EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 May 2022
EMA/CVMP/232862/2022
Committee for Veterinary Medicinal Products

CVMP List of questions to be addressed by the stakeholders

For veterinary medicinal products containing N-methyl pyrrolidone as an excipient

Article 82 of Regulation (EU) 2019/6

Procedure number: EMEA/V/A/146

Melovem 30 mg/ml solution for injection for cattle and pigs
EMEA/V/C/000152/A82/0014

Vectra 3D EMEA/V/C/002555/A82/0023

On 3 May 2022, the German National Competent Authority notified the European Medicines Agency, in accordance with Article 82 of Regulation (EU) 2019/6, informing on potential risks to the users and target animals of veterinary medicinal products containing N-methyl pyrrolidone (NMP) as an excipient. NMP should be considered as a substance which has the potential to cause developmental toxicity and has been legally classified as 'Repr. 1B (may damage the unborn child)' according to the harmonised classification and labelling (ATP09) approved by the European Union. It was considered that the user safety of veterinary medicinal products containing NMP should be reviewed and where relevant, appropriate risk mitigation measures should be included in the product information to ensure the safe use of the concerned products.

The notification of the German National Competent Authority triggering the procedure is available on the webpage of the procedure.

In accordance with Article 83 (1) of Regulation (EU) 2019/6, interested parties (e.g. veterinary healthcare professionals, farmers, academia) are invited to submit information relevant to the procedure, addressing the below Committee for Veterinary Medicinal Products (CVMP) list of questions by 13 September 2022:

Question 1

Please provide information or data related to potential teratogenic effects which could be relevant to update the risk assessment for target animals and pregnant users of veterinary medicinal products containing N-methyl pyrrolidone as an excipient.