

Pharmacovigilance regulatory actions by National Pharmacovigilance centres in fourteen Middle Eastern Countries following COVID-19 Pandemic

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March 07, 2024

Abstract

Background. Globally, pharmacovigilance activities were affected by COVID-19. Therefore, several competent health authorities around the world, including several countries in the Middle East, have issued guidelines and practices to ensure that pharmacovigilance activities are maintained and continued during the pandemic. **Objective.** The aim of this study was to assess the impact of COVID-19, preparedness and performance of national pharmacovigilance systems in participating countries during COVID-19 pandemic. **Methods.** This was a cross-sectional study that was conducted between July and October 2020. National pharmacovigilance centres in 18 Arab countries in the Middle East were invited to participate in this study. Descriptive analysis was used to summarize and present the results of this study. **Results.** Responses were obtained from 14 (77.8%) Arab countries. Ten of participating countries (71.4%) have either specific national PV guidelines or local PV practices during the COVID-19 pandemic. Adverse events reporting was the main PV activity that was covered by PV guidelines and practices. National guidelines and practices covered other PV activities in 8 (57.14%) of the participating countries. Performance and practices of national PV centres vary considerably among participating countries during the pandemic. **Conclusion.** The findings highlight the differences in preparedness and performance of different national PV centres in participating Middle Eastern countries. Improving digital infrastructure among participating countries could serve as a useful tool to minimize the impact of the pandemic on PV activities.

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