

Over the Counter Medication Moving to Prescription (OTC – Rx)

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What is changing?

Many prescription (Rx) antibiotic products used in food animal veterinary medicine have been under veterinary oversight. In January 2017, several over the counter (OTC) products were shifted from OTC to veterinary feed directive (VFD) status. In 2023, remaining OTC "medically important" antibiotics will transition to prescription status. These products will no longer be able to be sold as OTC products and will only be available with a veterinary prescription and will need to be purchased from a veterinarian or a pharmacy.

When?

Expect the change to happen around June, 2023. However, the change to OTC medication availability may occur earlier or later than this for a few reasons:

1. Some manufacturers have already shipped the last of their OTC products, some of which may run out before June 11, 2023.
2. Other products have plenty in retail so these products may be on the shelves beyond June 11, 2023.

Note: The FDA will honor these remaining products as OTC until their expiration date, so it will be legal to sell and use these products without a veterinary prescription until they expire.

Why?

The upcoming changes are part of a organized effort to improve antibiotic stewardship practices. The goal is to reduce the need for antibiotics through preventing disease and when needed, carefully choose and use antibiotics in order to:

1. Reduce the development of antibiotic resistance, which can lead to untreatable infections in both humans and animals.
2. Help make sure that these important medications can continue to treat human and animal disease for a long time.

Even though this may take some additional work, it is important to improve antibiotic stewardship and make sure that the medicine both human (physicians) and animal (veterinarians) doctors need to fight disease continues to work.

Only for Intravenous Use in Beef and Dairy Cattle.
Not for Use in Dry Dairy Cows and Veal Calves.
For Intravenous and Intramuscular Use in Horses.
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
NADA #101-479, Approved by FDA.



Prescription (Rx)

- Requires Veterinary, Client, Patient Relationship (VCPR)
- Drugs that require a veterinarian's written permission for use
- Label of a RX drug will state "CAUTION Federal law restricts use by or on the order of a licensed veterinarian."

Over-the-Counter (OTC)

- Can be purchased without a prescription,
- Should consult veterinarian before use, and
- **MUST** follow label instructions EXACTLY.



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What products are impacted?

The changes are targeted at products that are both OTC **and** "medically important" antibiotics. Medically important antibiotics are shared between human and veterinary medicine. These classes are effected because resistance to these types of antibiotics pose the most risk to both human and animal health.

Injectable Products	Intramammary Products (Mastitis Tubes)	Oral Liquids and Boluses	Eye Ointments
<ul style="list-style-type: none">• Penicillins• Tetracyclines• Sulfa Antibiotics• Erythromycin• Tylosin• Lincomycin• Spectinomycin• Gentamicin	<ul style="list-style-type: none">• Erythromycin• Penicillins• Dihydrostreptomycin• Novobiocin• Cephapirin• Cephapirin Benzathine	<ul style="list-style-type: none">• Dihydrostreptomycin• Sulfa Antibiotics• Tetracyclines• Spectinomycin• Gentamicin	<ul style="list-style-type: none">• Gentamicin• Tetracyclines

What products are NOT impacted?

The upcoming changes will not affect access to products that are already under veterinary oversight, including all VFD and prescription products. There are also a wide range of non-antibiotic and non-medically important antibiotic products that will remain available OTC. Examples of the types of products not impacted by these changes are shown in the box to the right.

Products ALREADY Under Veterinary Oversight

- Prescription Products
- Veterinary Feed Directive Products

OTC Animal Health Products

- Vaccines
- Dewormers
- Fly Control
- Hormone Implants
- Teat Sealants
- Ionophore Products

If the affected product was purchased as an OTC product prior to the move to Rx, it can be used as an OTC product until it expires (e.g., it doesn't have the Rx label) .

What should be done with impacted products already purchased as OTC?

The newly labeled prescription products will have the Rx label stating "use by or on the order of a veterinarian only" (Rx label). Prior to the change, the product label will not carry this type of a phrase, which allows it to be sold and used OTC (OTC label). Any product purchased with an OTC label will be honored as OTC until the product's expiration date.

How will this impact youth livestock project members?

Access to these medications will be no different than current requirements for prescription products. To obtain a veterinary prescription, you will need to establish a veterinary-client-patient relationship (VCPR) with a veterinarian.

Having a valid VCPR can help:

1. Make sure that the best antibiotic at the best dosage is used to improve the likelihood of recovery while minimizing the risk of resistance,
2. Manage the health of project animal(s), and
3. Prevent drug residues.

What is Needed for a Valid VCPR?



Veterinary Responsibilities

1. Be responsible for clinical judgements on the operation,
2. Has observed and has knowledge of the animal(s) to make good clinical judgements,
3. Has discussed the health plan or any treatments with the owner, and
4. Be available for follow-up, either personally or through collaboration with other veterinarians.

Owner/Farm Responsibility

1. Agree to get and keep a valid VCPR and
2. Owners and management agree to follow veterinarian's instructions.

How to establish a VCPR:

1. Invite a veterinarian to speak at your club or project meeting about health plans,
2. Have a farm tour with your club and invite the veterinarian to come along, and/or
3. Visit with your county fair veterinarian.

Once the VCPR is Established

The veterinarian can provide a prescription for products they deem appropriate.

To purchase the prescription, there are several options:

1. Directly from the veterinarian,
2. Via a mail order service through the veterinarian (e.g., Chewy, 1-800-Pet-Meds), or
3. From a pharmacy, often online, that carries livestock medications.

Note: Do not expect your local farm store to carry these products as they would require a pharmacy license and a pharmacist on staff.



Check out this video from our friends at OSU College of Veterinary Medicine and OSU Extension Delaware County!

www.go.osu.edu/VCPR

What if I have an emergency?

A veterinarian is not required to examine each animal individually to maintain a valid VCPR. After a VCPR is established, some veterinarians may allow specific products to be kept on hand for use as cases of common diseases arise. Although **establishing** a VCPR by telemedicine (e.g., phone, email, Zoom) is not allowed, once a VCPR is in place, telemedicine is allowed for continuing care as an option to get veterinary treatment recommendations when a visit may not be possible.

How should youth members and families prepare?

Be proactive!



Have a valid VCPR

- If you do not have a VCPR, establish one by calling local veterinarians to learn what is required to set up and maintain a VCPR.
- If you do have a VCPR, check with your veterinarian to make sure that your VCPR is up-to-date.



Take appropriate steps to decrease the need for antibiotics:

- Biosecurity programs,
- Proper ventilation,
- Proper nutrition, and
- Vaccination.



Have a health management plan for your animals that helps to:

- Control disease,
- Reduce the risk of drug residues, and
- Improve animal health and welfare.

How can I learn more?

Resources for youth and families: <https://ohio4h.org/livestock#VFD>

A full list of products affected is available on the FDA website: <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/list-approved-new-animal-drug-applications-affected-gfi-263>

Antibiotic Stewardship

- **Beef and Dairy Cattle:** <https://www.fda.gov/media/162069/download>
- **Poultry:** <https://www.fda.gov/media/162071/download>
- **Sheep and Goats:** <https://www.fda.gov/media/162073/download>