



POLICY & ACTION FROM CONSUMER REPORTS

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Comments of Consumers Union to the California Department of Food and Agriculture on the Proposed Rule Concerning Sales of Restricted Livestock Drugs and Medically Important Antimicrobial Drugs

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Summary

Consumers Union, the policy and mobilization division of Consumer Reports,¹ welcomes the opportunity to comment on the California Department of Food and Agriculture (CDFA) proposed rule concerning sales of restricted livestock drugs and medically important antimicrobial drugs. It is important to reduce the use of antibiotics in animals in order to preserve the effectiveness of these life-saving drugs in human medicine. The Centers for Disease Control and Prevention (CDC) estimates that 23,000 people die of antibiotic-resistant infections annually.² The measures outlined in this proposed rule are designed to help prevent unnecessary antibiotic use in animals in California.

We support the proposed rule because its definitions would ensure that all medically important antimicrobial drugs will be considered as “restricted livestock drugs,” only available under a veterinarian’s oversight. This means that all businesses selling such drugs in California would be required to have a restricted livestock drug license. We also support the scope of the proposed rule, which covers *all* sellers of medically important antimicrobials, whether they are brick-and-mortar stores, out-of-state stores, catalogs, or online stores. Finally, we support the type of information and records that must be kept for at least three years—specifically, sales of

¹ Consumers Union is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. It conducts this work in the areas of food and product safety, telecommunications reform, health reform, financial reform, and other areas. Consumer Reports is the world’s largest independent product-testing organization. Using more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 7 million subscribers to its magazine, website, and other publications.

² Pg. 6 in Centers for Disease Control and Prevention. 2013. Antibiotic Resistance Threats in the United States, 2013. At: <https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>

medically important antimicrobials and the veterinary prescription or veterinary feed directive (VFD).

Beyond what CDFA currently proposes, we urge the agency to gather data on sales and usage of medically important antimicrobials for all types of usage by collecting VFDs (for medicated feed) and prescriptions (for water, oral, topical, or injection).

Specific comments

We strongly agree with CDFA’s statement of the major benefit of the proposed regulation: “Clarifying that the existing livestock drug law requires all businesses, regardless of location (in state or out of state) or sales method (online, catalog, etc.), to have a restricted livestock drug license prior to selling restricted livestock drugs in California will help ensure that all restricted livestock drugs, including medically important antimicrobials drugs, are sold appropriately and in accordance with California law.”³ The proposed regulations define all medically important antimicrobial drugs (as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code) as “restricted livestock drugs.” California law already dictates that any seller of a “restricted livestock drug” must have a “restricted livestock drug license,” and that such drugs can only be made available with the oversight of a veterinarian, either via prescription or a VFD. We also support the clarification that all sellers of medically important antimicrobials, “regardless of location (in state or out of state) or sales methods (online, catalog, etc)” must have a restricted livestock drug license prior to any sale or use in California.

Furthermore, we support the requirement that a “restricted livestock drug license” is only good for one year, that all sellers of medically important must obtain or renew the license annually, and that “it is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail ... if the date of issuance of the veterinary prescription or veterinary feed directive is more than six months prior to the date of purchase.”⁴ Prohibiting sales of antimicrobial drugs for which the prescription or VFD is more than six months old is an important step to “ensure that medically important antimicrobial drugs are used for the shortest duration necessary ... and are not used in a regular pattern ... ”.⁵

The proposed requirement that any restricted drug licensee must keep records of each sale of a restricted livestock drug that includes the drug or trade name, route of administration (via feed, water, or injection), quantity, and date sold is especially important to enable tracking and drawing evidence-based conclusions about the levels of use of such drugs in meat production

³ Pg. 3 in CDFA. 2017. Notice of Proposed Rulemaking Action: Sales of Restricted Livestock Drugs and Medically Important Antimicrobial Drugs, 3 CCR §5000-§5012. At: https://www.cdfa.ca.gov/is/docs/AUS_NoticeOfProposedAction.pdf

⁴ Pg. 5 in CDFA. 2017. Proposed Regulation Text: Sales of Medically Important Antimicrobial Drugs, 3 CCR §5005-§5012. At: https://www.cdfa.ca.gov/is/docs/AUS_ProposedText.pdf

⁵ Pg. 13 in CDFA. 2017. Initial Statement of Reasons: Sales of Restricted Livestock Drugs and Medically Important Antimicrobial Drugs, 3 CCR §5000-§5012. At: https://www.cdfa.ca.gov/is/docs/AUS_InitialStatementOfReasons.pdf

in California. We also support the additional recordkeeping requirements for medically important antimicrobials sold, and the retention of such records for a period of three years, , including the name and California Veterinary Medical Board license number of the prescribing veterinarian, a unique transaction identification number, and copies of the VFD or prescription labeled with the corresponding unique transaction identification number. Maintaining such records is necessary to ensure that CDFA has the necessary information to implement the law.

At a June 12, 2017, meeting of the CDFA's Antimicrobial Use Advisory Committee, CDFA stated that it had already contacted the feed mills that were authorized to sell medicated feeds containing medically important antimicrobials in California and were collecting copies of the VFDs. We think this is a good step forward, since according to national data from 2015, 74% of medically important antimicrobials are administered via feed.⁶ However, medically important antimicrobials can also be administered via water, by injection, and by oral and topical methods. We urge CDFA to collect data on use of medically important antimicrobials via water, oral, topical, and injection methods by obtaining copies of the prescription for such uses.

In sum, we believe that the proposed regulations on sales of medically important antimicrobial drugs used in food animals are important steps toward implementing the requirements of California Senate Bill 27 as it relates to licensees, and so we support the finalization of these regulations.

Thank you for your consideration of our comments.

Respectfully submitted,



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⁶ Table 11a, pg. 44 in FDA. 2016. 2015 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. At: <https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM534243.pdf>