

Global Regulatory Dossier Framework For Veterinary Medicinal Products

Taseer Bashir¹

Manisha Kolakshyapati¹, Donald Sibanda¹ and Maria Trainer¹

¹ Australian Pesticides and Veterinary Medicines Authority (APVMA)

Aiming to protect Australia's trade and the health and safety of people, animals, and the environment, Australian Pesticides and Veterinary Medicines Authority (APVMA), the regulator of veterinary medicines and agricultural chemicals also ensures that the best and upcoming products remain accessible to users.

For the purpose of registering new products in various countries, developing, structuring and submitting data dossiers can be a challenge due to diverse regulatory requirements for each jurisdiction. To address this, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) embarked upon an initiative, aiming to develop a guideline for uniform dossier content under a Global Regulatory Dossier Framework (GRDF) for pharmaceutical Veterinary Medicinal Products (VMPs). The development of this guideline aims to facilitate the construction of a single dossier framework (with the level of granularity defined in local legislation) to support submissions for all VICH members, observers and Forum member countries.

A VICH taskforce developed the mandate and concept papers for the purpose and now an Expert Working Group (EWG) is formed to progress this initiative, setting out a modular skeleton of dossier content.

The APVMA is actively contributing towards this initiative since the inception of the idea. The GRDF is expected to lower the regulatory burden for companies to submit applications and improve industry compliance with regulatory requirements. It may also facilitate the assessment process, including potential of parallel and joint assessments, and recognition of existing approvals.

References

1. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). Concept Paper on a VICH Guideline on a Global Regulatory Dossier Framework for pharmaceutical Veterinary Medicinal Product (VMP) applications. 2024. Available at: <https://vichsec.org/wp-content/uploads/2025/02/24048-Fin.pdf>. Accessed 28 February 2025.

2. Australian Pesticides and Veterinary Medicines Authority (APVMA). International participation. 2024. Available at: <https://www.apvma.gov.au/about/international-collaboration/international-activities/international-participation>. Accessed 28 February 2025.