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EDITORIAL

MITIGATING THE IMPACT OF COVID-19 ON PHARMACOVIGILANCE

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COVID-19 is changing the pharmacovigilance (PV) landscape. Traditionally, regulatory authorities used to follow well developed standard procedures to ensure safety of new products and had ample time to review the evidence. Low-and-middle-income countries (LMIC) are benefited from stringent reviews made by well-established regulatory systems in more advanced countries.

The urgency posed by the COVID-19 pandemic for development of new drugs, vaccines, diagnostics and medical devices demands accelerated procedures with rapid assessment in a short time frame under high public scrutiny and more transparency. Conditional market authorizations means that real world monitoring of medicines, diagnostics and vaccines on the market becomes critical. Regulatory authorities may need to sponsor observational studies to generate relevant safety data. Signal management required establishing causality of adverse events. Regulatory authorities need to participate actively in guiding requirements for vaccine trials such as duration of follow ups during Phase III trials, and set standards together collaboratively.

All these add a big strain on the PV systems, especially on those which have less capacity (1). Only 27% of national medicine regulatory authorities (NMRAs) have Maturity Level 3 on the Global Bench-marking Tool of the WHO, a tool which assesses the capacity to perform the functions required to ensure medicines, vaccine and other health products actually work and do not harm patients (2).

The other aspect is the impact of the disruptions caused by COVID-19 on health systems and ongoing PV activities. Workforce assignments to additional responsibilities reduce time for PV work. Lock downs have interrupted communications between the PV centers of NMRAs and health professionals, patients as well as the public at large. Adverse event reporting is given less emphasis under the pandemic due to competing priorities. Resources and funding for these activities are very limited. On the other hand, irrational prescribing prevails frequently with the ongoing pandemic, especially in intensive care units. Exposure to certain medicines may affect risk of infection or clinical course of COVID-19 (as had been noted for nonsteroidal anti-inflammatory drugs, hydroxychloroquine and chloroquine). The quality of safety data is affected by the change in the epidemiology of the virus and measures taken to control the disease. The changing thresholds of testing, hospitalization or admission into intensive care units (ICU) and the variable exposure risks, with differences in adherence to quarantine measures or self-medication complicate data analysis.

What it means in general is that collection of a high-quality data is more challenging but essential (3). Risk communication and engagement with the public is critical to combat false claims (infodemics), and this requires reliable real-time data (4). This means that it's high time for more vigilance and documentation and a greater need for leveraging internal capacity in particular for LMIC. Accelerated approvals mean with limited safety data at hand but expected to be gathered in future in countries going forward. Export bans of medical technologies and priority medicines are leading to supply chain stock-outs. Local manufacturing of medical products and innovations add additional challenges to regulatory authorities. Shortage enhances the risk of substandard and counterfeit medical products.

This is the time which calls upon for more vigilance and stronger collaboration among regulatory authorities (5). Inefficient regulatory systems can themselves be barriers to make safe and effective products available. Adopting comprehensive laws, such as the African Union Model Law (6,7) and harmonization of technical requirements of products could be some of the means to speed up capacity strengthening in LMIC. Close collaboration among regulatory authorities, sharing experiences in regulatory decisions, working on social media communications together, sharing knowledge and scientific data and creating platforms to stay connected could mitigate the risks posed by COVID-19 on PV in LMIC. LMIC regulatory authorities should collaborate closely with research and academic institutions in their countries to generate evidence they would need for effective response (for example to probe spontaneous reports in databases, conduct observational studies (8) or adjust communication strategies with

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health care professionals, patients and the public to combat fake news, or monitor relevant publications to keep up with the avalanche of information on COVID-19.

Regulatory systems need to rise up to the challenges posed by COVID-19 to ensure that pharmacovigilance plays its essential role in the COVID-19 response. In Ethiopia, where the COVID 19 pandemic is on the rise, it is necessary to prevent public health damage from this complex pandemic as early as possible. Pharmacovigilance should be one of the priority interventions to this end. It is important that regulatory bodies ensure manufacturers and importers fulfil the required documentations and put in place efficient authorization processes to meet urgent public health needs, while protecting the public from unsafe and poor-quality medical products related to the diagnosis and prevention of COVID-19. The directive recently issued by the Ethiopian Food and Drug Authority (EFDA) (9), which provides directions for COVID-19 medical products conditional approval and import permit authorization is a useful step in the country's effort to guide and monitor the national response to the pandemic. Further measures need to be taken to strengthen pharmacovigilance in the broader sense, while keeping efficiency in perspective.

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