November 2007

Summary of Amendments of the Standard for Biological Product for Animal Use Prepared by the Ministry of Agriculture, Forestry and Fisheries of Japan

Japan approves distribution of vaccines for veterinary medicine manufactured in the processes of seed lot system ("seed lot products") in Japan (applicable for both domestic and foreign products). For this approval, Japan will add the following provisions as a revision of the Standards for Biological Products for Animal Use.

(1) General Notices

Definitions for relevant terms are added.

- Seed Lot (defined as "suspension homogeneously containing one specific strain of viruses, bacteria and cells etc. generated through mono-cloning process, whose strain is sufficiently stable in its genetic characters")
- Seed Lot Product(defined as "vaccines manufactured in the processes of seed lot system")
- Master Seed, Working Seed and Production Seed
- Cell Line
- Master Cell Seed, Working Cell Seed and Production Cell Seed
- Master Primary Cell Seed, Working Primary Cell Seed and Production Primary Cell Seed

(2) Testing procedures for the strains of viruses, bacteria and cells to ensure the safety, uniformity and stability of the seed lot products

- Detection Test of Extraneous Virus for Vaccine Seed
- Immunogenicity Test using Subject Animals for Vaccine Seed
- Subject Animal Safety for Vaccine Seed
- Test of Vaccine Seed using Subject Animals for Absence of Reversion to Virulence

(3) Specifications for seed lots of viruses, bacteria and cells suitable for manufacturing seed lot products

- Specifications of Seed Lot
  - Vaccine Seed
  - Cell Seed
- Specifications of SPF animal
  - Embryonated eggs for manufacturing seed lot products
  - SPF animal for primary cells for manufacturing seed lot products

The vaccine satisfying current standards can be distributed in Japan as before.