

TERMS OF REFERENCE OF THE PHARMACEUTICAL PRODUCT WORKING GROUP (PPWG)

Background

The ASEAN Consultative Committee for Standards and Quality (ACCSQ) was formed by the ASEAN Economic Ministers (AEM) in 1992 to facilitate the implementation of the Common Effective Preferential Tariff (CEPT) Scheme for ASEAN Free Trade Area (AFTA) through reduction of technical barriers to trade.

The Pharmaceutical Product Working Group (PPWG) was established following the recommendation from the 13th ACCSQ Meeting (held from 18-19 March 1999 in Manila, Philippines) to the SEOM 1/30 (held from 28-30 January 2000 in Jakarta, Indonesia) to establish a product working group to facilitate economic integration initiatives for pharmaceutical products without compromising their safety, efficacy and quality.

In 2008, PPWG concluded harmonized requirements of ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR). In 2009, the PPWG concluded the ASEAN Sectoral MRA for Good Manufacturing Practice (GMP) Inspection of Manufacturers of Medicinal Products in 2008 which was signed by the ASEAN Economic Ministers (AEM) on 10 April 2009 during the 14th ASEAN Summit. In 2016, PPWG concluded the ASEAN Sectoral MRA on Bio-equivalence (BE) Study report for Generic Medicinal Products, which was signed by the AEM in November 2017.

Article 1 – Objective

1. The PPWG shall function as the focal point within ASEAN Economic Community (AEC) to facilitate the development of strategies and integration initiatives/approaches to support: (i) reduction of technical barriers to trade in the pharmaceutical products and (ii) access to pharmaceutical products, without compromising the safety, efficacy and quality of pharmaceutical products placed in the ASEAN market.

Article 2 – Scope

2. The scope of the PPWG shall include the following:
- 2.1 Development of regional strategies for the harmonisation and convergence of regulatory standards and technical requirements, guidelines and development of appropriate MRAs for pharmaceutical products;
 - 2.2 Overseeing and monitoring, where appropriate, the implementation of the harmonisation and convergence initiatives and measures whilst also addressing the implementation gaps that may hinder the achievement of the objective;
 - 2.3 Identification of appropriate technical assistance and capacity building programmes to enhance capability in the implementation of harmonised and converged approaches through close cooperation with Member States, relevant

stakeholders, Partner Development Agencies and Dialogue Partners within the framework for cooperation and harmonisation.

Article 3 – Roles and functions

- 3.1 The PPWG shall develop and review harmonised technical requirements and procedures in line with international standards and best practices for pharmaceutical products.
- 3.2 The PPWG shall identify new areas for harmonisation and convergence of pharmaceutical products, including mutual recognition arrangements for conformity assessment.
- 3.3 The PPWG shall monitor and evaluate the effective implementation of the harmonised technical requirements and procedures, including the ASEAN Sectoral MRAs, through its relevant sub-groups.
- 3.4 The PPWG shall strengthen the information sharing platform on safety and quality of pharmaceutical products, including the Post Market Alert System covering pharmaceutical products as well as other relevant healthcare products.

Article 4 – Structure

- 4.1 The PPWG shall comprise of:
 - 4.1.1 Chair and Vice Chair, who shall not be from the same ASEAN Member State;
 - 4.1.2 Heads of Delegation (HOD) from National Drug Regulatory Authorities (NDRA) from each ASEAN Member State;
 - 4.1.3 Chair/Vice-Chair of PPWG sub-groups (Joint Sectoral Committees (JSCs), expert groups/technical committees);
 - 4.1.4 Representatives from the ASEAN Secretariat;
- 4.2 The HOD may be accompanied by their official delegations at the meeting of PPWG.
- 4.3 The current structure of PPWG (as of December 2017) is attached as **ANNEX 1**.

Article 5. Meeting and Procedure of PPWG

- 5.1 The decisions of the PPWG Meeting shall be achieved only through the consensus of the Heads of Delegation or their designated representatives.

