National Pharmaceutical Control Bureau (NPCB)
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ASEAN HARMONISATION EFFORTS FOR PHARMACEUTICALS

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Background

Efforts toward ASEAN harmonization were initiated through the ASEAN Consultative Committee for Standards and Quality (ACCSQ), which was formed by the ASEAN Economic Ministers in 1992 to facilitate and complement the objectives of the ASEAN Free Trade Area (AFTA). At the 4th Senior Economic Officials Meeting (SEOM) in September 1997 in Jakarta, the ACCSQ was authorized to involve ASEAN regulatory bodies to achieve the mandate of eliminating technical barriers to trade. At the 12th ACCSQ Meeting held in August 1998 in Bangkok, the concept paper on harmonization of pharmaceutical regulations in ASEAN was presented by Malaysia. Subsequently, SEOM, at its meeting held in January 1999 in Jakarta, agreed to the proposal. Hence, at the 13th ACCSQ Meeting held in March 1999 in Manila, it was agreed that a Product Working Group on Pharmaceuticals, now referred to as Pharmaceuticals – Product Working Group (P-PWG) be set up, with Malaysia being designated as the lead country.

Objective

The objective of the ACCSQ Pharmaceutical - Product Working Group (P-PWG) is to develop harmonization schemes of pharmaceutical regulations of the ASEAN member countries in order to complement and facilitate the objective of AFTA, particularly, the elimination of technical barriers to trade posed by regulations, without compromising the quality, efficacy and safety of drugs.

Scope

The scope of activities of the P-PWG includes :

1. Exchange of information on the existing pharmaceutical requirements and regulations implemented by each ASEAN member country
2. Review existing pharmaceutical requirements and regulations and prepare a comparative study of the requirements and regulations
3. Study of harmonized procedures and regulatory system currently implemented in other regions notably the International Conference on Harmonization (ICH) on pharmaceutical requirements and regulations
4. Development of harmonization guidelines of technical procedures and requirements applicable to the ASEAN pharmaceutical industry, taking into account other regional and international developments on pharmaceuticals
5. Development of common technical documents with a view of arriving at Mutual Recognition Agreement (MRA)

Strategies

The P-PWG has identified four strategies to achieve the desired goal of harmonization of ASEAN pharmaceutical regulations:-

1. To compare existing pharmaceutical product registration requirements of ASEAN member countries
2. To develop common technical requirements (CTR) for pharmaceutical product registration for ASEAN
3. To develop common technical dossier (CTD) for pharmaceutical product registration for ASEAN with a view of arriving at MRA
4. To implement the harmonized ASEAN pharmaceutical product dossier

Meetings Update

The P-PWG, comprising of national regulatory and standard bodies, and industry representatives from ASEAN, has held three meetings to date. The meetings were attended by delegates and observers from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam and the ASEAN Secretariat.

The 1st meeting which was held in September 1999 in Kuala Lumpur, Malaysia deliberated on various key issues including the terms of reference and proposed work-plan. The meeting also provided an update on the progress in implementation of the Common Effective Preferential Tariff (CEPT) Scheme for ASEAN Free Trade Area (AFTA) and important features of the pharmaceutical sector towards realization of AFTA.

The 2nd meeting which was held in March 2000, in Bangkok, Thailand discussed the study reports of various core activities and also highlighted other important issues such as Trend of Pharmaceutical Harmonization : WHO and ICH, Report on the APEC Workshops on the Food/Drug Interface and overview of the ASEAN Working Group on Technical Co-operation in Pharmaceuticals. Formation of Ad-hoc Committees on Quality led by Indonesia, Safety (Pre-clinical Study) led by Philippines, Efficacy (Clinical Data) led by Thailand and Administrative Data led by Malaysia were agreed.

The 3rd meeting which was held in February 2001 in Ho Chi Minh City, Vietnam was attended by 29 delegates and 36 observers from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Vietnam and the ASEAN Secretariat. It was noted that 33 of the participants were from the regulatory and governmental agencies. The meeting was preceded by plenary sessions of the various Ad-hoc Committees, tasked to review and discuss the relevant CTRs. Relevant international guidance documents particularly those of ICH and WHO were used as references. The proposed CTRs on Quality, Safety (Pre-clinical Study), Efficacy (Clinical Data) and Administrative Data were presented by the respective Ad-hoc Committees for further deliberation. A standardized format for the CTR was proposed and adopted.

The meeting also dwelled on the ICH-5 activities, held in November 2000 in San Diego, USA. The P-PWG agreed on the need for ASEAN to participate in the ICH Global Co-operation Group and Non-ICH countries.

The 4th P-PWG meeting, scheduled for September 2001 will be hosted by the ASEAN Secretariat and will be held in Jakarta, Indonesia.

Progress and Achievements

In tandem with the strategies laid down in the three-year work-plan, the P-PWG has accomplished the following targeted outputs as at February 2001:-

1. Report of comparative study on pharmaceutical product registration of ASEAN member countries
2. Setting up of Ad-hoc Committees and designation of lead country to study key areas of technical documents submitted for registration, namely
    - Pharmaceutics (Quality) – Indonesia
    - Pharmacological and Toxicological Data (Safety - Pre-clinical Study) – Philippines
    - Clinical Data (Efficacy) – Thailand
    - Administrative Data - Malaysia
3. Preparation and circulation of relevant CTRs on Quality, Safety, Clinical Data, and Administrative Data.
4. Presentation and consensus for adoption of relevant CTRs

Pursuant to the decisions agreed at the 3rd meeting, the designated Ad-hoc Committees will now work towards preparation of the respective CTDs, simultaneously focusing on key issues such as Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) requirements. The final draft of the harmonized ASEAN CTD for Pharmaceutical Product Registration is expected to be ready for adoption by December 2002, after which a specified date will be determined for the implementation and monitoring phase.

Moving towards the final goal of achieving MRA, the P-PWG will further pursue to look into the concepts and requirements as laid down under the ASEAN Frame work Agreement on MRA, and to formulate an appropriate MRA on ASEAN Harmonization for Pharmaceuticals.

Conclusion

With growing inter-dependence among nations as well as expanding global opportunities in pharmaceutical trade, efforts toward developing a new strategic partnership in pharmaceutical regulatory harmonization has recently become an important agenda of ASEAN. Current global modalities such as the International Conference On Harmonization (ICH) for pharmaceuticals, Global Harmonization Task Force (GHTF) for medical devices and Pharmaceutical Inspection Co-operation Scheme (PIC/S) have resulted in mutual benefits through constructive forums.

Inspired by these concerted efforts and taking into consideration the current international best practices of expediting product registration process, the ACCSQ – Pharmaceutical Product Working Group has thus taken a harmonized approach to facilitate the availability and accessibility of quality, safe and efficacious products, in the interest of patient and public health.