Regulatory Brief

Senate HELP Committee solicits feedback from AVMA on pharmacy compounding (October 31, 2012)

To help members of the U.S. Senate Committee on Health Education Labor and Pensions (HELP) better understand current federal and state oversight of pharmacy compounding, any gaps that may exist, and the possibilities for and implications of any potential legislative solution, stakeholders, including the AVMA, were invited to provide feedback to questions posed by the committee.

Brief Description:
Following the fungal meningitis outbreak of 2012 resulting from pharmaceuticals produced at the New England Compounding Company in Framingham, Massachusetts, the Senate HELP Committee posed questions to stakeholders in preparation for their November 15th hearing, “Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak”.

AVMA Response:
Given the importance of compounding to the veterinary profession and treatment of animals, the AVMA appreciated the opportunity to provide feedback to the committee. The term “compounding” comprises both compounding from FDA-approved drugs and from unapproved, bulk active pharmaceutical ingredients (API). Science-based evidence should be utilized to determine whether compounding a particular preparation should be done using a bulk API or an FDA-approved product with excipients. The AVMA is committed to the availability of FDA-approved animal drugs. At the same time, the AVMA believes it is medically necessary for veterinarians or pharmacists, under the direction of a veterinarian, to compound from bulk ingredients in limited circumstances:
- the approved drug is not commercially available, or
- the needed compounded preparation cannot be made from the approved drug.

AVMA asked that the committee recognize the unique circumstances in which veterinarians practice every day. The species veterinarians treat that have regular compounding needs include household pets, such dogs, cats, ferrets, and birds; horses; exotic animals; and wildlife. Although many medical conditions are found across species, there are also species-specific exceptions that lend themselves to the need for compounded preparations.

Background Documents:
- Full AVMA Response – November 1, 2012 (PDF)
- Senate HELP Committee Hearing - Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak (November 15, 2012)
- Relevant AVMA Policy
  - Compounding
  - Compounding from Unapproved (Bulk) Substances in Food Animals
  - Compounding from Unapproved (Bulk) Substances in Non-Food Animals