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Dimethyl Sulfoxide (DMSO) Advisory

Withdrawal guidance of HISA's Anti-Doping and Medication Control (ADMC) Detection Times

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The Racing Medication and Testing Consortium's (RMTC) Scientific Advisory Committee (SAC), in response to requests by industry stakeholders, has performed an analysis of the Horseracing Integrity and Safety Authority's (HISA) Anti-Doping and Medication Control (ADMC) screening limits and detection times and developed a withdrawal guidance for two (2) additional substances, Dimethyl Sulfoxide (DMSO) and Pentosan (Zycosan). Following review of all available data, given a dose of 70 mL of 90% DMSO in 500 mL LRS IV single administration, the SAC recommends a withdrawal guidance of 120 hours with the understanding that **the recommendation only applies to the FDA approved medical-grade product (e.g., RIMSO-50)**. For Pentosan (Zycosan), given a dose of 3 mg/kg IM once weekly for four (4) weeks, the SAC recommends a Restricted Administration Time (RAT) of 48-hours.

Additionally, RMTC's SAC has been asked by industry stakeholders to review its withdrawal guidance of Dantrolene. In earlier work, the SAC provided withdrawal guidance of 96 hours for Dantrolene, which was based on the rigorous, objective process considering administration data of both FDA approved capsules and compounded paste dosing forms. Further review of administration data of FDA approved capsules, in both blood and urine, supports a 48-hour detection time. Understanding the potential variables associated with use of compounded substances, given a 500 mg oral dose once daily for three (3) days, using the agreed-upon methodology, RMTC's SAC recommends a withdrawal time of 72 hours with the understanding that the recommendation only applies to the **FDA approved capsules**. This recommendation does not apply to compounded products.

Further, there are risks associated with use of compounded products as drug concentrations in a formulation may differ from that declared on the product label, and from batch to batch for a single product. For these reasons, there is no reliable withdrawal guidance for the use of any compounded product.

For the complete list of *Withdrawal guidance of HISA's Anti-Doping and Medication Control* (*ADMC*) *Detection Times, go to <u>RMTC Advisories & Bulletins on our website.*.</u>