CVMA Update on Compounding

In January, new California Board of Pharmacy (BOP) compounding regulations went into effect. While the regulations were written for compounding pharmacies, they have impacted the veterinary profession and its ability to obtain certain compounded medications. The new regulations have more stringent requirements for pharmacies that formulate sterile compounds, including injectable medications, ophthalmic drops and emulsions, and other aqueous based oral suspensions. As a result, some compounders have opted not to offer these products, while others must change their compounding practices to meet the new requirements.

What this means for veterinary practices

Neither the VMB nor the BOP restrict how much compounded medication a veterinarian can dispense to a client, but the BOP does limit how much compounded medication a pharmacy can provide to a veterinary practice for in-house use and dispensation. This restriction, coupled with the new manufacturing requirements that went into effect in January, may result in some compounded drugs being difficult to obtain. For the time being, veterinary practices may have to call several different compounding pharmacies in order to obtain sufficient amounts of compounded medications. To date, the CVMA is not aware of any compounded medication that is unavailable altogether.

What the CVMA is doing to help the profession

On June 2, the CVMA attended a meeting of the Board of Pharmacy's Enforcement and Compounding Committee in Anaheim. It was held to hear feedback from the public on compounding regulations that took effect in January of this year. Over 200 representatives from pharmacies and various other industry groups voiced their concern over the new stringent beyond-use-dates allowed for oral aqueous compounded medications as well as other new requirements that the industry is finding difficult to implement and maintain. The committee was receptive to feedback from the public and made recommendations to be considered by the Board of Pharmacy to change the beyond-use-dating requirements for oral aqueous compounded medications to align with the United States Pharmacopeia (USP) guidance 795, and for sterile compounds to align with USP 797. This means that in many cases, the beyond-use-date for compounded medications could be extended beyond 14 days. The committee also directed staff to research over a dozen more sections of the new regulations to determine if and how changes can be made to ensure that compounders are able to provide medications to veterinarians for use on their patients, while maintaining the high level of safety and efficacy that pharmacies have provided in the past. A summary of the public feedback and requests can be viewed here. To view the complete meeting webcast, click here.

In addition to talks with the BOP, the CVMA worked in 2015 to pass legislation that would allow California veterinarians to perform select basic compounding in-house. The regulations that accompany the legislation are now being written by the Veterinary Medical Board (VMB.) The CVMA is actively involved in refining the draft regulations to meet the needs of the profession and anticipate that they will advance through the regulatory process at the VMB this year.

What can veterinary practices do?

If the VMB or the BOP propose new compounding regulations that affect veterinary practices, a public comment period will be provided. The CVMA will alert members through the CVMA Weekly e-mail

notifications and the CVMA website about the regulations to inform members who wish to submit comments.

If your practice is having difficulty obtaining a particular drug, or you have further questions regarding compounding, members may contact Dr. Grant Miller, Director of Regulatory Affairs at the CVMA at (916) 649-0599 or gmiller@cvma.net