

16. <http://www.fda.gov/cber/review/rotamer020306rp2.pdf>
17. Ruiz-Palacios GM etc. 2006. Safety and Efficacy of an Attenuated Vaccine against Severe Rotavirus Gastroenteritis. The New England Journal of Medicine 354: 11-22.
18. Timo Vesikari, M.D. etc. 2006. Safety and Efficacy of a Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine. The New England Journal of Medicine 354: 23-33.



## Survey on Batch Release of Vaccines and Toxoids in Taiwan During 2006

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### ABSTRACT

This report presents the results of batch release of imported and domestic vaccines and toxoids during the period from January 1<sup>st</sup> to December 31<sup>st</sup>, 2006. There were 26 items and 2,894 tests of inspecting and analyzing 169 batches of 12,253,203 doses totally. All complied with the Chinese pharmacopoeia and other regulations. These 169 batches of vaccines and toxoids belong to 33 licenses held individually by 6 vaccine companies and 8 factories, 38.7% domestic and 61.3% imported. The certified number of batches from GlaxoSmithKline Biologicals Belgian factory is the highest and the certified number of doses from Sanofi Pasteur French factory is the highest. In 12,253,203 doses of vaccines and toxoids, 35.4% doses are for bacteria and 60.7% for virus, for both virus and bacterial are 3.9%. Top 3 by batches are influenza vaccines, tetanus toxoids and hepatitis vaccines in order. Top 3 by dosages are influenza vaccines, tetanus toxoids and oral polio vaccines in order. 44 batches of 3,352,689 doses of influenza vaccines were certified in 2006.

Key words: vaccine, toxoid, batch release