Evolving Veterinary Pharmacovigilance Frameworks in Europe: *What Manufacturers Need to Know*

European pharmacovigilance (PV) frameworks have been updated to provide risk-based, data-driven oversight of processes to increase transparency and better protect animal health, public health and the environment. Though this can add to the administrative burden for marketing authorisation holders, robust PV systems can help create added value for manufacturers by continuously delivering critical data to support product development, while strengthening confidence in the safety and reliability of veterinary medicines.

Animal health pharmacovigilance (PV) the science of detecting, assessing and preventing adverse events (AE) related to veterinary medicinal products has undergone major reform in recent years in Europe. These changes, driven by new legislation and international harmonised guidance (VICH), aim to strengthen PV systems and improve efficiency to deliver greater protection for animal and public health and the environment. In practice, adapting to new PV requirements can add to the administrative burden for marketing authorisation holders (MAH). However, robust PV systems can be used to create added value for manufacturers by continuously delivering critical data to guide regulatory and product development decisions throughout the product lifecycle while strengthening confidence in the safety and reliability of veterinary medicines – an issue currently in the public spotlight. In this article, we highlight the recent changes and challenges from the evolving PV frameworks in Europe of which manufacturers should be aware.

New PV Regulatory Frameworks

A package of EU Veterinary Medicines Regulations (2019/6 and 2021/1281) and Veterinary Good Pharmacovigilance Practices (VGVP) have been the launchpad for a modernised veterinary PV framework across Europe. These changes represent a shift toward a more streamlined and scientifically oriented approach to monitoring the safety and efficacy of veterinary medicines. The new EU requirements took effect on January 28, 2022, with a subsequent phased introduction of key IT systems, including the Union Product Database and the Union Pharmacovigilance Database (EudraVigilance Veterinary, EVV); the latter attained its full functionality earlier this year. The Great Britain PV framework was similarly updated on May 17, 2024, through amendments to the Veterinary Medicines Regulations 2013, with new PV tools still being developed, including the UK's 'enhanced online reporting portal,' targeted for release in early 2026. Manufacturers must continue to adapt as the full functionality of the online PV databases is implemented.

PSMF

A central PV requirement is for MAHs to maintain a comprehensive Pharmacovigilance Master File (PSMF) that details their entire PV system, including processes for adverse event reporting, signal management, risk minimisation and quality assurance. The PSMF replaces the previous Detailed Description of the PV System (DDPS) and covers the MAH's whole product portfolio. Under the prior system, a single change to the DDPS needed to be applied to every product held by the MAH, whereas the PSMF covers all products held by the MAH, so only a single change is required. The PSMF must be kept up to date and available for inspection, serving as a central document to demonstrate compliance and therefore crucial for regulator PV inspections.

PSURs

One of the most notable recent changes to PV frameworks in Europe is the abolition of mandatory Periodic Safety Update Reports (PSURs) submissions. Instead of requiring routine PSURs (estimated to be 50 PSURs per veterinary pharmaceutical company per year), MAHs must now carry out continuous signal management. This shift is intended to enable MAHs to focus resources on real-time analysis rather than periodic reporting, but manufacturers should be aware that regulators may still request targeted safety updates if signals indicate potential risks.

Suspected Adverse Events (SAE)

The animal health industry has long advocated a 'One Health,' approach that takes into consideration animal, human and environmental health at the same time rather than considering them in silos. Consistent with this approach, the EU framework broadens the scope of suspected adverse events (SAE): It now includes not only any unfavourable and unintended reaction in any animal to a veterinary medicine but also includes incidents in humans; the environment; observation of lack of efficacy of a veterinary medicine following its administration to an animal, whether or not in accordance with the summary of product characteristics; a finding of an active ingredient or marker residue exceeding the maximum residue limit (MRL); suspected transmission or an infectious agent via a veterinary medicine; and any unfavourable and unintended reaction in an animal to a medicinal product for human use.

The Great Britain Veterinary Medicines Regulations take a similar approach by adopting the VICH GL24 definition of 'adverse event,' as 'any observation in animals that occurs after any use of a veterinary medicinal product, whether or not considered to be product-related, that is unfavourable and unintended;' by including definitions of 'human adverse event' and 'adverse environmental event;' and by creating reporting obligations for unintended transmission of an infectious agent through a veterinary medicine, lack of efficacy and exceeding MRLs.

While the EU and Great Britain requirements broadly and intentionally align, in practice, manufacturers should be aware that international divergence in the definition of AE/SAEs among jurisdictions can lead to different reporting requirements and different product information requirements from jurisdiction to jurisdiction, complicating product communication and potentially creating regulatory inefficiencies. The Veterinary Dictionary for Drug Regulatory Activities provides a list of standard clinical terms to be used in reporting SAEs in animals or humans after exposure to veterinary medicinal products and is revised on an annual basis, promoting harmonisation of SAE reports.

