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COVID-19 Pharmacovigilance Flexibilities 'Must Remain' In Non-EU Markets

Companies Are Concerned Positive Changes May Be Rolled Back After Pandemic Ends

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Executive Summary

An EU industry group is scrutinizing the several 'impactful' changes made by countries to their pharmacovigilance processes amid the ongoing COVID-19 pandemic. The group is hoping these changes can help its ongoing efforts to create 'right size' systems where there is a need to further develop infrastructure for pharmacovigilance.

COVID-19 HAS DRIVEN CHANGES TO SAFETY REPORTING PROCEDURES *Source: Shutterstock*

The COVID-19 pandemic has driven changes in many areas of drug regulation, and pharmacovigilance has been no exception.

It has resulted in some countries embracing electronic means for receiving safety documents, others experimenting with virtual inspections, and most countries allowing greater flexibility on the timing for receiving certain safety reports. Also, it has created a greater appetite for global collaboration on safety monitoring and assessment of medicines.

These changes – deployed in varying degrees in different countries – are being closely monitored by an EU industry group that is focused on driving "right-size pharmacovigilance systems" in non-EU nations that are still shaping their safety monitoring frameworks.

The group was set up by the European Federation of Pharmaceutical Industries and Associations in 2016 in response to a spurt in new pharmacovigilance requirements in non-EU countries. Called the EFPIA International Pharmacovigilance Group (IPVG), its focus is on supporting elements that generate value for patients and eliminating requirements that do not contribute to benefit-risk insights.

The IPVG is monitoring COVID-19-related changes to identify key trends and potential opportunities, "which would help us advocate and use as leverage to help develop a more effective PV system" in these non-EU countries, said Patricia Hawthorne of Eli Lilly & Company.

Hawthorne was speaking at the Drug Information Association's virtual Europe 2021 conference during a session on 'Globalization of Pharmacovigilance and Impact of COVID-19' on 15 March.

The biggest changes in pharmacovigilance processes following the pandemic have been in relation to safety reporting, said Hawthorne, who is lead consultant, medicines quality organization, at Lilly. While most regulators have issued guidance on how adverse events relating to COVID-19 treatments should be reported, they have also introduced new reporting procedures.

These changes, Hawthorne said, have been "far reaching," affecting, for example, the reporting of individual case safety reports (ICSRs), periodic safety update reports (PSURs), risk management plans (RMPs), domestic side-effects, foreign suspected unexpected serious adverse reactions (SUSARs), line listings, and development safety update reports (DSURs).

While many countries have switched from paper to electronic mode for receiving these reports, "others didn't mind how safety reports were reported," said Hawthorne. In Kazakhstan, for example, she explained that a PSUR can be submitted by email or post. The requirements for electronic reporting have also varied among countries– some prefer to receive reports via secure emails, others are asking for submissions in XML format or via online templates.

Additionally, many countries either extended or suspended the submission timelines for some of these safety reports. Mexico extended the deadline for all submissions, while in Argentina the due dates were suspended completely. In other countries, non-serious ICSR reporting due dates were extended from 90 days to six months.

Reversing Progress?

The COVID-19 crisis has resulted in some "impactful changes" and the IPVG is keen to ensure "we don't roll back to pre-pandemic regulatory environment or lose some of the good positive changes," said Hawthorne.

The industry is concerned that some countries have already announced plans to withdraw some of these regulatory flexibilities, such as electronic reporting of some safety documentation, when the pandemic is over. "Although this is disappointing," the IPVG "will continue to advocate for wider use of electronic reporting," she said.

The industry is hopeful that its advocacy efforts will reap benefits as "already we have seen some positive changes," Hawthorne said. The medicines agency in Serbia, for example, has announced plans to continue supporting electronic reporting processes after the pandemic. And India intends to have electronic ICSR reporting going forward, she added.

While the pandemic in ongoing, Hawthorne said the IPVG would continue monitoring the regulatory environment for changes and possible sources of regulatory flexibility. "Hopefully, going forward, we can leverage these impactful changes, which have been the result of the [COVID-19] crisis, to advocate for effective [national] PV systems development."

Driving Harmonization

As part of its efforts to advocate for "right size pharmacovigilance," the IPVG in December 2020 published consensus recommendations on how key components of a pharmacovigilance system should be developed and implemented. The paper is relevant for countries and systems where there is a need to further develop infrastructure for pharmacovigilance.

The recommendations in the paper draw on the "broad and deep experience" acquired by global drug companies whilst meeting the expectations of a large array of diverse PV systems across the world. The paper outlines a range of elements important for an effective PV system, but the order in which these should be introduced is "free" and will depend on "a number of factors that may be country specific," said Willemijn van der Spuij of Bristol-Myers Squibb, who co-authored the paper.

The IPVG intends to create awareness about the concepts outlined in the paper by engaging with regulators and stakeholders in different regions, especially focusing on Latin America and Africa. The group is already working on plans to hold a dialog with Brazil on this topic.

Additionally, the IPVG, in collaboration with the international federation of drug manufacturers (IFPMA), has proposed setting up an online workshop focusing on pharmacovigilance requirements in East Africa, some of which are stricter than those in the EU, said Hawthorne. The workshop will include a "brainstorming session" on collaborative solutions to increase the effectiveness of the East African PV system, she added.

Through these efforts, “we really hope to drive harmonization across the different markets,” said Van der Spuij.