

Article

Potency of Veterinary Rabies Vaccines Marketed in Sri Lanka

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Abstract: Seven brands of veterinary rabies vaccines are commercially available in Sri Lanka, but there is no established procedure to test the potency of the vaccines at the local level, especially prior to their release. The aim of this study was to test the potency of these vaccines using a mouse challenge test in collaboration with the EU/WOAH/WHO Reference Laboratory for Rabies, ANSES-Nancy, France. Based on the European Pharmacopoeia, the inactivated rabies vaccines complied with the mouse potency test if the estimated potency is ≥ 1.0 IU in the smallest prescribed dose. Among the eight tested vaccines, four single-dose preparations (RabisinTM, RaksharabTM, NobivacTM RL, and NobivacTM Rabies) were compliant, with potencies of 12 IU/dose, 7.2 IU/dose, 4.4 IU/dose, and 3.4 IU/dose, respectively. Three of the single-dose preparations (CanvacTM R, DefensorTM 3, and Rabies killed vaccine) were not compliant, with potency values < 1.0 IU/dose. One multidose preparation (RaksharabTM multidose) had a potency of 1.3 IU/dose, even though the test was not validated. Based on these results, it appears that some rabies vaccine batches that are currently available in the local market do not comply with the mouse potency test. Testing the vaccines' potency before registration and release to the market appears to be an important step to allow good immunization to animals during pre-exposure vaccination programs.

Keywords: antirabies vaccine; NIH test; rabies; Sri Lanka; potency



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1. Introduction

Rabies is a viral neglected disease that is 100% fatal once a patient becomes ill [1]. Apart from the disease burden and the large number of human deaths reported annually, rabies is responsible for huge economic losses too. This includes dog vaccination costs in excess of USD 130 million and livestock deaths of USD 512 million in rabies-endemic countries [2], such as Algeria, Egypt, and Libya in Africa, Sri Lanka; Pakistan and India in south Asia; Uzbekistan and Georgia in Central Asia; Indonesia, Philippines, and China in southeast and east Asia; and Colombia, Brazil, Bolivia, and Ecuador in South America.

In Asia and Africa, dog bites are the main reason for human deaths following rabies infection [3]. As a rabies-endemic country, Sri Lanka has reported 20–30 human deaths annually due to rabies [4]. Rabies virus has been principally maintained in the dog population (*Canis lupus familiaris*), and the main source of human rabies cases in Sri Lanka has mostly been household pet dogs and stray dogs, the latter being the most involved [5].

The prevention of rabies in animals is fully based on vaccination. The pre-exposure immunization of animal populations, mainly dogs, using effective and safe modern cell culture-derived vaccines, prevents rabies infection and, consequently, transmission to humans [2]. In Western European countries and North America, dogs have been parenterally vaccinated for many years, resulting in the elimination of rabies in dog populations with a