WOAH RABLAB warns of risk of using substandard dog rabies vaccines.

The World Organisation for Animal Health Rabies Reference Laboratory Network (RABLAB) is highly concerned about reports regarding the use of subpotent parenteral rabies vaccines (imported or locally produced) in rabies-endemic countries.

Scaling up the delivery of dog vaccination campaigns against rabies at national levels must not be at the expense of vaccine quality.

The use of poor-quality vaccines will lead to continued high rabies incidence due to insufficient herd immunity thereby jeopardising national rabies control programmes.

It may even run the risk of leading to uncertainty among Competent Authorities, especially in low- and middle-income countries in Africa and Asia about the concept of controlling the disease at its animal source and jeopardise the global goal of eliminating human deaths from dog-mediated rabies by 2030.

WOAH RABLAB emphasises the importance of using approved, high-quality rabies vaccines that meet international standards in terms of efficacy, safety, and sterility.

Rabies vaccines for parenteral use should be compliant with the recommended potency of at least 1 IU/dose to guarantee its biological protective activity. As there are many factors that can impact the quality of (even approved) vaccines, RABLAB urges regulatory authorities to accept their responsibilities and regularly check a vaccines’ potency as an important indicator of the consistency and stability of batch production before registration and release to the market.

Quality control
Vaccine manufacturers should be compelled to provide quality control data of each vaccine batch during the procurement procedures organised by the national regulatory authorities, based on the WOAH international Standards. Independent verifications of the quality of commercial vaccines for potency as part of the authorisation process are strongly recommended to identify and disqualify unregulated and non-compliant vaccines. Animal rabies vaccines should only be used if they meet the international standards of quality and potency, which will ultimately contribute to achievement of the objective of zero human deaths from dog-mediated rabies by 2030.

Procurement of dog rabies vaccines
If rabies vaccines for national programmes are to be procured, RABLAB strongly recommends rabies endemic countries to follow WOAH’s Practical Guidelines for National Procurement of Veterinary Vaccines. Acknowledging the added value of internationally recognised high-quality vaccines, WOAH and the Pan American Health Organization (PAHO) through its WOAH vaccine bank and Revolving Fund, respectively, have established effective mechanisms to ensure procurement of high-quality vaccines manufactured in line with WOAH international standards and delivered in a timely manner. However, as the vaccines listed there are not the only vaccines that meet international standards, vaccine manufacturers or vaccine purchasers wishing to request further guidance on how to clarify the quality of commercial vaccines should contact any RABLAB expert.
References