Medicated Premixes Expert Working Group

Chairperson: Erik De Ridder

Introduction

The stability testing of Medicated Premixes, (also called “Type A medicated article” in USA or “drug premix” in Canada), was first described in VICH GL 8 in 1999.
Following a request of the VICH Forum, and a review by Japanese authorities, the Steering Committee (SC 37) requested AnimalhealthEurope to provide first a Discussion Paper (which was approved after SC 38). A Task Force then wrote a Concept Paper on the development of further guidance on Medicated Premixes. Any updated or new guidance would only pertain to medicated premixes and would not be about registration requirements of medicated feed as such.
The Concept Paper was approved by the SC and gave the EWG the mandate to take a two-step approach, with a first revision to address immediate needs and in a second step a reflection on further guidance that should be developed.

Guidelines adopted

The current and short VICH GL 8 (Stability Testing for Medicated Premixes) came into operation by December 2000. It was designed as an addition to the first stability GL3 (Stability testing of new drug substances and products) that was implemented in May 2000.

Guidelines under development

The EWG has completed in September 2024 a draft revision of the VICH GL8, which is being discussed at the current SC (step 2).
Completing their first mandate, the EWG addressed stability in climatic zones III and IV, the fitness of the premix to manufacture medicated feed, the stability of the medicated premix after opening of the pack and the use of bracketing and matrixing in the statistical evaluation.

New topics

The EWG is now discussing the need for further guidance. A new Concept Paper might describe the need for further guidance on specific requirements for the analytical method validation and the sampling methodology for premixes as well as homogeneity and segregation testing for medicated premixes. More discussion will be required on the need for guidance on the potential concurrent use of medicated premixes. The EWG will be submitting a new Concept Paper to the Steering Committee in 2025.

Key scientific issues resolved

The guideline 8(R) is describing the requirements for new substances and premixes. The application of the guideline to existing substances and products is left to the local jurisdictions. Its scope is also limited to Mediated Premixes, so in-feed additives for non-veterinary purposes are out of scope.

Key benefits of the harmonized guidelines

Clear and harmonized guidance on technical requirements are essential to enable global development of veterinary medicinal products, including medicated premixes.

Development of additional requirements in Guideline 8 on stability data for medicated premixes will provide opportunity to develop a harmonized dossier for submission in VICH regions as well as in VICH Outreach Forum countries.

Reducing discrepancies in requirements between the Member regions will provide more opportunity to develop the medicated premixes for more global markets, which would increase the availability of this important pharmaceutical form.

Within VICH Forum regions, Regulatory Authorities look to VICH to understand what appropriate requirements would be for veterinary products. Now they will find a global guideline that addresses most of their questions on the requirements for medicated premixes. By developing further VICH guidance on medicated premixes, harmonized guidance on aspects such as for instance homogeneity or segregation is now available for VICH Forum regions.

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Amsterdam
November 2024