PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 37/2019
1 January 2020

PIC/S WORK PLAN FOR 2020

Approved by the PIC/S Committee
at its meeting in Toyama on 11-12 November 2019

1. The present Work Plan has been prepared for the year 2010 in line with the goals and priorities defined in the PIC/S Road Map for the period 2018-2020 (see PS/W 23/2016). Indicated dates are confirmed while timelines (e.g. "by Q4") are estimates. For further details on PIC/S activities, see www.picscheme.org.

2. In 2010, the PIC/S Committee (CO) and the PIC/S Executive Bureau (EB) will meet as follows:

Date	Place	Meeting	Organised / hosted by
21 April 2020	Geneva (CH)	PIC/S EB	PIC/S Secretariat
21-22 April 2020	Geneva (CH)	PIC/S CO	PIC/S Secretariat
16 November 2020	Bangkok (Thailand)	PIC/S EB	Thai FDA
16-17 November 2020	Bangkok (Thailand)	PIC/S CO	Thai FDA

COMPLIANCE

3. On 1 January 2020, Italy's Directorate General for Animal Health and Veterinary Medicinal Products (DGSAF) will join PIC/S to become the 53rd Participating Authority (PA).

4. In 2020, the following Competent Authorities having applied for accession or pre-accession will be assessed:

In alphabetical order

Name	Status	Step	By (estimate)
Armenia / SCDMTE	Applicant	Paper assessment	Q1/Q2
		On-site assessment visit	Q3/Q4
Bangladesh / DGDA	Pre-Applicant	Gap analysis / pre-accession assessment in line with new procedure	Q3/Q4
Brazil / ANVISA	Applicant	Review of assessment visit report by SCC and CO	Q1/Q2

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Bulgaria / BDA	Applicant	On-site assessment visit	Q1
		Review of assessment visit report by SCC & CO	Q3/Q4
Jordan / JFDA	Pre-Applicant	Review of gap analysis by SCC & CO	Q1/Q2
Pakistan / DRAP	Pre-Applicant	Gap analysis by Rapporteur	Q1/Q2
Russian Federation / Minpromtorg & FSI SID&GP	Pre-Applicant	Closure of Pre-accession	Q4 2019 / Q1 2020

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

In alphabetical order

Name	**Approx. Date of On-Site Assessment Visit**	**Report and FUP discussed by SCC and CO**
Indonesia / NADFC	Second half of 2020*	2021*
New Zealand / Medsafe	November 2020*	2021*
South Africa / SAHPRA	June 2020*	Q4 2020*

* subject to confirmation

6. 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.

7. The SCC will also consider the possible introduction of an annual reporting system (in order to monitor the continued compliance of PAs with PIC/S requirements) and define the procedure for desk-top re-assessments.

8. The Working Groups established under the SCC will continue their work in relation with the revision of the Accession / Pre-Accession Guidelines and the interpretation of the audit checklist.

9. The SCC will establish a resource pool of expert auditors who would be available to assist and advise Rapporteurs and auditors. It will also consider ways on engaging Pre-Applicant Authorities once the process has been completed.

10. 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.

TRAINING AND EXPERTS DISCUSSIONS

11. PIC/S will provide training to GMDP inspectors and organise experts' discussions on various GMDP topics. For the full list, see table below. The main event will be the annual PIC/S Seminar in Bangkok (Thailand) on 18-20 November 2020 on "How to be a Good GMP Inspector in 2020".

Training Events

Date	Place	Activity	Organised by
26-28 May 2020	Kyiv (Ukraine)	Expert Circle on GDP	SMDC
18-20 November 2020	Bangkok (Thailand)	Seminar on How to be a Good GMP Inspector in 2020	Thai FDA
TBD	Dublin (Ireland)	New Inspectors Training Course	HPRA
TBD		Expert Circle on Quality Risk Management (QRM)	
TBD		Expert Circle on Controlling Cross Contamination in Shared Facilities (CCCISF)	

12. If recorded, these events will also be made available on the PIC/S Inspectorates' Academy (PIA). The implementation and development of PIA, in particular of a PIA training programme and its related curricula, training and qualification tools and materials such as e-learning modules, will remain a key focus and priority of the Sub-Committee on Training (SCT) in 2020 and of the most important challenges will be its funding.

