U S T A

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California Horse Racing Board
Delaware Harness Racing Commission
Indiana Horse Racing Commission
Maine State Racing Commission
Maryland Racing Commission
Massachusetts Gaming Commission
Michigan Gaming Control Board
Minnesota Racing Commission
New Jersey Racing Commission
NY State Gaming Commission
Ohio State Racing Commission
PA Bur. of Standardbred Horse Racing
Florida Div. of Pari-Mutuel Wagering
Illinois Racing Board
Kentucky Horse Racing Commission
Virginia Racing Commission

To the Standardbred Regulators:

The USTA recently formed the Harness Racing Medication Collaborative (HRMC) to develop reliable, consistent medication regulations for application specifically to Harness Racing.

Some regulators have been referring to the Controlled Therapeutic Substances (CTS) list maintained by the Racing Medication and Testing Collaborative, and applying CTS guidelines on withdrawal times, route of administration, dosage, and threshold levels to Harness Racing. But the CTS list was developed for application to Thoroughbred racing, and Harness Racing's vastly different racing and training models require certain differences in the CTS list specifications. Despite the USTA's years of effort, these concerns were not adequately addressed for our industry.

Moreover, the CTS list has met criticism in some scientific circles for referencing confidential, unpublished data, inaccurate thresholds (resulting in undeserved infractions), disregard of clinical practice realities (such as intra-articular dosages allowing for treatment of only one knee or hock), and inappropriate statistical application (such as the 95:95 threshold, which puts as many as 1 in 20 appropriately-treated horses at risk of a threshold violation).

HRMC brings together a distinguished panel of academic, practicing, and regulatory veterinarians who are conversant with pharmacological and

pharmacokinetic scientific studies, veterinary practice norms, and relevant regulatory issues. Where appropriate and necessary, HRMC will also conduct or help support new research pertinent to Harness Racing.

Our work has begun. We offer the attached position papers on clenbuterol and betamethasone, and we request that all regulators with Harness Racing jurisdiction adopt the specifications stated therein.

We welcome any questions.

Respectfully submitted,

Russell C. Williams, President

Joe Faraldo, Esq., HRMC Chair

RCW:hs
Sent via email and certified mail, rrr.

United States Trotting Association
Harness Racing Medication Collaborative

Position Paper

Medication: CLENBUTEROL

Clenbuterol is a β_2-adrenoreceptor agonist widely used therapeutically in horses as a bronchodilator.

Clenbuterol is administered to harness horses post-race to aid in clearance of pulmonary secretions and debris inhaled during the course of the race.

The regulatory concern is that clenbuterol, if administered too close to the time of an upcoming race, might enhance performance by reducing normal respiratory secretions occurring during racing, or by improving respiratory function in some other way.

Data

To identify a plasma testing level that would be uniformly acceptable, HRMC reviewed all U.S. harness racing jurisdictions. Deference was given to Ohio, which uses the threshold level recommended herein, and New York, which has a history of usage at the same threshold level.

Recommendation

The permissible threshold level should be set at 25pg/mL in plasma for harness horses, with a recommended withdrawal guideline of 96 hours. This is based on the paper (Lehner, et al., 2001) cited in the References section below, where 96 hours after oral administration of 0.08 uk/kg ventipulmin, 5 in 10,000 horses are estimated as being at risk of violating a 30 pg/mL threshold. This dosing schedule / regulatory threshold has a long history of successful application in Kentucky, California, Arizona, Minnesota, New Mexico, Ohio, and Washington (Tobin, et al., 2011, p. 36).

The stated threshold and use guideline are appropriate for horses racing approximately weekly.

The veterinary panel was unanimous in this recommendation.

References

Lehner, A.F., and J.D. Harkins, W. Karpiesiuk, W.E. Woods, N.E. Robinson, L. Dirikolu, M. Fisher, and T. Tobin. "Clenbuterol in the Horse: Confirmation and Quantitation of Serum Clenbuterol by LC-MS-MS after Oral and Intratracheal Administration." *Journal of Analytical Toxicology* 25 (2001): 280-87.

Tobin, Thomas, K. Brewer, and K.H. Stirling. *World Rules for Equine Drug Testing and Therapeutic Medication*. Nicholasville: Wind Publications, 2011. Print.

Clenbuterol: promulgated 11-27-2018
Revised 11-29-2018 (add Tobin reference)

United States Trotting Association
Harness Racing Medication Collaborative

Position Paper

Medication: BETAMETHASONE

Betamethasone is a corticosteroid that acts to prevent release of substances in the body that cause inflammation. It is an approved therapeutic medication in horses administered for the purpose of reducing inflammatory responses from traumatic, oxidative, and allergic sources.

The regulatory concern is that betamethasone could mask injury and therefore place the horse at risk of further injury. Specifically, if betamethasone were administered too close to race time, horsemen and veterinarians would be unable to assess response to treatment before putting the horse at risk by racing.

Data

To establish a plasma testing level that would be uniformly acceptable, HRMC reviewed all research results known to the panel, testing history in Pennsylvania at this threshold, the necessity of covering outliers, and the in-place Canadian action levels. These data included Menendez, et al. (2015), where a 30 mg dose of betamethasone was split between two joints. Using extrapolated pharmacokinetic data from this paper, most horses are predicted to be below the 100 pg/mL threshold at 4-1/2 days post administration.

Recommendation

The permissible plasma threshold should be set at 100pg/mL in plasma for harness horses, with a recommended withdrawal guideline of 6-1/2 days.

Further, for betamethasone acetate and betamethasone sodium phosphate, the permissible threshold level under the industry practice of

injecting joints bilaterally should be set at 100 pg/mL in plasma with a recommended withdrawal guideline of 6-1/2 days.

The veterinary panel was unanimous in this recommendation.

References

Menendez, M.I., M.A. Phelps, and A.L. Bertone. "Pharmacokinetics of intra-articular betamethasone sodium phosphate and betamethasone acetate and endogenous hydrocortisone suppression in exercising horses." *Journal of Veterinary Pharmacology and Therapeutics* dol: 10.1111/jvp. 12229.

Betamethasone: promulgated 11-27-2018
Amended 11-29-2018 (threshold level for bilateral intra-articular injection)