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An Industry Analysis of the Impacts of the COVID-19 Pandemic on Medication Management Planning

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DESCRIPTION

The COVID-19 pandemic threatens global corporate ties and dynamics in new ways. Because of its highly organized compliance efforts, pharmaceutical corporations' pharmacovigilance functions are especially vulnerable to shifting external demands. We performed an industry-wide poll to get insight into how the pharmacovigilance function responded to the pandemic's issues. We examined the influence on portfolios and operational activity parameters of smaller and larger enterprises. The COVID-19 pandemic led the world to an unexpected realization of the coronavirus and its developing genome's significant, unprecedented threat to human health, organizational structures, and global commercial linkages and dynamics. Business continuity has become the catchphrase, and robustness and resilience are the desired aims, but recognition of the pandemic's effects on systems at the granular level has been gradual. Since the 1970s, when the fundamental model mostly represented a reactive approach to crisis management when faced with unforeseen challenges, the discipline of business continuity has progressed dramatically. In the United States, for example, the White House Security Council created a National Strategy for Pandemic Influenza in 2006 without explicitly including business continuity. In contrast, Ireland's Department of Enterprise, Trade, and Employment deliberately addressed the problem of business continuity in 2007 by completing 12 case studies in several economic sectors, including food processing, financial services, and technology and medical equipment. Today, business continuity management is a distinct profession, and the World Health Organization is in the third iteration of global health recommendations for business continuity planning in the event of an influenza pandemic. The pharmaceutical industry's business continuity planning has evolved into a critical role. Maintaining business operations with the least amount of disruption in the face of disaster necessitates the development of safeguards for business personnel as well as the development of other measures that can ensure the availability of essential drug products and compliance with regulatory requirements, such as inspections. In terms of Pharmacovigilance (PV), the European Medicines Agency recognised important

PV activities from a business continuity standpoint in its Good Pharmacovigilance Practices as early as 2012, and issued further recommendations following the COVID-19 pandemic in 2020. To assist the no disruption of important processes, the US Food and Drug Administration has a guidance paper in place called Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products. Similarly, emerging nations have developed training programmes to identify important PV operations in order to construct business continuity strategies in accordance with the European Medicines Agency's Good Vigilance Practices.

PV is now defined as the science and actions involved in the detection, evaluation, comprehension, prevention, and communication of adverse effects or any other medicine-related concern to the right stakeholders. The PV system, in general, contains the following primary kinds of functions:

- Case management (collection of events, case processing, Individual Case Safety Report (ICSR), and reporting of probable unanticipated significant adverse reactions.
- Signal management (signal monitoring, detection, evaluation, governance, communication, and documentation to regulatory authorities, and aggregate case evaluation and reporting to regulatory agencies).
- Benefit-risk management.

To operationalize these functions, track activities at the evidentiary level of standards, maintain security against global hackers, and ensure compliance with health care standards of confidentiality of the information under the company's control, today's PV systems rely on sophisticated, proprietary databases. Argus, ArisG, and IQVIA are among current providers in this field. We conducted an industry-wide convenience sample survey to provide descriptive insights into the impact of the COVID-19 pandemic on the PV function in smaller and larger biopharmaceutical companies, specifically how these companies responded to the challenges of a changing pandemic dynamics landscape on PV infrastructure and methods. We give comparisons of the influence on product portfolios and PV operational activity measures across smaller and bigger enterprises.