Good pharmacovigilance practices and RMP: Improvement to the strategy of implementation for the new Pharmacovigilance standard in Mexico

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On July 19, 2017 the Official Mexican Standard "NOM-220-SSA1-2016, Pharmacovigilance Installation and Operation" was published in the Federal Official Gazette. Such Standard becomes effective 180 days after its publication, i.e. on January 15, 2018. In that Standard are stablished new responsibilities of the holders of sanitary registries (marketing authorizations) and / or legal representatives in Mexico. The Risk Management Plan (RMP) is now applicable for all medicines, but it´s related to the risk and post marketing experience relationships. According to the safety profile and risk assessment of each drug or vaccine, the RMP may have 3 categories: Category I: Generic drugs, including their innovator. Category II: Marketed medicines and vaccines, for which there is a safety concern at national or international level that affects the risk/benefit ratio; New molecules, biological or biotechnological drugs with a sanitary registry issued by a regulatory agency (RA) recognized by COFEPRIS; Category III: New molecules, biological or biotechnological drugs without an approval issued by a RA recognized by the COFEPRIS. Despite there was a strategy of its implementation, the observations of the analysis of the results along 10 months, show that it´s necessary to do some improvement actions. These actions are related to three different needs. First, Technical: The professional profile should be related to the pharmacovigilance skills, experience and qualifications. It´s important to have well stablished criteria to evaluate the RMP. Second, administrative: It´s need to create a simplify way to submit and evaluate the RMP. It´s suggested turning electronic review to those ones who are low risk and the last one, training and communication: It´s is crucial to transmit the same information to all training sessions to share the same format and solve the questions. Recommendations are made to strength the pharmacovigilance activities and its implementation to contribute to the health protection.