

NOTICE – MELDONIUM

30 June 2016

Dear stakeholders,

On 13 April 2016, the World Anti-Doping Agency (WADA) issued a stakeholder Notice regarding meldonium. The Notice provided you with clarification regarding meldonium's inclusion on the Prohibited List. It also advised that further urinary excretion studies had been commissioned¹ and provided guidance regarding the Results Management and Adjudication process to be followed.

This week, WADA received the results from some of the urinary excretion studies that we had commissioned, which enable us to provide the following updated guidance regarding the Results Management and Adjudication process to be followed for cases involving meldonium. Whilst other excretion studies are ongoing, and remain unpublished at this time, the results of these first studies allow WADA to provide guidance for cases where athletes claim that the substance was taken before 1 January 2016; the guidance is determined by the Urine Collection Date and Urinary Concentration of meldonium found in an athlete's sample.

Urine Collection Date: From 1 January to 29 February 2016			
Urinary concentration	> 15 µg /mL	< 15 µg /mL and > 5 µg /mL	< 5 µg /mL
Action	Normal results management	Normal results management, Anti-Doping Organization (ADO) may request the assistance of WADA to facilitate the scientific review and interpretation.	<ul style="list-style-type: none"> In the absence of other evidence of use on or after 1 January 2016, a finding of no fault may be made. In the absence of other evidence of use after 29. September 2015, no disqualification of results (see below).

NOTICE – MELDONIUM

Urine Collection Date: From 1 March to 30 September 2016			
Urinary concentration	> 5 µg /mL	< 5 µg / mL and > 1 µg /mL	< 1 µg /mL
Action	Normal results management	Normal results management, ADO may request the assistance of WADA to facilitate the scientific review and interpretation	<ul style="list-style-type: none"> In the absence of other evidence of use on or after 1 January 2016, a finding of no fault may be made. In the absence of other evidence of intake after 29 September 2015, no disqualification of results (see below).
Urine Collection Date: After 30 September 2016			
Urinary concentration	Above the limit of detection (≥ 100 ng /mL or above)		
Action	Normal results management		

To summarize, this means that for urinary concentrations of meldonium:

- below 1 µg/mL, for samples collected on or before 30 September 2016, results management may proceed and a finding of no fault may be made unless there is other evidence indicating use of meldonium on or after 1 January 2016.
- between 5 and 15 µg/mL, for samples collected on or before 29 February 2016, and concentrations between 1 and 5 µg/mL for samples collected between 1 March and before 30 September 2016, ADOs may contact the WADA Science Department at Science@wada-ama.org for assistance facilitating scientific review and interpretation.

NOTICE – MELDONIUM

- above 0.1 µg/mL (or 100 ng/mL), for samples collected after 30 September 2016, normal results management shall proceed in accordance with the World Anti-Doping Code and the relevant ADO's rules.
- given the results of the studies, it cannot be excluded that, at very low dosages, as indicated in the above table, the use of meldonium could have occurred before the Prohibited List was published by WADA on 29 September 2015. In these unique circumstances, WADA would consider it acceptable that the athlete's results not be disqualified or be reinstated in the absence of any evidence that meldonium was used after 29 September 2015.

Finally, Specific Gravity should be taken into account to correct the concentration of the samples (corrected to 1.020) in cases where the correction would be more favorable to the athlete.

We trust that this guidance will be helpful to all anti-doping organisations that are managing meldonium cases.

Yours sincerely,

The World Anti-Doping Agency

¹ As a matter of course, for reasons of efficiency, WADA does not conduct excretion studies before including a substance on the Prohibited List. This information is generally provided by the manufacturer. In the case of meldonium, no information was provided as it relates to urinary excretion.