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TOPICS IN MEDICATIONS FOR POULTRY

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As part of the recent meeting of the American Association of Avian Pathologists in Pittsburgh, Pa., July 8-12, 1995, a symposium was held to address the topic of drugs and therapeutics for poultry.

Many aspects relating to the use of therapeutic agents designed to control infectious diseases in poultry were covered by leading authorities in these areas. Of particular interest to many was the use of antibacterial drugs.

Answers to the following common questions were presented.

• Why are so few poultry drugs available?

Dr. Martin K. Terry of the Animal Health Institute spoke about the need to improve the review and approval processes for drugs, which is currently very cumbersome and costly, in order to allow more drug approvals in less time. Terry illustrated the poultry industry's experience with the effects of the recent slowdowns in animal drug approval processes. He said that in the last 10-year period, five new chemicals have been approved for use in poultry, only one of which is approved for therapeutic (treatment) purposes. During that same time interval, many more useful, effective products have been taken off the market, most of which had treatment applications. In most cases, the product withdrawals were for reasons *other* than human or animal health concerns. The overall effect has been a major net loss of useful antimicrobials.

There are no appropriate approved drugs to treat several specific poultry diseases. For example, there are no legal treatment drugs for "blackhead" or histomoniasis in turkeys at this time. Additionally, there are few effective treatments for certain respiratory conditions in chickens and turkeys. Important contributors to the problem of lack of approved drugs are the time and costs involved in the current drug approval process.

Food animal drugs are often twice as expensive to develop as a comparable companion animal drug or human drug. Not only must safety and efficacy be tested and proven in the target animal, but also safety in the human consumer of the animal product must be determined. If the high costs of getting approval for a drug for use in perceived "minor" species such as turkeys, ducks, game birds, and even chickens in some instances exceeds the expected sales market return, then incentives for a pharmaceutical company to pursue development and clearances are nil.

Dr. R. Greg Stewart, consulting poultry veterinarian and scientist in Watkinsville, Ga., gave some interesting figures pertaining to the drug developing process. He said the average cost to a pharmaceutical company to develop a new chemical drug for food animals is approximately $22 million, and that it takes an average of 11 years. More than three of these 11 years are spent in review of the product by government regulators. Five million dollars is the average cost for a supplemental approval for an existing drug to expand or change its use in some way.

• What is being done to enhance current drug availability?

Dr. Martin K. Terry spoke about the efforts of industry and the Center for Veterinary Medicine to work toward a "flexible labeling initiative." The new animal drug product labels would allow veterinarians more flexibility in the use of the products. They would be able to better tailor drug doses, routes, etc. to particular disease indications in particular food animal species.

Terry also described the proposed "Veterinary Feed Order" (VFO) drawn up in response to a proposed rule by the Food and Drug Administration (FDA) designed to take all new therapeutic drugs away from feed manufacturers and require that the drugs be used only by veterinary prescription. This plan, if allowed to proceed, could cause problems of increased costs and lower availability for the poultry industry. The VFO proposes to keep many drugs from prescription-only status, while still fostering a level of veterinary involvement above that which often exists with some "over-the-counter" medications sold today.

Dr. Peter Poss, a well-known turkey veterinarian currently affiliated with the Veterinary Teaching Hospital in St. Paul, Minn., addressed drug use in the turkey industry. He proposed that the approval process be streamlined by having the FDA retain the approval process for the safety aspects of drug testing, while letting the industry carry out the efficacy aspects. He says, "FDA should not be concerned with efficacy since a drug sponsor will not expend the resources to clear a useless compound and the industry will know if it works very quickly, once it is on the market."

Dr. Tom Holder, an experienced broiler industry veterinarian based in Salisbury, Md., echoed that thought in his presentation on antibiotic use in broilers. He said that efficacy testing needs to be practical, and small pen trials may be of limited value in predicting a drug's usefulness under commercial field conditions. "A drug company is not going to spend several million dollars on a drug that will fail after six months of use. The industry will determine the efficacy and/or the feeding program best suited for a product," Holder said. He encouraged the drug companies and CVM to work together with the broiler industry to help meet drug therapy needs in that area.

• Is it safe to mix different drugs or other additives to treat poultry?

Dr. Jim E. Riviere, a veterinary pharmacologist at the North Carolina State University College of Veterinary Medicine, spoke on "drug compounding," which is the practice of combining two or more medications. Riviere pointed out that while there are a few drugs approved to be mixed or applied with another drug for a specific purpose, most combinations have not been evaluated scientifically for compatibility. The all too common thinking that "if one drug is good, two or three should be better" is flawed and can be, at best, wasteful, and at worst, dangerous. One drug may inactivate or make another drug unavailable for the body to use or, it may potentiate the effects of another drug, leading to toxicity or long residence of drug in the tissue. Antibacterials with different mechanisms of action should not be combined in most instances. Many vitamins and electrolytes, which are widely used in the drinking water, can modify water pH, thereby changing the effectiveness of certain added antibiotics applied in the water concurrently. Specific interactions relevant to poultry are known to most poultry veterinarians who can advise on this subject.

• How can we better target appropriate antimicrobials to specific bacterial diseases? "Antimicrobial susceptibility testing has become an integral part of the therapeutic process," said Dr. W. Douglas Waltman, microbiologist at the Georgia Poultry Laboratory. He was referring to the process whereby a bacterial pathogen is isolated from diseased birds in the laboratory, and the specific bacteria is reacted against several different antimicrobial agents (drugs). This process determines if the bacteria can live and grow in the presence of the drug, or if it is inhibited or killed by the drug within the environment of the test system. The test is a good predictor of whether or not a given drug, if applied correctly, will work to limit the infection in the flock. The antimicrobial susceptibility test tends to be a better predictor of drugs that will *not* be effective (bacterial resistance) than those that *will work* (bacterial sensitivity), but still serves as the best tool available for medication selection.

In certain instances, a drug treatment may be started immediately once a tentative diagnosis of a certain bacterial disease has been made (0-24 hours after the birds have been examined). Meanwhile, an antimicrobial susceptibility test will be set up, with results often available by 48 hours. At that time, if the drug being used is determined to be ineffective, a switch to

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