Pharmacovigilance in China: A review

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Abstract

Drug-related adverse reactions are among the main reasons for harm to patients under care worldwide and even their deaths. The pharmacovigilance system has been proven to be an effective method of avoiding or alleviating such adverse events. In 2019, after two decades of implementation of the drug-related adverse reaction reporting system, China formally implemented a pharmacovigilance system with the Pharmacovigilance Quality Management Standards and a series of supporting technical documents created to improve the safety of medication given to patients. China's pharmacovigilance system has faced many problems and challenges during its implementation. This spontaneous reporting system is the main source of data for China's medication vigilance activities, but it has not provided sufficiently powerful evidence for regulatory decision-making. In conformity to the health-centered drug regulatory concept, the Chinese government has accelerated the speed of examination and approval of urgently needed clinical drugs and orphan drugs along with the requirement to improve the safety supervision of these drugs after their listing. China's marketing authorization holders(MAHs)must strengthen its pharmacovigilance capabilities as the primary responsible department for drug safety. Chinese medical schools generally lack professional courses on pharmacovigilance. The regulatory authorities have recognized such problems and have made efforts to improve the professional capacity of pharmacovigilance personnel and to strengthen cooperation with stakeholders through the implementation of an action plan of medication surveillance and the establishment of patient-based adverse events reporting system and active surveillance systems, which will help China bridge the gap to bring its pharmacovigilance practice up to standards.

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