Abstract

Background: In response to the COVID-19 pandemic, emergency use approval (EUA) systems for new therapeutics have been introduced in many countries. Clinical trials provide important information about a drug, but in the case of EUA, complete information about the safety of a drug is not available at the time of approval and marketing authorization. Under this situation, pharmacovigilance (PV) is increasingly important. In order to implement safety measures, it is essential for governments to monitor safe use and collect information on adverse drug reactions (ADRs) under appropriate regulations for those drugs whose safety profile has not been fully elucidated. However, among the six WHO regions, PV systems in the Western Pacific Region have never been comprehensively studied. This project analyzed the PV systems of countries in the Western Pacific Region with a focus on international cooperation among national regulatory authorities (NRAs) to monitor the safety of drugs, including new therapeutic drugs for COVID-19 in countries with no/fragile PV systems.

Methods: In this study, the countries were divided into mainly two categories: Pacific Island Countries (PICs) and Non-Pacific Island countries (non-PICs) following the WHO classification. Information on PV systems in each country was obtained from official websites of government agencies, reports published by international organizations and government bodies, and articles published by medical and research institutions that were reliable. Information on the approval status of COVID-19 drugs was obtained from NRAs' websites, and information on their distribution status was adopted from web news that are reliable. Information on international partnerships which have contributed to PV strengthening were extracted from the websites of the NRAs. Alliances involving NRAs

in the Western Pacific Region that were found in the process of creating PV profiles for each country, and whose purpose was to strengthen PV, were selected and their main activities were investigated. Based on the information collected, major findings and policy implications were suggested.

Results: Most countries in the Western Pacific Region have policies in place to regulate PV for some form of medicinal product to collect AE reports from HCPs and Marketing Authorization Holders (MAHs). However, PICs largely have no policies regulating PV and their laws and regulations are weak or outdated. There is cooperation among NRAs and networks on PV, and some countries benefit from participation by harmonizing safety data, sharing safety information, and providing training and educational opportunities. Nevertheless, not all countries in the Western Pacific Region are members of these networks. LMICs such as Mongolia, the Philippines, Laos, Cambodia, and Vietnam were strengthening PV through donor programs such as the Asian Development Bank and Global Fund. Cooperation programs specific to PV of medicines for PICs were limited to small-scale support from specific countries. Some countries rise issues of underreporting from HCPs. Most of the non-PICs in the Western Pacific Region have regulations and guidelines in place that dictate safety measures for MAHs, but the strength of the regulations varies widely from country to country. Active surveillance for COVID-19 therapeutics was identified in several countries but was not major in the region. The websites of the regulatory authorities for all non-PICs were accessible and information on the regulation of PV was available. On the other hand, there were a few countries where it did not contain easy-to-understand information for the general public. There was a country where new COVID-19 therapeutics can be purchased without a prescription, and misuse has been a problem.

Conclusion: The PV regulatory landscape in the region varied widely. To strengthen the PV system throughout the region, the following areas were identified: strengthening regulatory policies where needed, addressing regional harmonization, improving funding for PV, building and strengthening partnerships among NRAs, leveraging donation programs, creating an environment that facilitates ADR reporting by, reinforcing industry commitments, improving active surveillance, improving safety administrative measures, promoting PV transparency to the public, enhancing appropriate regulation of COVID-19 new therapeutics, and encouraging membership in Programme for International Drug Monitoring (PIDM).

Keywords: Western Pacific Region, Pharmacovigilance