An industry change on labels

In order to make GFI 209 and its two main principles effective, the FDA issued another document to make sure drug labels reflect the changes in use for antibiotics.

GFI 213 came out in the summer of 2013, Apley says, and “gave a roadmap for companies to fulfill the voluntary term of Guidance 209.”

GFI 213 recommends companies comply with Guidance 209 by removing label indications for growth promotion and inserting label requirements for veterinary authorization. In exchange for doing that, the companies will not have to redo any other label claims for microbial safety, Apley says.

Critics hammered this document, saying because it was a voluntary rule, it would be toothless in changing how antimicrobials are used.

But that has been disproved, Apley says. Three months after its release, GFI 213 got the approval of all 26 drug companies for all 283 labels. Again – the December 2016 timeline has significance. That’s the date all 26 drug companies for all 283 labels. According to GFI 213, Apley says. “Veterinarians now aren’t hopeful can send electronic copies to prepare themselves for more rigid standards as well.

Apley says states will be more about what’s actually going on in a conversation. The following antimicrobials have been designated as critically important by the World Health Organization. Under Guidance for Industry 209 – after December 2016, these drugs will be limited to veterinary oversight or consultation, and will no longer be labeled for growth promotion.

* Glycopeptides – not used in food animals, illegal in U.S.
* Fluoroquinolones – Baytril (enrofloxacin), Advocin (danofloxacin)
* Cephalosporins – Naxcel, Excenel, Excede (ceftiofur)
* Macrolides – Tylan (tylosin), Micotil (tilmicosin), Draxxin (tulathromycin), Zactran (garnithromycin), Zuprevo (tildipirosin)

Medically important antimicrobials with current feed and water labels (will change after December 2016)

* Aminoglycosides: gentamicin, neomycin
* Lincomasamides: lincomycin
* Macrolides: tylosin, tilmicosin (Pulmotil currently requires a VFD in swine and cattle)
* Penicillins (natural): penicillin 5 included in combination products
* Florfenicol
* Streptogramins: virginiamycin

Sulfonamides: Both potentiated (trimethoprim/sulfa) and non-potentiated sulfonamides

Tetracyclines: chlorotetracycline, oxytetracycline, tetracycline

Antimicrobials NOT classified as medically important

Appenones – monensin, lasalocid
Flavophospholipol – bambergycin, Flavomycin, Gainpro
Bacitracin
Pleurotomutins: Tiamulin (not medically important in U.S., but classified as highly important by WHO)

Preparing for change

Apley says the veterinary feed directive and rules requiring more veterinary oversight require a longer perspective of planning for operators, and communication with a licensed vet they trust will be critical. Electronic systems are being developed “that will allow a vet to keep all your information stored.” Vets will update and renew information for clients and send it to the retail point it is sold – just like a standard medical prescription.

Apley says states will be responsible for defining veterinarian oversight and creating the standard details for prescriptions. Vets still need to specify duration of use, number of animals to be treated and the level of the VFD drug in the feed. The vet community, Apley says, wants a standard VFD duration to be six months.

But producers in the future need to prepare themselves for more rigid standards as well.

Then they’ll go into it at the required time and renew it … and hopefully can send electronic copies to who you are buying from.

“Be prepared for discussions,” Apley says. "Veterinarians now aren’t just going to be responsible for the antibiotic use; they are accountable. We are working hard as a veterinary profession to bone up on justification for all the uses, what the evidence is for efficacy, when they are going to do you good. But don’t expect it to be: ‘I want this, I want you to write it.’ I hope everyone approaches that as a conversation.

‘If it gets vets and producers talking more about what’s actually going on in a place, that’s a good thing.”

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