Vermont Veterinary Medical Association
www.vtvets.org
76 Beech Street, Essex Junction, VT 05452
(802) 878-6888 voice • www.vtvets.org • info@vtvets.org

February 5, 2024

To the Honorable Vermont Senate Judiciary Committee,

On behalf of the Vermont Veterinary Medical Association, thank you for bringing our attention to S.58, which addresses the inclusion of xylazine in the list of regulated drugs. We appreciate the opportunity to share our perspective on this matter.

The VVMA supports the inclusion of language that specifically exempts the veterinary use of xylazine. I t has come to our attention that some states have regulated xylazine without providing exemptions for its legitimate veterinary applications. This discrepancy in language across states has already led to a manufacturing company withdrawing from producing the drug.

Currently, there are only two legal manufacturers of xylazine, and we have concerns about the potential impact on the availability of the drug if regulatory requirements diverge significantly. To address this, the AVMA has proposed the following verbiage for your consideration:

"We recommend the following language when seeking an exemption for xylazine:
Xylazine shall be classified as a Schedule III substance, except when used in any of the following manners:

"Dispensing or prescribing for, or administration to, a nonhuman species of a drug containing Xylazine approved by the Secretary of Health and Human Services under section 512 of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b).
Dispensing or prescribing for, or administration to, a nonhuman species permissible under section 512(a)(4) of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b(a)(4)).
Manufacturing, distribution, or use of Xylazine as an active pharmaceutical ingredient for manufacturing an animal drug approved under section 512 of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b or issued an investigation use exemption under subsection (j) of § 512).
Manufacturing, distribution, or use of a Xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians.
Any other use approved or permissible under The Federal Food, Drug, and Cosmetic Act.

We acknowledge that the allowance for compounding may be a point of contention. However, its inclusion would enable veterinarians and veterinary patients to access xylazine at various concentrations as needed."

Thank you for considering our input, and please let us know if you need additional information or further discussion on this matter. I am also including AVMA's published FAQ's on this issue.

Best regards,

Linda J Waite-Simpson

Linda Waite-Simpson
VVMA Executive Director

Xylazine: an essential animal sedative used across veterinary medicine

Veterinary access to legitimate xylazine must be preserved while combating the emerging public health threat of illicit xylazine

KEY POINTS:

- Xylazine is an essential drug for the safe handling of many species, particularly cattle, given there is **no** practical alternative for sedation in cattle.
- Any legislative or regulatory interventions to combat illicit xylazine need to safeguard the availability of veterinary prescription xylazine and its responsible use by veterinarians and our clients.
- Scheduling of xylazine without a provision for its unique uses in veterinary medicine will severely disrupt or eliminate the legitimate supply and prohibit critical uses of the drug.
- The AVMA supports public health efforts and policy intended to combat illicit xylazine.

What is the issue?

- Illicit xylazine is being mixed with illicit fentanyl. This potent drug combination poses grave health and safety risks for humans.
- As policy is crafted to help stop the illicit supply, we are concerned that new enforcement tools could severely impact the legal and responsible access and use of xylazine by veterinarians and our clients.
- **Limiting veterinary access to xylazine will jeopardize animal welfare and human safety.**

Why is xylazine so important in veterinary medicine?

- Xylazine is a prescription animal sedative used to facilitate safe medical evaluation, treatment, and surgical care of many species and is critical when working with livestock, zoo, laboratory, and wildlife species.
- In cattle, xylazine is the **only** safe and effective sedative drug.
- Xylazine can be reversed in veterinary patients, which prevents secondary injuries and allows them to quickly and safely re-enter the herd or the wild.

How is xylazine currently regulated for veterinary use?

- Xylazine is an FDA-approved prescription animal drug that can only be used by or under the order of a licensed veterinarian and can only be dispensed in the course of the veterinarian's professional practice.
- Federal and state laws require all prescription drugs (for people and animals) to be distributed only to those who are legally entitled to obtain and possess them, and veterinarians are required to keep extensive records.
- Manufacturers and distributors have established internal compliance systems to ensure they are only providing products to those legally entitled to them.

Why is the AVMA concerned about scheduling of xylazine without addressing the unique veterinary uses?

- Without legislation from Congress, the AVMA is concerned the DEA will move to schedule xylazine without a veterinary exemption which would limit how veterinarians are able to use the drug.
- Additionally, without federal legislative and regulatory uniformity, some states will individually regulate xylazine creating a patchwork of rules and regulations for manufacturers and distributors to navigate, increasing the likelihood for supply disruption.
- Xylazine is a low-volume, low-margin generic animal drug. If the regulatory burden or facility investments are too high, these manufacturers will likely choose to discontinue production.
- It is our understanding that there is not significant diversion of xylazine from U.S. veterinary supply channels. In discussions with the Administration, federal agencies, and state law enforcement, illicit manufacturing and importation of xylazine from overseas is commonly raised as a concerning source.

Contact: Dr. Lindsey Hornickel at 202-289-3211 or lhornickel@avma.org

Last updated 12/18/23

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What type of legislation would the AVMA support?

- The AVMA would support legislation that exempts the legitimate veterinary uses from any policy interventions, such as scheduling. This has been done before for an animal drug and will strike the right balance of protecting communities from illicit xylazine while maintaining critical veterinary access.
- The AVMA supports continued FDA-oversight of xylazine in non-human species as a prescription animal drug.
- The AVMA supports requiring manufacturers and distributors of legitimate xylazine to report sales to the DEA through an existing tracking system (ARCOS) that identifies unusual activity or changes in ordering patterns.

Status of current xylazine legislation:

- Xylazine language was included in H.R. 4531, the Support for Patients and Communities Reauthorization Act, which recently passed the House with overwhelming bipartisan support on a vote of 386-37. The included provision schedules xylazine as a Schedule III drug and exempts the FDA-approved veterinary product and its use from scheduling. The Senate will now consider the House version of the bill.
- Additionally, H.R. 1839/S. 993 Combating Illicit Xylazine Act is a bipartisan, bicameral bill that would help combat illicit xylazine trafficking while maintaining veterinarians' access under its current prescription status.

Contact: Dr. Lindsey Hornickel at 202-289-3211 or lhornickel@avma.org

Last updated 12/18/23