Landing in the EU – The importance of choosing the right experts for EU/EEA QPPV

Kausik Maiti, M.D., Senior Medical Director
Carmen Arques, QPPV, Qualified Person, Responsible for Pharmacovigilance
Paolo Malerba, Associate Director, Safety Services

Countless biopharmaceutical companies target the European Union (EU)/European Economic Area (EEA) to launch their first medicinal/biological product or expand their existing product portfolio and the territories in which their drugs are authorized. However, the EU/EEA legal regulations and requirements to ensure patient safety are in a state of constant evolution. This creates a need for Marketing Authorization Holders (MAH) to develop robust pharmacovigilance (PV) systems according to legal frameworks that are nimble yet efficient to make amendments in line with the rapidly changing regulatory landscape. Hence, the importance of having experienced and committed professionals appointed to manage the responsibilities seamlessly should be a priority for MAHs.

The EU/EEA Qualified Person for Pharmacovigilance (EU/EEA QPPV) is a mandatory requirement for all biopharmaceutical companies to authorize a medicinal/biological product within the EU/EEA.

The EU/EEA QPPV is legally responsible for complying with multiple key pharmacovigilance functions. Those include the establishment and maintenance of the MAH PV system—including the responsibility for the Pharmacovigilance System Master File (PSMF), acting as the contact person for the authorities during inspections, and being available on a 24/7 basis for the competent authorities in any member state and the European Medicines Agency. Thus, the EU/EEA QPPV role is not only critical to meeting the legal obligation of the MAH, but it is also an essential component of the PV system to ensure patient safety and smooth business operations. Furthermore, having an EU/EEA QPPV who demonstrates expertise, knowledge, leadership, and responsibility for the PV system allows MAHs and their companies to focus on other business areas while ensuring inspection readiness at all times.

If the complexity of the European legislation wasn't enough, some member states have local PV

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legislation and requirements, which may include the mandatory appointment of a local PV person. This role is known as a local QPPV (or contact person for PV, national PV responsible person, or local safety officer) and is responsible for PV activities for the MAH at the country level. Deep knowledge of relevant local legislation is crucial since the level of responsibility for the PV system, the requirements for residency in a specific country, and even around-the-clock availability vary from one country to another. Local language skills and residency in the given country are standard requirements for this role.

The EU/EEA QPPV should ensure a global approach for the integrated PV system and be up-to-date on global and local legislation, including knowing who is part of the local QPPV network and appointing the right experts in the more demanding countries. EU/EEA QPPVs must have expertise in team management and guarantee fluent and constant communication across various stakeholders.

The situation outside of the EU/EEA presents itself as another challenge because legislation differs from country to country. Moreover, the requirements may be as strict and complex as in the EU/EEA.

Territories like the Eurasian Union (composed of the Russian Federation, Belarus, Kazakhstan, Kyrgyz, and Armenia) have requirements similar to the EU/EEA with the mandatory requirement of having a Eurasian Union QPPV located in one of its member countries with full responsibility for the PV system for those territories. There is also an additional requirement for a local QPPV in some of these countries. The same applies in various other continents, such as the League of Arab Countries with its own QPPV and PV system requirements.

Brexit and its impact on pharmacovigilance

The UK's exit from the EU is now a reality, after the transition period ended in Dec 2020. As of Jan. 1st, 2021, EU pharmaceutical law still applies to Northern Ireland, but not any other UK countries, while MHRA legislation applies to all of the UK (England, Wales, Scotland, and Northern Ireland). This new situation puts even more pressure on companies to ensure adherence to new legislation and requirements.

As a result of this new situation, one of the biggest challenges that companies now face is the location of the QPPV. EU QPPV can no longer be located within the UK, and at the same time, MHRA requests companies to nominate a UK QPPV located either in the UK or within the EU. This opens a range of possibilities for MAHs to find a structure to suit their needs.

To fully understand both legislations, the specific needs of the company, its organizational structure relevant to the PV system, and the requirements within the UK and EU markets, it is crucial to choose the right PV partner and QPPV structure. Possible scenarios include having one expert located in the EU who acts as EU QPPV and UK QPPV with a national contact person located in the UK, or two different QPPVs located in the EU and the UK with the same level of responsibility for each one of the PV systems.

MAHs also need to consider the Northern Ireland Protocol, which defines special requirements

that apply to Northern Ireland, including pharmacovigilance. The situation with this territory may be a bit ambiguous due to its singularity. Northern Ireland is not considered a third country for the EMA; therefore, Union legislation applies, and MHRA legislation also applies as it is a UK territory.

Choosing the right PV partner

Access to the best local experts in each of the MAH's target markets should be the top selection criteria when outsourcing the QPPV role, together with a flexible, scalable, and sustainable solution customized to the specific needs of the biopharmaceutical company.

A global approach to the PV system should extend beyond focusing only on QPPV duties to include awareness of comprehensive safety activities, communication, and support from key stakeholders within the PV system. Outsourcing selection criteria should also include broad experience in establishing and maintaining PV systems and a dedicated team with a track record of success.

Effective pharmacovigilance requires experienced medical and safety professionals who have the tools and expertise to collaborate within a complex, cross-functional environment. As pharmacovigilance compliance complexity continues to rise and the need to demonstrate product stewardship and commitment to patient safety put additional pressure on biopharmaceutical companies, key questions for MAHs are focused on how they can access the right expertise, global coverage, and infrastructure support in a rapidly evolving regulatory environment.

The QPPV Office at Parexel has QPPV experts covering all major territories. Our QPPV experts have the appropriate background, significant expertise, continuous training, and cross-functional support for QPPVs and related activities by our subject matter expert (SME) networks within Parexel's Safety Services. Our QPPV office and global PV infrastructure exist within the same PV organization, creating a unique opportunity for seamlessly integrated and well-coordinated global PV system and effective oversight required by the QPPV.

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