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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 interdependence 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.

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From pharmacogenetics to personalized medicine: A Cuban regulatory perspective

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The science of pharmacogenomics has advanced significantly in the last five years, but it is still in infancy and is mostly used on research basis. The pharmacogenomics helps identify inter-individual variabilities in drug response (both toxicity and effectiveness). This information will make it possible to individualize therapy with the intent of maximizing effectiveness and minimizing risk. The aims of this work are to present the bases of pharmacogenetic, the advantage and challenges of this specialty, the main enzymes characterized for the genetic polymorphism and the existing regulations about this topic (EMA, FDA, ICH) and Cuban Regulatory perspective, taking into account the increase of biological product registration. We will show the main biomarkers for pharmacogenetics studies and a general guidance for submission of this type of research. The hope for the future is that through personalized medicine, doctors and patients will be able to make better-informed choices about treatment. This treatment will avoid the adverse drug reaction to the medication and will improve the diagnosis diseases as well as the prevention and treatment of diseases.

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