PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 18/2018
1 January 2019

PIC/S WORK PLAN FOR 2019

Note by the Secretariat
(reviewed by the SC COM and the EB)

1. The present Work Plan has been prepared for the year 2019 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.

ORGANISATIONAL MATTERS

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

Date	Place	Meeting	Organised / hosted by
9 April 2019	Geneva (CH)	PIC/S EB	PIC/S Secretariat
9-10 April 2019	Geneva (CH)	PIC/S CO	PIC/S Secretariat
11 November 2019	Toyama (Japan)	PIC/S EB	MHLW & PMDA
11-12 November 2019	Toyama (Japan)	PIC/S CO	MHLW & PMDA

3. Elections will be held at the PIC/S Committee meeting in Toyama (Japan) in order to elect a new Chair and a new Deputy Chair as well as to renew the Executive Bureau and the Sub-Committees for the period 2020-21.

4. PIC/S Sub-Committees (SCs) and Working Groups (WGs) will operate by means of teleconferences or e-mails. Efforts will be made to streamline SCs and WGs' activities, in particular the reporting to the PIC/S Committee. The issue of whether to space out meetings of the PIC/S Committee (to allow sufficient time for SCs and WG to prepare an input) will be discussed.

5. Subject to the PIC/S Committee's agreement, the PIC Scheme (PIC/S' constitution) will be revised in order to clarify the definition of Members as well as the legal status of PIC/S. The process should be completed by Q4.

COMPLIANCE

6. In 2019, the following Competent Authorities having applied for accession or pre-accession will be assessed:

In alphabetical order

Name	Status	Going through	By (estimate)
Armenia / SCDMTE	Applicant	Paper assessment	Q2
		On-site assessment visit	Q4
Brazil / ANVISA	Applicant	Update of application	Q1
		Paper assessment	Q3
		On-site assessment visit	Q4
Bulgaria / BDA	Applicant	Paper assessment	Q1
		On-site assessment visit	*TBD*
Italy (Vet) / DGSAF	Applicant	On-site assessment visit	Q1
Jordan / JFDA	Pre- Applicant	Clarification of PIC/S requirements*	Q4
Pakistan / DRAP	Pre- Applicant	Clarification of PIC/S requirements*	Q2
Russian Federation / Minpromtorg & FSI SID&GP	Pre- Applicant	Update of application & checklist	Early Q1
		Closure of Pre-accession*	Q2
Saudi Arabia / SFDA	Pre- Applicant	Closure of Pre-accession*	Q1

* subject to discussions in Chicago

7. The following Participating Authorities (PAs) 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
Argentina / INAME	5-9 November 2018	By Q2 2019
Canada / RORB	Q1 2019	Q2 or Q3 2019
South Africa / SAHPRA	TBD	By Q4 2019 at the latest
Switzerland / Swissmedic	15-19 October 2018	By Q2 2019
Ukraine / SMDC	22-26 October 2018	By Q2 2019

8. All assessment and reassessment activities will be co-ordinated and monitored by the Sub-Committee on Compliance (SCC). The latter will also discuss the possible introduction of an annual reporting system in order to monitor the continued compliance of PAs with PIC/S requirements.

9. 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.

10. Close contacts will be established (or maintained) with non-Member Competent Authorities, which have signalled an interest to join PIC/S, in particular China / NMPA and India.

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 Toyoma (Japan) on 13-15 November 2019 on "Quality Assurance of Sterile Medicinal Products – Annex 1".

Training Events

Date	Place	Activity	Organised by
19-21 June 2019	Taipei (Chinese Taipei)	Expert Circle on Controlling Cross Contamination in Shared Facilities (CCCISF)	TFDA
13-15 November 2019	Toyama (Japan)	Seminar on Quality Assurance of Sterile Medicinal Products – Annex 1	MHLW & PMDA
Q3 2019	Dublin (Ireland)	New Inspectors Training Course	HPRA
Q3 2019	Spain	Expert Circle on Active Pharmaceutical Ingredients (API)	AEMPS
Q3 2019	Indonesia	Expert Circle on Human Blood, Tissues, Cells and ATMPs	NADFC
TBD		Expert Circle on Quality Risk Management (QRM)	
TBD		Expert Circle on GDP	

12. If recorded, these events will also be made available on the PIC/S Inspectorates' Academy (PIA), which will be further developed, in particular with regard to a Training Curriculum for PIC/S Inspectors. This training programme will have three segments: basic training for new inspectors; specialised training for more experienced inspectors; and ongoing training for all inspectors. Training priorities under PIA will be confirmed by an additional survey to be carried out by the Sub-Committee on Training (SCT). An information brochure on PIA will be issued by Q1. The development of PIA will be a priority for PIC/S in 2019.

