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Strengthening regional collaboration among ASEAN regulatory laboratories to ensure quality assurance in pharmaceuticals

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ASEAN's development, though gradual and slow, has consistently demonstrated an uphill shift from a focus on regional peace and stability to closer economic integration. The ultimate goal is to achieve an integrated ASEAN community by the year 2015 with a common regional identity. Efforts toward ASEAN harmonization were initiated through the ASEAN Consultative Committee for Standards and Quality (ACCSQ). Hence, it was agreed that a Product Working Group on Pharmaceuticals, now referred to as Pharmaceuticals - Product Working Group (P-PWG) be set up. The ASEAN's PPWG is contributing to the ASEAN Economic Community 2015 vision by establishing the pharmaceutical harmonization scheme. The goal is to create common regulations for pharmaceuticals in the region, reduce barriers to trade and to ensure that pharmaceutical products penetrating the ASEAN markets show sufficient safety, quality and efficacy. 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. Inspired by these concerted efforts and taking into consideration the current international best practices of expediting product registration process, the ACCSQ - PPWG 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. And one of the milestones in the harmonized approach is the establishment of pharmaceutical reference standards. The project on the Production of ASEAN Reference Standards (ARS) was initiated in 1980 under the Technical Cooperation among ASEAN countries on Pharmaceuticals, and was supported by UNDP and WHO with Thailand as the coordinator. The objective of the project is to enable the ASEAN countries to produce pharmaceutical reference standards for utilization within the region. Through thirty three (33) years of cooperation among member countries, the overall implementation of the activities in terms of manpower training and the production of ARS were considered satisfactory. The outcome of the project has benefited all participating countries.

Biography

Maria Soledad Lopez-Distor has completed her Bachelor of Science in Chemistry from the University of the Philippines, Los Banos and post-graduate studies in Management major in Public Administration from Laguna College of Business and Arts. She is a Senior Food Drug Regulation Officer of the Food and Drug Administration Philippines, a regulatory agency mandated to ensure the safety, quality and efficacy of pharmaceuticals, processed foods, cosmetics, household hazardous substances and medical devices. She is currently assigned at the ASEAN Reference Standards-Central Laboratory, tasked to establish and develop pharmaceutical Reference Standards in collaboration with other national and regional regulatory laboratories of ASEAN member states. She has a number of oral presentations on conventions and symposiums, both local and international invitations.

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