Auditor's financial report on the 2020 financial accounts; to monitor PIC/S' finances in 2021 – including PIA income and expenses; to prepare the annual budget for 2022; and to implement the multiannual budget plan (2021-23), including the proposed fee increase.

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