



2 DOPING QUESTIONS 2 DETAILED ANSWERS

THIS EDITION OF THE IPOD ADDRESSES TWO CURRENT MAINSTREAM TOPICS. WE TRUST THE ANSWERS PROVIDED TO QUESTIONS THAT HAVE BEEN ASKED WILL SHED SOME LIGHT ON THESE IMPORTANT ISSUES.

THANK YOU FOR YOUR QUERIES.

QUESTION:

WHAT IS MELDONIUM AND WHY IS IT CURRENTLY SUCH A PROBLEM IN SPORT?

ANSWER:

Meldonium is a prohibited substance that has been on the WADA Prohibited List (the List) since January 1 2016, after the List was adopted by the WADA Executive Committee on September 16, 2015.

Meldonium is classified under Section S4 (5.3) of the List as a Metabolic Modulator. It is a non-specified substance and is prohibited at all times (in-competition and out-of-competition). While it was only officially added to the List this year, Meldonium had previously been added to WADA's Monitoring Program on January 1, 2015.

As is the case every year, WADA sent the 2016 Prohibited List to all WADA stakeholders together with an explanatory note three months before its publication. Last year, they sent the notice on September 29, 2015. On the same date, these documents were posted on the WADA website, as is also customary every year. The inclusion of Meldonium on the 2016 Prohibited List was therefore known by all WADA Stakeholders, and conversely should have been known by all athletes, by October 2015, three months prior to the entry into force of the 2016 Prohibited List.

WHAT IS MELDONIUM AND WHY WAS IT ONLY ADDED TO THE LIST THIS YEAR?

Meldonium was developed to treat ischaemia: a lack of blood flow to parts of the body, particularly in cases of angina or heart failure. Meldonium works by dilating blood vessels and increasing blood flow, which in turn improves exercise capacity, physical and

mental endurance, and also brain function. It is manufactured in Latvia under the name "Mildronate" and only distributed in Baltic countries and Russia. It is neither approved for use or authorized in the rest of Europe, nor is it approved for use or authorized a medical treatment in the rest of the world.

The inclusion of Meldonium on the 2016 Prohibited List concluded a long process conducted by the WADA List Committee between the years 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.

WADA found evidence that rather than using Mildronate for valid therapeutic reasons, some athletes were using it with the intention of enhancing performance by virtue of carrying more oxygen to muscle tissue. This allows athletes to have greater endurance, energy, etc. Therefore, Meldonium is, or at the very least can be, performance enhancing.

So far, Meldonium seems to have been typically used by athletes practicing sports with cardio vascular output as a key component. For example, the most high-profile cases so far are in tennis, hockey, swimming and track and field, all well-known to be cardio vascular sports. That said, adverse analytical findings of Meldonium have nonetheless been found in a variety of athletes from sports of all sorts.

WHY IS THE SITUATION GETTING COMPLICATED?

Meldonium is on the Prohibited List and is a non-specified substance. This means, under the Code and the ISSF Anti-Doping Rules, that the mandatory sanction resulting from an anti-doping rule violation involving Meldo-

nium would be four (4) yrs. The imposition of the maximum sanction for a first anti-doping rule violation may of course be circumvented first by the athlete satisfying the burden of proving the use of Meldonium was not intentional and second by the athlete trying to reduce the sanction further based on his or her degree of fault.

Because every Code Signatory is bound by the List and the Code, Meldonium classification should have made results management and adjudication of Meldonium cases as straight forward as the procedures for any other anti-doping rule violation involving the use or presence of a non-specified substance. However, to complicate matters, WADA published a statement in April 11, 2016 which indicated that some athletes who tested positive for Meldonium before March 1, 2016 could have their bans overturned or profit from greater leniency in sanctioning. This is because WADA established that there could be grounds for proving no fault or negligence or no significant fault or negligence on the part of the athlete in light of the fact that (at the time) it remained unclear how quickly Meldonium is excreted by the human body.

In fact, WADA confirmed that the conclusions derived from current studies render it unable to establish how quickly the drug clears the human body and said there was a lack of clear scientific information on excretion times. As a result, it is difficult to know whether an athlete may have taken the Meldonium before or after January 1, 2016, when it became prohibited.

Logically, it can not be argued that if an athlete took Meldonium for medical reasons before it became prohibited or in other words before January 1, 2016 and had no reason to believe it would stay in his or her system for 3 months or more, then it should not be considered an anti-doping rule violation. But, currently, it is very hard to ascertain with certainty if this would be the case because there are no clear indications as to how long the drug actually stays in an athlete's system.

