

## EU Veterinary Medicines Regulations one year on from application

Brussels, 17 February 2023 - At the [Veterinary Medicines Info Day](#) organised by the European Medicines Agency, industry and regulators discussed both positive progress and challenges experienced during the first transition year since the new [EU Regulation on veterinary medicine](#) became applicable on 28 January 2022. With some bumps in the road still to be ironed out, a continued pragmatic and flexible approach will be very welcome.

All stakeholders agreed that there had been some immediate positives from the new rules which aimed to deliver in four areas: reducing administrative burden; stimulating innovation; increasing availability of animal health products; and addressing AMR. Deletion of some elements within the marketing authorisation process seemed to ease burden somewhat, but the challenge of implementing three new databases within three years was even more resource intensive than originally expected.

Duplication of certain procedures at national level on top of EU requirements were also a topic of concern. Animal health companies took the opportunity of the event to highlight a lack of harmonisation amongst the Member States, with additional reporting at national level only serving to increase the administrative burden and workload. With some of the national legislation still under development, the discussion focused on ensuring alignment where possible and eliminating additional national requirements.

EMA representatives shared important updates on the implementation activities, including the fixes being applied to the IT systems. The event also included presentations on both the activities of the [CVMP](#) and the work of the [CMDv](#) relating to application of the revised guidance and procedures.

Commenting on the event AnimalhealthEurope Technical Director Rick Clayton said:

“Despite the challenges highlighted, the collaboration between the EMA, the national competent authorities and our industry has been very positive. The responsiveness of the EMA staff to the various issues raised is highly appreciated. There is still a long way to go, but we are hopeful that we are getting on the right track again. We remain optimistic that, in the long-term, the new rules will deliver the promise of significant simplification, transparency and reduction of administrative burden to the benefit of animal health.”

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AnimalhealthEurope represents 12 of Europe’s leading manufacturers of animal medicines and 16 national associations in 19 countries, covering 90% of the European Market.