- 5.2 The PPWG may form sub-groups, i.e expert committees, JSC in case of implementation of MRA, to undertake detailed work activities and deliberation on technical issues delegated by the PPWG, leading to recommendations for actions, which will be submitted to PPWG for review and endorsement prior to implementation.
- 5.3 The PPWG may invite the following Parties, whenever appropriate, depending on the issues, with endorsement of PPWG HODs and to be coordinated by the ASEAN Secretariat:
- 5.3.1 Representative (s) from other relevant international/regional organizations/ASEAN Partner Development Agencies, such as WHO;
 - 5.3.2 Representative (s) from ASEAN Dialogue Partners;
 - 5.3.3 Representative from ACCSQ and/or its WGs/PWGs as well as other relevant ASEAN Sectoral Bodies, such as Health Cluster 3;
 - 5.3.4 Representatives from national pharmaceutical industry and national pharmaceutical industry associations, who are based in ASEAN and endorsed by the respective Heads of Delegations.
 - 5.3.5 Representative (s) from ASEAN Pharmaceutical Industry associations, to provide inputs whenever appropriate. In relation to point 5.3.4 and 5.3.5, their attendance shall follow the Rules and Procedure for Private Sector Engagement (PPE) under ASEAN Economic Community, endorsed by 23rd AEM Retreat on 9 March 2017, Pasay City, Philippines, as appears in **ANNEX 2**.
- 5.4 PPWG may conduct capacity building activities on the sideline of its meetings, such as seminar/trainings/workshops for both regulatory authorities or industries in cooperation, where relevant, with any ASEAN Dialogue Partners, international/regional organizations, or regional/national pharmaceutical associations.
- 5.5 PPWG may arrange a Public Private Forum on the sideline of its meetings to share and update information of PPWG activities. The Public Private Forum may be arranged following the conclusion of any PPWG Meeting and on interactive manner with attendance of representatives from (i) ASEAN pharmaceuticals industry, (ii) ASEAN pharmaceutical industry associations and (iii) other relevant stakeholders, who are based in ASEAN, and endorsed by their respective Heads of Delegations.
- 5.6 Any PPWG sub-groups may invite Expert (s) from any international/regional organizations, regional associations, academia, whenever appropriate, to support their technical works. Meeting of PPWG sub-groups may be arranged back to back or separate with PPWG meetings. Proceeding of such PPWG sub-groups meetings shall be reported to PPWG, as appropriate.

- 5.7 The ASEAN Secretariat is responsible for the PPWG. His/her duties shall include the convening of meetings, the submission of requests and forwarding decision of the meeting and approvals to the appropriate sub group of PPWG. He or she will also facilitate or assist Member States in preparing policy and technical papers to be submitted for consideration and discussion at the Meetings, keeping a record of the minutes of PPWG meetings and monitoring the follow up actions from each decision made by PPWG.
- 5.8 The Meeting Arrangement of PPWG appears as **ANNEX 3**.

6. Duties and Responsibilities of Chair and Vice-Chair

- 6.1 The Chair shall be present at every meeting of the PPWG and ensure that all decisions made are based on consensus. The Chair should ensure that all interests are heard, keep discussion to the point, and the minutes are clear and precise.
- 6.2 The Vice-chair shall assist the Chair in all Meetings. In the absence of the Chair, the Vice-chair shall assume the duties and responsibilities of the Chair.
- 6.3 Prior to any of its Meetings, the Chair with assistance of the ASEAN Secretariat, will consult with the members of the PPWG on the agenda to be covered during the Meetings.
- 6.4 The Chair/Vice-Chair shall, on behalf of PPWG, report to the ACCSQ on the proceedings and the decisions made during the PPWG Meetings for endorsement by ACCSQ.

7. Meetings and Reports

- 7.1 The PPWG shall meet at least once a year.
- 7.2 At the conclusion of each meeting, the PPWG will determine the time, date and venue of its next meeting.
- 7.3 Any member of the PPWG can request for a meeting with the approval of the Chair and Vice-chair upon consultation with the ASEAN Secretariat, and all other members.
- 7.4 Members shall be given at least three (3) months' notice of the next meeting unless there is an urgent matter that needs to be addressed by the PPWG, for which a shorter notice is allowed.
- 7.5 Attendance by representatives from at least six Member States shall be required to constitute a quorum

Article 8: Term of Office

The tenure for the PPWG chairmanship shall be for a period of one year and followed by alphabetical order. In the event an AMS cannot take up the position of Chair or Vice-Chair, the next AMS by alphabetical order will be offered the position.

Chair of PPWG

Vice-chair of PPWG