News

Archives

November 2023

New PIC/S Chairperson and Executive Bureau

Geneva, 20 November 2023:

A new PIC/S Chairperson and Executive Bureau were elected as from 1 January 2024 by the PIC/S Committee at its meeting in Bangkok (Thailand) on 6-7 November 2023.

At this occasion, the PIC/S Committee unanimously elected Mr Jacques Morénas (France / ANSM) as Chairperson for the period 2024-2025. Mr Morénas will be assisted by Ms Kathleen Sinninger (US FDA), PIC/S Deputy Chairperson. The full Executive Bureau for the period 2024-2025 consists of:

- **Mr Jacques Morénas** (France / ANSM), PIC/S Chairperson;
- **Ms Kathleen Sinninger** (US FDA), PIC/S Deputy Chairperson and Chair of the Sub-Committee on Expert Circles (SCEC);
- **Mr Paul Gustafson** (Canada / ROEB), immediate past PIC/S Chairperson;
- **Dr Kentaro Hara** (Japan / PMDA), Chair of the Sub-Committee on Communication (SC COM);
- **Mr Henning Willads Petersen** (Denmark / DKMA), Chair of the Sub-Committee on Compliance (SCC);
- **Ms Jennifer Burnett** (Australia / TGA), Chair of the Sub-Committe on Strategic Development (SCSD);
- **Dr Theresa Mullin** (US FDA), Chair of the Sub-Committee on Budget, Risk and Audit (SCB);
- **Mr Boon Meow Hoe** (Singapore / HSA), Chair of the Sub-Committee on Training (SCT); and
- **Ms Ying-Hua (Ellen) Chen** (Chinese Taipei / TFDA), Chair of the Sub-Committee on GM(D)P Harmonisation (SCH).

The PIC/S Committee elected the Members, Deputy Chairs and Chairs of the PIC/S Sub-Committee structure for the period 2024-2025. Office holders were elected for the following seven Sub-Committees: Training (SCT); Expert Circles (SCEC); Strategic Development (SCSD); Compliance (SCC); GM(D)P Harmonisation (SCH); Budget, Risk and Audit (SCB) and Communication (SC COM). All Sub-Committee Chairs will be Members of the PIC/S Executive Bureau as listed above.

With **more than 90 Sub-Committee Members** for the period 2024-25, PIC/S has a truly global representation to support diverse perspectives that will help excel on its mission in the interest of public health.

February 2026

Concept paper on the revision of EU-PIC/S GMP Annex 6 - Manufacture of medicinal gases

Geneva, 12 February 2026:

The joint EMA - PIC/S drafting group has developed a **concept paper on the revision of the Annex 6 (Manufacture of medicinal gases)** of the EU-PIC/S GMP Guide.

This concept paper aims to outline the rationale, objectives, and proposed changes for updating the Annex 6 - Manufacture of medicinal gases, of the Good Manufacturing Practice (GMP) Guide, that is common to the Member States of the European Union (EU) / European Economic Area (EEA), as well as to the Participating Authorities (PAs) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

The aim of the revision is to carry out a limited review and update of the guideline to reflect industry's current practices, including the use of new technologies and computerized systems.

This concept paper is submitted to a joint EMA - PIC/S public consultation **from 11 February 2026 until 11 April 2026** and can be downloaded on the PIC/S website (link) as well as on the EMA website (link).

Comments should be submitted via the EU Survey tool (link) in accordance with the PIC/S - EMA Harmonised Consultation Procedure.

February 2026

Concept paper on the revision of EU-PIC/S GMP Annex 15 (Qualification and validation)

Geneva, 10 February 2026:

The joint EMA - PIC/S drafting group has developed a **concept paper on the revision of the Annex 15 (Qualification and validation)** of the EU - PIC/S GMP Guide.

This concept paper aims to outline the rationale, objectives, and proposed changes for updating the Annex 15 - Qualification and validation, of the Good Manufacturing Practice (GMP) Guide, that is common to the Member States of the European Union (EU) / European Economic Area (EEA), as well as to the Participating Authorities (PAs) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

The aim of the revision is to extend the scope of the annex to active substances manufacturers and to consider the revision of ICH Guideline Q9 (R1) on quality risk management.

This concept paper is submitted to a joint EMA - PIC/S public consultation **from 9 February 2026 until 9 April 2026** and can be downloaded on the PIC/S website (link) as well as on the EMA website (link).

Comments should be submitted via the EU Survey tool (link) in accordance with the PIC/S - EMA Harmonised Consultation Procedure.

February 2026

Kazakhstan applies for PIC/S membership

Geneva, 10 February 2026:

On 20 March 2025, Kazakhstan's **Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan** ("**CMPC**") and the **State Enterprise on the right of economic management** "**National center for expertise of medicines and medical devices**" ("**NCEM**") of the Committee applied for PIC/S membership.

The application request was confirmed as complete at the PIC/S Committee meeting in Hong Kong (Hong Kong SAR, China) on 3-4 November 2025, further to which a Rapporteur and Co-Rapporteur were appointed.

February 2026

Ghana applies for PIC/S pre-accession

Geneva, 3 February 2026:

The Ghana Food and Drugs Authority has applied for PIC/S pre-accession.

The pre-accession process started on 4 November 2025 following the appointment of a Rapporteur, which marks the start of the pre-accession process under the revised PIC/S pre-accession procedure.

January 2026

Jordan / JFDA joins PIC/S

Geneva, 1 January 2026:

On 1 January 2026, the **Jordan Food & Drug Administration (JFDA)** became the 57th PIC/S Participating Authority.

JFDA submitted a complete membership application in January 2021, after successfully completing the pre-accession process. A paper assessment was carried out followed by an on-site assessment visit, which took place in April 2025. The Audit team recommended to the Committee to accept the PIC/S membership application of JFDA. After endorsement by the PIC/S Sub-Committee on Compliance (SCC), the PIC/S Committee then unanimously decided at its meeting in Hong Kong on 3-4 November 2025 on the participation of JFDA in PIC/S as of 1 January 2026.

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