

Introduction

Meldonium is a non-specified substance prohibited at all times (in- and out-of-competition) since 1 January 2016. It had been added to the Monitoring Program on 1 January 2015.

The 2016 Prohibited List was adopted by the WADA Executive Committee on 16 September 2015.

WADA sent the 2016 Prohibited List to all WADA stakeholders together with an explanatory note on 29 September 2015. On the same date, these documents were posted on the WADA website, as is customary every year. The inclusion of meldonium of the 2016 Prohibited List was therefore known by all WADA Stakeholders three months prior to the entry into force of the 2016 Prohibited List.

A. Inclusion on the Prohibited List and excretions studies

The inclusion of meldonium on the 2016 Prohibited List concluded a long process conducted by the WADA List Committee between 2011 and 2015. This process, which included a review of the available scientific information and the generation of specific data (in particular via the 2015 Monitoring Program, which revealed a high prevalence of the use of meldonium by athletes and teams of athletes) ultimately led to the conclusion that meldonium met two of the three criteria listed at Article 4.3.1 of the World Anti-Doping Code (Code). In particular, claims of performance enhancement had been made by various authors, including the manufacturer of meldonium.

Limited data exists to date on the urinary excretion of meldonium. Several studies are currently being conducted involving WADA-accredited laboratories, and WADA will share these results with its stakeholders when available. For the time being, the following can be taken into account based on preliminary results discussed with the research teams:

- The renal elimination of meldonium is expected to vary significantly between individuals, depending on the dosing and duration of the drug administration protocol.
- Preliminary results obtained from single and multiple drug applications indicate that the urinary elimination of meldonium at recommended doses includes an initial rapid excretion phase (estimated half-life 5-15 h), which is followed by a second, longer elimination phase with an estimated half-life of more than 100 h.
- Based on the preliminary results of the aforementioned studies, this translates to urinary concentrations higher than 10 µg/mL up to 72 h (first elimination phase), followed by a persistent long-term excretion (second elimination phase) yielding concentrations up to approximately 2 µg/mL over the following three weeks. Long term urinary excretion below 1 µg/mL down to several hundred ng/mL can persist for a number of weeks and in the low tens of ng/mL for a few months.

B. Results Management and adjudication

The mere presence of meldonium in an athlete's sample collected on or after 1 January 2016 constitutes an anti-doping rule violation under article 2.1 of the Code, which triggers the results management process.

As meldonium is a non-specified substance, provisional suspensions shall be imposed in accordance with Article 7.9.1 of the Code.

Athletes must ensure that no prohibited substance is present in their samples. Therefore, if athletes take a substance that is soon to be banned under a new Prohibited List, such substance should have cleared their system by the time the new List enters into force i.e. 1 January.

When a prohibited substance is detected, it is up to the athlete to establish the circumstances surrounding the entry of the substance into his or her body (including the timing of such entry), in order for the hearing panel to be in a position to assess the question of intent, fault and negligence, and to determine the appropriate consequences.

In the case of meldonium, there is currently a lack of clear scientific information on excretion times. For this reason, a hearing panel might justifiably find (unless there is specific evidence to the contrary) that an athlete who has established on the balance of probabilities that he or she ingested meldonium before 1 January 2016 could not reasonably have known or suspected that the meldonium would still be present in his or her body on or after 1 January 2016. In these circumstances, WADA considers that there may be grounds for no fault or negligence on the part of the athlete.

However, given that the presence of meldonium in the athlete's sample collected on or after 1 January 2016 constitutes an anti-doping rule violation, the disqualification of the athlete's results shall (even where there is no fault or negligence) be dealt with in accordance with the applicable Code provisions. If the sample was collected in competition, then the results in the competition in question will be automatically disqualified in accordance with Article 9 of the Code.

For all cases where the athlete is considered to be at fault for the presence of meldonium in his or her sample, all relevant criteria to assess the degree of fault/negligence and intention shall be assessed: the

level of the athlete's due diligence, any medical justification, declaration on the doping control form, etc.

Taking into account the above-mentioned situation with regard to excretion studies and the assessment of fault under the Code, WADA recommends the following with respect to results management:

NOTICE - MELDONIUM

1) Results management shall proceed:

- a. If the athlete admits having taken meldonium on or after 1 January 2016.
- b. If there is other evidence that the substance was taken after 1 January 2016.
- c. If the concentration is above 15 µg/mL, representing recent intake of meldonium.
- d. If the concentration is between 1 µg/mL and 15 µg/mL and the doping control was undertaken on or after 1 March 2016.

2) Results management may be stayed:

- a. If the concentration is between 1 and 15 µg/mL and the test was taken before 1 March 2016, given that the results of ongoing excretion studies are needed to determine the time of the ingestion.
- b. If the concentration is below 1 µg/mL and the test was taken after 1 March given that the results of ongoing excretion studies are needed to determine the time of the ingestion.

The following options may be followed, at the discretion of the Results Management Authority when the results management is stayed:

- i. The athlete continues serving his or her provisional suspension until the excretion studies results are available and a decision can be taken.
- ii. The provisional suspension is lifted. However, in this case, the athlete shall be informed that if it is later established based on the results of the excretion studies that he/she did take the drug on or after 1 January 2016, (i) all the results during the period in which the provisional suspension is lifted may be cancelled and prizes returned, and (ii) the ineligibility period ultimately imposed is likely to start on the date of the decision (with a credit for the provisional suspension already served).

3) Cases where the concentration is below 1 µg/ml and the test was taken before 1 March 2016 are compatible with an intake prior to January 2016. If the anti-doping organization finds that the athlete could not reasonably have known or suspected that the substance would still be present in his/her body on or after 1 January 2016, then a finding of no fault or negligence may be made.

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