Draft amendment of the Ministerial Ordinances "Regulatory Rules for Veterinary Medicinal Products" and "Manufacturing Quality and Quality Control of Veterinary Pharmaceutical Products"

1. Current system

Based on the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, pharmaceuticals designated by the Minister of Agriculture, Forestry and Fisheries including veterinary biologics to be sold, provided, stored or displayed for the purpose of the sale or provision thereof in Japan must be undergone and passed an official assay provided by the National Veterinary Assay Laboratory (NVAL) to prevent the occurrence of hazards to public health and hygiene. Procedure and contents of the official assay are set up by the Ministerial Ordinance "Regulatory Rules for Veterinary Medicinal Products". Also, the manufacturers must keep a certain number of pharmaceuticals, as designated by the Ministerial Ordinance "Manufacturing Quality and Quality Control of Veterinary Pharmaceutical Products" for use in the quality control tests after the distribution.

2. Contents of amendment

1) In existing regulationthe NVAL have conducted laboratory assays in accordance with the National Assay Standard (Ministerial Announcement) on a part of quality control tests conducted by manufacturers.

   Recently, due to the prevailing manufacturing control on each manufacturing process, therefore, most of the products have passed the official assay (laboratory tests) conducted by the NVAL.

2) Based on these facts, MAFF will amend this Ministerial Ordinance to introduce more efficient and effective quality control measures. In the amended Ministerial Ordinance, when the marketing authorization holders submit the official assay, they must attach the document which summarize manufacturing and quality control records. As the official assay, the NVAL will review these documents instead of laboratory tests.

   However, important veterinary biologics for animal health have to pass the laboratory tests conducted by the NVAL to review the efficacy of them even after the amendment of this Ministerial Ordinance.

   Furthermore, the number of pharmaceuticals that manufacturers must keep after the distribution will be changed.

3. Date of enforcement

Date of publication

4. Transitional measure

Current ruled before the amendment can be applied for three years after the publication.