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Study for establishment of 1st National Reference Standard for cell-derived Japanese encephalitis vaccine (Beijing strain)

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Japanese encephalitis virus (JEV) is a mosquito-born flavivirus that causes public health problems in Asian countries. Until quite recently, the primary JE vaccine in use internationally has been the mouse brains JE vaccine, which is now commonly replaced by cell culture-based vaccines. The Vero cell derived JE vaccines have been licensed for routine use in Korea, 2013. In Korea, we have the system of National Lot Release. Unlike chemical drugs, biologics such as viral vaccine, bacterial vaccine and blood products are produced using organism-origin materials, so it is difficult to maintain consistency and safety throughout the manufacturing processes. Also, the reference standard is indispensable for the consistent potency management of viral vaccine. The candidate 1st National Reference Standard was manufactured in GMP facility and all quality test results including potency test meet the acceptance criteria. In this study, the candidate 1st National Reference Standard was manufactured in GMP facility and all quality test results including potency test meet the acceptance criteria. To determine relative potency of candidate material, a collaborative study involving 4 participants including both NCL and manufacturers was carried out potency test using plaque reduction neutralization test (PRNT). Therefore, it plans to determine and establish the quality of the candidate of the 1st National Reference Standard based on a long-term stability test data and collaborative results and use it to establish the quality of the vaccine.

Biography

Ji Young Hong has completed her Master's degree in Molecular-Biology from Korea University. She has worked in the Division of Enteric Hepatitis Virus, National Institute of Health for about 5 years. She is working on Vaccines Division, National Institute of Food and Drug Safety Evaluation since 2009.

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