ANIMAL INDUSTRY ACT (EXCERPT)
Act 466 of 1988

287.743 Autogenous veterinary biologicals; requirements for revocation and permission to distribute veterinary biologicals; experiments and field trial requirements; liability; reporting of adverse reaction.

Sec. 43.

(1) A person in another state shall not export any autogenous veterinary biologicals into this state unless notification prior to import is given to the director and any stipulations set forth in or under 9 CFR part 102 and all amendments to that publication adopted in rules promulgated by the director are met.

(2) A person manufacturing an autogenous veterinary biological within this state shall not distribute or sell any veterinary biological within this state unless notification before distribution or sale is given to the director and any stipulations under 9 CFR part 102 and all amendments to that publication adopted in rules promulgated by the director are met.

(3) The director shall pursue restrictions on the distribution and use of autogenous veterinary biologicals when the director determines that those restrictions are necessary for the protection of the public health, animal health, or the animal industry as set forth in 9 CFR part 102 and all amendments to that publication as adopted in rules promulgated by the director.

(4) Veterinary biologicals shall be administered only by a licensed veterinarian or under the supervision of a licensed veterinarian unless used in compliance with section 18814 of the public health code, 1978 PA 368, MCL 333.18814.

(5) A veterinary biological required in 9 CFR part 102 and all amendments to that publication adopted in rules promulgated by the director to be administered by, on the order of, or under the supervision of a veterinarian shall be distributed only to veterinarians, distributors who distribute the veterinary biological only to veterinarians, or pharmacies and other appropriate retail outlets to be sold only on the prescription or order of a veterinarian.

(6) When the director determines with advice and consultation from the animal industry involved and the veterinary profession that the protection of the public health, animal health, or the animal industry or that a control or eradication program for a disease or condition necessitates the report of the sale, use, distribution, or administration of a veterinary biological, an autogenous veterinary biological, or a diagnostic test, the director may require that a person that sells, uses, distributes, or administers a veterinary biological or diagnostic test report that information to the department within 10 working days in a manner prescribed by the director.

(7) Notwithstanding any other provision of this act, the director may at any time revoke the distribution of a veterinary biological or an autogenous veterinary biological if the veterinary biological or autogenous veterinary biological has a substantial impact on public health, animal health, or the animal industry.

(8) A person that requests permission to distribute in this state veterinary biologicals that are conditionally licensed by the United States Department of Agriculture or that are subject to import permits for distribution and sale issued by the United States Department of Agriculture shall submit all of the following information to the department:

(a) A copy of the current United States Department of Agriculture license.

(b) Any restrictions set forth by the United States Department of Agriculture.

(c) A complete name of the product, including the generic and trade name.

(d) Product information, including directions for use.

(e) Slaughter withdrawal times, if applicable.

(9) A person that desires to import into this state or to distribute intrastate, for experimental or field trial use, a veterinary biological that is not conditionally licensed by the United States Department of Agriculture shall request and obtain permission from the director before importing that veterinary biological into this state on a form approved by the director.

(10) A person that requests permission to import or distribute intrastate a veterinary biological to be administered to animals owned by the public for experimental or field trial purposes shall submit a written statement to the department, which shall be given to the owner of the animals before the administration, prescription, or distribution of the veterinary biological. The written statement required by this subsection shall state all of the following:

(a) That the veterinary biological to be administered, prescribed, or dispensed to an animal is an experimental or field trial veterinary biological.

(b) That the veterinary biological has not been approved by the United States Department of Agriculture or the department for unconditional use.

(11) A determination of whether to allow the import or intrastate distribution of a veterinary biological for experimental or field trial purposes shall be based upon, but not limited to, all of the following:

(a) Need for the product by the animal industry.

(b) Safety of the product for the target animal species.

(c) Safety of the product for a person that administers the biological.

(d) Safety of the human food chain, if the veterinary biological is used in food-producing animals.

(12) A veterinary biological for experimental or field trial purposes shall be shipped only to a veterinarian and shall only be used by the veterinarian to whom the product is shipped or by an individual who is under the direct supervision of the veterinarian to whom the product is shipped.

(13) A person that consigns, ships, or transports a veterinary biological for experimental or field trial purposes into or within this state shall file a report of each requested shipment with the department within 5 business days of the shipment. The report required by this subsection shall contain all of the following information:

(a) The quantity consigned, shipped, or transported.

(b) The expiration date of the product.

(c) The complete name of the veterinary biological.

(d) The name and address of the veterinarian receiving the veterinary biological.

(14) The department is not liable to a person that has received permission to import or distribute intrastate a veterinary biological for experimental or field trial purposes for any injury due to the use of that veterinary biological to humans or animals or for the loss of any animals.

(15) A person that receives permission to import or distribute intrastate a veterinary biological for experimental or field trial purposes shall report an adverse reaction to the department within 5 business days after the reaction.

(16) The director may limit the distribution of a veterinary biological for experimental or field trial purposes to certain geographical areas within this state and for specific time periods.

(17) The director may at any time revoke permission to distribute a veterinary biological for experimental or field trial purposes.

History: 1988, Act 466, Eff. Mar. 28, 1989 ;-- Am. 1994, Act 41, Imd. Eff. Mar. 14, 1994 ;-- Am. 1996, Act 369, Imd. Eff. July 3, 1996 ;-- Am. 2019, Act 132, Eff. Feb. 19, 2020