SAE Reporting

In the EU, marketing authorisation holders must record in EudraVigilance Veterinary all suspected adverse events reported to them and those published in the scientific

literature, without delay and within 30 days of receipt of the suspected adverse event report.

Similar obligations apply in the UK (including the extended reporting period from 15 days to 30 days that was introduced to improve the quality of the reports), but concerns have been raised that SAEs are being underreported by the public and veterinarians while the new UK PV portal is developed, which has therefore placed greater reliance on veterinarians and owners reporting SAEs directly to manufacturers. In the past week, the UK regulator, Veterinary Medicines Directorate (VMD), has reiterated that throughout this time, SAEs can be reported to the MAH and directly to the VMD by email.

Importantly, since 2019, EU SAEs have been publicly accessible via the EudraVigilance database. Similarly, since 2020, the U.S. Food and Drug Administration Centre for Veterinary Medicine has made adverse event reports (AERs) related to animal drugs and devices used in animals available on openFDA.gov, a platform electronically accessible to the general public. The impact of this has been that public access to AERs has improved transparency and increased scrutiny of SAEs by the public. In practice, manufacturers have needed to enhance their communication and education programs to address concerns raised and to provide the necessary scientific balance and context to AERs to strengthen confidence in the safety and reliability of veterinary medicines.

Annual Benefit Risk Reports (BRR)
Marketing authorisation holders must continuously assess the benefit-risk of their products and must immediately (within 30 days) notify competent authorities or the European Medicines Agency (EMA) of any new risk or change to a product's benefit-risk balance identified through signal management – a process for performing active surveillance of PV data to assess whether there is any change to the benefit-risk balance to animals, the public, or the environment. They must also record in the EU pharmacovigilance database, at least annually, all signal management outcomes including conclusions on the benefit-risk balance.

Similarly, in Great Britain, since 2024, MAH's must submit an annual benefit-risk report (BRR) for each veterinary medicine. The report must be provided immediately on request and, in any case, once every year during the validity of the authorisation. Each report must include (i) a statement on the product's benefit-risk balance; (ii) sales volumes in the UK and abroad, with UK figures broken down by calendar year; (iii) details of any signals detected requiring regulatory action, including a summary of adverse event reviews; and (iv) where it appears from the observed data that there is cause for concern in relation to the safety of the product, recommendations on the need for further intervention.

EU Databases
The creation of the EU Pharmacovigilance Database (Eudravigilance Veterinary, EVV) and the Union Product Database has significantly modernised the way adverse event reporting and product information management are conducted throughout the EU. These centralised databases are designed to enable more efficient, standardised and transparent collection and analysis of safety data for veterinary medicinal products. Additionally, the introduction of IRIS, a dedicated online platform for managing product-related scientific and regulatory procedures, is intended to streamline and enhance the effectiveness of signal management activities, allowing for quicker identification and response to potential safety concerns. The EMA updated its preliminary requirements for all IRIS submissions, including substance and Research Product Identifier registration on July 18, 2025, providing essential procedural guidance for accessing the IRIS platform, which supports various regulatory submissions, including those related to veterinary PV. The guide primarily addresses administrative prerequisites (such as EMA account registration) as well as some key veterinary-specific elements MAHs should review to ensure compliance when using IRIS for PV activities. As noted, the UK's new enhanced online reporting portal is currently in development, with a target launch date in early 2026.

Recommendations
The European PV frameworks have been updated to focus on providing risk-based, data-driven oversight of PV processes, to better protect animal health, public health and the environment.

These objectives are critical and have received widespread support from industry and other stakeholders, but the improved transparency that has come with public access to AERs needs to be met with improved communication and education from manufacturers to the public, to respond to concerns and to provide the necessary balance and context to this new public source of information.

To achieve the aim of stimulating innovation and investment, the implementation of regulatory requirements must be proportionate and must avoid unduly adding to administrative burden. As these burdens are multiplied where there is a divergence of requirements between jurisdictions, companies should consider pushing for further international regulatory alignment to minimise this impact while implementing PV mechanisms that seek to avoid duplication of effort across jurisdictions.

Finally, companies should look to drive value from increased data gathering and transparency measures, to guide regulatory and product development decisions throughout the lifecycle, and to enhance communication strategies.

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Dr. Chris Boyle

Dr. Chris Boyle (Partner, Sidley Austin LLP) combines his qualifications as a veterinarian and life sciences lawyer to guide animal health companies through regulatory, compliance and litigation matters in animal health. Chris founded and chairs Sidley Austin LLP's Animal Health Legal Forum.

Anna Melin

Anna Melin (Counsel, Sidley Austin LLP), lead of Global Life Sciences out of Munich, focuses on life sciences regulatory work. Anna co-leads Sidley's benchmarking group for in-house pharmacovigilance (PV) lawyers and is recognised for her expertise in PV regulations, including as pertaining to animal health.