

Annual Surveillance of Batch Released Vaccines and Toxoids in Taiwan, 2010

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ABSTRACT

Batch release for biological products is an important regulation for safety and quality and is carried in accordance with the Chinese pharmacopoeia in Taiwan. In this study, we summarized and analyzed the batch release of domestic and imported vaccine and toxoids. One hundred and sixty one batches (12,751,951 doses) belonging to 25 licenses and 7 vaccine companies were investigated in the batch release tests in 2010. Among them, proportions of domestic and imported products in batches and doses were 28.6% (46 batches) and 46.0% (5,870,554 doses), and 71.4% (115 batches) and 54.0% (6,881,397 doses), respectively. Totally, the performed examinations covered 25 items 2,175 tests. All test results were conformed to the regulations in Taiwan. In summary, order of the most release batches was influenza vaccines, measles/mumps/rubella vaccine and JE vaccine. Order of the most release doses was influenza vaccines, tetanus toxoids and DTP/polio/hib combination vaccine. These results could be provided for the further batch release regulations.

Key words: vaccine, toxoid, batch release