13. The SCT also plans in 2020 to further improve communication with the Sub-Committee on Expert Circles (SCEC) in order to ensure training priorities identified by PIC/S PA, as outcome from the additional survey carried out in 2019 are fed into the training activities of PIC/S Expert Circles.

14. The Sub-Committee on Expert Circles (SCEC) will revise the guidelines on Expert Circles, which are too restrictive in certain areas, in order to respond to the need to review the organisation of Expert Circles and allow for increased flexibility in composition and structure as well as facilitate the expansion of their respective Co-ordinating Committees membership.

15. 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, who cannot attend face-to-face Expert Circle training events.

16. Opportunities for joint training events with Partner Organisations (in particular EMA and WHO) and other organisations (e.g. ICH) will continue to be explored.

HARMONISATION OF GM(D)P

17. 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 2020, 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]*	

* TBC / not established yet
** with WHO

18. 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, the revised EU Annex 13 on Investigational Medicinal Products (IMP) and EU Annex 16 (Certification by a QP & Batch Release).

19. 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 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 043 PI 052 PI 053	Aide Memoire on Cross-Contamination in Shared Facilities; Aide Memoire on Inspection of Cross Contamination in Shared Facilities; Aide Memoire on HBEL Exposure Limits and HBEL Q&A	SCH

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

21. The Working Group on Data Integrity will review the comments received following the focused public consultation on the draft “PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments” (PI 041-1 (Draft 3)). Additional guidance documents for inspectors on data integrity will also be finalised.

22. 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).

23. 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 hopefully finalised during 2020.

24. The PIC/S Committee will also continue with the priorities established under the 2018-2020 Roadmap to:

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

STRATEGIC DEVELOPMENT AND CO-OPERATION

25. In 2020, the Sub-Committee on Strategic Development (SCSD) will monitor the implementation of the revised PIC Scheme, which will be adopted at the Toyama Committee meeting. The revised PIC Scheme will enter into force on 1 January 2020.

26. The SCSD will carry out a first assessment of the PIC/S Guidance on GMP Inspection Reliance (PI 048-1). Although the implementation is voluntary, PIC/S has agreed to monitor the use of the guidance, notably by collecting statistics. The latter, covering the year 2019, will be collected in early 2020 and assessed by the SCSD. A summary will be circulated.

27. In addition to this, the SCSD 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. Encouraging joint inspections under the PIC Scheme is one of the objectives set under the 2018-20 Road Map. The possibility of collecting data on either joint inspections or the sharing of inspection data will also be considered.

28. The SCSD will launch a voluntary pilot on 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.

29. The following three 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

30. As the year before, PIC/S will further co-operate with its Partner Organisations, i.e. EMA, EDQM, 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.

31. Exchanges of letters, setting the basis for future co-operation, will be finalised with the ASEAN Pharmaceutical Product Working Group (PPWG) as well as with the World Organisation for Animal Health (OIE).

32. The possibility to co-operate with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as well as the ASEAN Product Working Group (PWG) on Traditional Medicine and Health Products (TMHP) will be further explored.

33. High priority will be given to relations with China / NMPA and India / CDSCO. A large number of medicinal products, in particular APIs, is imported from these two countries and the GMP compliance of their products impacts on all PIC/S PA. Forging strong working relationships with NMPA and CDSCO is essential, as it will set a confidence level necessary for them to apply for PIC/S membership.

COMMUNICATION AND FINANCING

34. The general objective of the Sub-Committee on Communication (SC COM) will be to improve communication (both internally and externally). This will include better communicating with HoA 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.

35. The goals of the Sub-Committee on Budget, Audit & Risk (SCB) in 2020 will be to review the External Auditor's financial report on the 2019 financial accounts; to monitor PIC/S' finances in 2020; to have more detailed information on PIA income and expenses; and to prepare the annual budget for 2021 and the multiannual budget plan (2021-23).

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