13. A new Expert Circle on Veterinary Medicinal Products (VMP) will be established.

14. The guidelines of the Joint Visits Programme (JVP) will be revised by the SCT while the guidelines on Expert Circles will be revised by the Sub-Committee on Expert Circles (SCEC).

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

HARMONISATION OF GM(D)P

16. The PIC/S GMP Guide will be further revised in close co-operation with the EMA's Inspectors Working Party (IWP) on GMDP. PIC/S normally participates through experts in IWG Drafting Groups in line with the EMA-PIC/S Joint Consultation Procedure. In 2019, the following revisions will be initiated, respectively 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]*	
Annex 21	Importers of medicinal products	X	

* TBC / not established yet

** with WHO

17. The above-mentioned revisions are monitored by the Sub-Committee on GM(D)P Harmonisation (SCH), which will also work on transposing, for PIC/S purposes, the revised EU Annex 13 on Investigational Medicinal Products (IMP) and EU Annex 16 (Certification by a QP & Batch Release).

18. PIC/S GMDP-related guidance documents will be further revised as follows:

Reference	Topic	SC
PE 005-3 & PE 008-3	Revision of PIC/S GMP Guide for Blood Establishments (PE 005-3) and PIC/S Guide to Inspections of Source Plasma Establishment and Plasma Warehouses (PE 008-3)	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 011	PIC/S Guidance on Good Practices for Computerised Systems in Regulated GxP Environments	SCEC
PI 023-2	Aide Memoire on Inspection of Quality Control Laboratories	SCH
PI 030-1	Aide-Memoire on the Inspection of APIs	SCH

19. The PIC/S Guidance on Classification of Deficiencies (PI 040-1) will enter into force on 1 January 2019.

20. 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.

21. An Aide-Memoire on Inspection of Manufacturers and Wholesale Distributors for Compliance with GDP and Q&A for the PIC/S GDP Guide should also be finalised in the course of 2019.

STRATEGIC DEVELOPMENT AND CO-OPERATION

22. In 2019, the Sub-Committee on Strategic Development (SCSD) will finalise the revision of the PIC Scheme (see paragraph 5 above) following a consultation of PIC/S PAs and a review of possible comments.

23. The SCSD will also work on the implementation of the recently adopted Guidance on GMP Inspection Reliance (PI 048-1) and monitor its voluntary implementation, as requested by the International Coalition of Medicines Regulatory Authorities (ICMRA), notably by collecting statistics on the application of the Guidance. It will monitor the work of the following three Working Groups:

- Working Group on Unique Facility Identifiers (UFI)
- Working Group on Inspector Travel Safety
- Whistle-blowers / Confidential Informants

24. 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.

25. PIC/S will also work on establishing a basis for co-operation with the ASEAN Pharmaceutical Product Working Group (PPWG). Co-operation with other organisations (such as ICH) as well as with non-Members such as China / NMPA and India (see paragraph 10) will be further strengthened.

COMMUNICATION AND FINANCING

26. PIC/S will endorse a revised Standard PIC/S Presentation as well as a Stakeholder Mapping prepared by the Sub-Committee on Communication (SC COM). A Working Group on Quality Defects Procedures will be established to transpose 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.

27. PIC/S finances will further be consolidated following the increase of the annual membership fee in 2019. The additional income will be used to finance PIA (see paragraph 10). The Working Group on Third Party-Funding, which should become operational in early 2019, will explore additional sources of income (e.g. donations). This Working Group is placed under the Sub-Committee on Budget, Risk and Audit (SCB). The SCB will also review the External Auditor's financial report on the 2018 financial accounts, monitor PIC/S' finances in 2019 and prepare the annual budget for 2020 as well as the multiannual budget plan (2020-22).

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