



August 30, 2010

The Honorable Margaret A. Hamburg, MD
Commissioner
c/o Division of Dockets Management (HF A305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

ATTN: Comment Docket No. FDA-2010-D-0094

Dear Commissioner Hamburg and Principal Deputy Commissioner Sharfstein:

While APUA welcomes FDA's draft guidance, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" as a step forward, there are miles to go before our goal of curtailing the non-judicious, overuse of antibiotics in food animal production in the United States is achieved. According to the Union of Concerned Scientists, 70% of all antibiotics sold in the United States are administered to or consumed by food animals. We shall address our comments to the two new principles that FDA is recommending regarding judicious use of medically important antimicrobial drugs in food-producing animals.

Principle 1: Concerns the necessary uses of medically important antimicrobial drugs in food-producing animals for safeguarding animal health

Although FDA believes use of antibiotics for growth promotion or for feed efficiency is "injurious," it is not actionable. As an opinion- FDA does not create regulatory policy to mandate responsible use of antibiotics by all relevant stakeholders (vets, farmers, industry). APUA recommends the following:

- Terminate use of antimicrobial for economic purposes, such as growth promotion or feed efficiency.¹²
- Define specifically what is meant: prevention, control & treatment.
- Target diseased/infected animals for treatment; reduce or eliminate massive administration of low -dose antibiotics in feed and water unless the entire herd or flock is infected. Where possible, use alternative strategies for disease prevention

¹ FAAIR Scientific Advisory Panel, Policy Recommendations, CID, vol. 34, Supplement 3, June 2002

² WHO Recommendations, 2001, WHO Global Strategy for Containment of Antimicrobial Resistance, "Use of Antimicrobials in Food Producing Animals, p.5

and control: vaccines, use of probiotics, changes in management and animal hygiene.¹

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- Create a national integrated surveillance system to monitor antimicrobial resistance and usage in animals and humans (1.2). FDA can look to its European colleagues, who are uniting all surveillance efforts (EARSS, ESAC, ESVAC) across all EU member states. Currently, Kari Grave, EMA, is leading the effort for the design and implementation of the newest surveillance system, European System of Veterinary Antimicrobial Consumption. All of the systems -- EARS-Net now, will be transferred to the ECDC (European Centre for Disease Control) in June 2011.³

Principle 2: Concerns limiting uses of medically important antimicrobial drugs in food-producing animals to those that include veterinary oversight or consultation.

APUA concurs with following recommendations made by the FAAIR Advisory Committee and the World Health Organization ^{1,2}:

- Require obligatory prescriptions for all antimicrobials used in disease control in food animals, except in special circumstances when they may be dispensed on advice of a trained health care professional.
- Link prescription-only status to regulations on sale, supply, dispensing; institute mechanisms of compliance by practitioners and systems to monitor compliance.
- Eliminate economic incentives that encourage inappropriate prescriptions of antimicrobials and create economic incentives for appropriate use of antimicrobials.
- Educate veterinarians to target specific areas of misuse.
- Develop up-to-date guidelines re: dosage, interval and duration.

Thank you for this opportunity to share our perspective on the problem and for your thoughtful attention.

Sincerely yours,



Kathleen Young
Executive Director, APUA

³ Herman Goossens, presentation, *Evolution of Monitoring Systems for Antimicrobial Resistance and Antimicrobial Use*, at the APUA Roundtable on "The EU Ban on the Use of Antibiotics for Growth Promotion in Agriculture: Review of Scientific Evidence and Implications for Public Health, May 29, 2010, Paris, France.