Pharmacogenomics: Regulatory Guidance in Cuba. Implications for Latin America

Diadelis Remirez

Register Department, National Centre for State Quality Control of Drugs, equipment and medical devices., Cuba

Background: The science of pharmacogenomics has advanced significantly in the last five years. The Pharmacogenomics helps identify interindividual 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.

Objectives. The aims of this work are to present the state of art about pharmacogenomics regulations and implications of this discipline for Latinamerican countries. Besides that, to show the results about Cuba and its pharmacogenetic guideline.

Methods. It was done a revision in the international literature about the existing regulations, guidance, concept paper, scientific articles and the national regulations related with this topic will be shown.

Results. Regulations from FDA, EMA and ICH about Pharmacogenomic were revised, and the common points of these were identified. From these elements and the Cuban context (the increase of biological product registration and authorized clinical trials in Cuba), the Cuban guidance was elaborated and will be presented. Another important element is the implementations in Latin-American taking into account the medical access, discrimination of people, importation of drugs and posologies among others, some solutions of it will be shown.

Conclusion. This Cuban guidance will be considered the first guidance related with pharmacogenomic in Latin America. Pharmacogenetic has several advantages in order to get rational use of drugs but still there are many challenges, which will be shown in this work. 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.