To explain in simple non-scientific terms: Based on the preliminary results of WADA's

studies, when an athlete uses Meldonium, the concentration of the drug in the athlete's urine will be very high for the first 72 hours, and then it diminishes greatly. But, even after 1-2-3 + months, traces of it could still be found in urine depending on doses, duration of treatment and sensitivity of testing methods. The exact excretion period is still unclear. This means that athletes who used Meldonium before it was put on the List on January 1 2016, might be able to prove they did not take it when it was prohibited and therefore have their bans reduced or eliminated altogether.

RESULTS MANAGEMENT AND ADJUDICATION

The mere presence of Meldonium in an athlete's sample collected on or after January 1, 2016 constitutes an anti-doping rule violation under article 2.1 of the Code (and by reference 2.1 of the ISSF Anti-Doping Rules). This in turn triggers the results management and adjudication processes. The following provides an overview of these processes with regards to Meldonium.

First, because Meldonium is a non-specified substance, provisional suspensions are to be imposed in accordance with Article 7.9.1 of the Code and ISSF Rules.

Second, because athletes must ensure that no prohibited substance, including Meldonium, is present in their samples, under article 9 of the Code and ISSF Rules, if an athlete tests positive in-competition for Meldonium, regardless of the outcome of the case, the athlete's individual results in that competition will be disqualified.

Third, as is always the case, when a prohibited substance is detected in a sample, 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 intent, fault and negligence, and to determine the appropriate consequences.

As stated above, when it comes to Meldonium, there is currently a lack of clear scientific information on excretion times. Therefore, it will be necessary for arbitral panel to balance conflicting possibilities.

For example:

On the one hand, if an athlete took Meldonium for valid and documented medical reasons for a limited period of time before it was banned in 2015, he or she would not have known that they had to make sure that the Meldonium cleared their system by the time the new List entered into force i.e. January 1 2016 even if they were aware that it was to be placed on the List. There was no way to know that the substance could stay in their system over 3 months. So should that athlete be sanctioned if minute traces of the substance are found in his/her urine?

Then, on the other hand, what if an athlete has been taking Meldonium years for no truly valid medical reason (and therefore assumingly for performance enhancing reasons) and then tests positive for it in very high concentrations?

Should both athletes be treated the same way? Surely not.

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 January 1, 2016 could not reasonably have known or suspected that the Meldonium would still be present in his or her body on or after January 1, 2016. In these circumstances, it is considered that there may be grounds for no fault or negligence on the part of the athlete, which means that that he or she could be totally absolved from any wrongdoing.

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 by a Panel in the course of a hearing; this includes the level of the athlete's due diligence, any medical justification and details on dosages and length of treatment, declaration on the doping control form, etc.

Again, it must be noted that regardless of the outcome of the hearing, given that the presence of Meldonium in the athlete's sample collected on or after January 1, 2016 constitutes an anti-doping rule violation, the disqualification of the athlete's results shall – *even where there is no fault or negligence on the part of the athlete* – be dealt with in accordance with the applicable Code provisions.

In accordance with Article 9 of the Code this means that if the sample was collected in-competition, then automatically, the results in the competition when the sample was collection will be disqualified. So if an athlete won a Gold medal or broke a World record and is absolved from any wrong doing with regards to an anti-doping rule violation involving Meldonium, he or she will still be stripped of his or her medal and lose the World Record.

WADA's position on disqualification may, and probably should, eventually be challenged but until it is Article 9 will need to be applied strictly by all hearing panels.

WADA GUIDELINES FOR RESULTS MANAGEMENT AND ADJUDICATION

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

1) Results management shall proceed:

- a. If the athlete admits having taken Meldonium on or after January 1, 2016.
- b. If there is other evidence that the substance was taken after January 1, 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 March 1, 2016.

2) Results management may be stayed with varying options:

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

Obviously, there are many important variables that will need to be carefully taken into by relevant anti-doping organisations before proceeding with results management and disciplinary procedures in any Meldonium cases.

BOTTOM LINE

As of April 30, there were over 172 positive samples for Meldonium for athletes across numerous countries and sports. Understandably, dealing with positive findings of Meldonium will continue to pose an important challenge for many International Federations and National Anti-Doping Organizations in order to ensure they are properly and carefully administering such adverse analytical findings when reported and dealing with results management in accordance with the guidelines provided by WADA.

These Meldonium findings will also surely pose an important challenge for all arbitral bodies in the course of disciplinary procedures. While it is imperative that cheaters are caught and sanctioned, it is even more important that athletes only be sanctioned when they truly have violated an anti-doping rule. Until the WADA excretion studies are completed, clean athletes took Meldonium when it was not prohibited should not be subject to any periods of ineligibility. This would be counter productive, unjust and against the principles behind fair sport. The Meldonium problem is not new, but it is currently frequently talked about in mainstream media.

Keeping in mind the high profile athletes involved, the amount of ongoing cases reported, and the ongoing problems WADA has inadvertently created by being unable to provide clear and scientific excretion times prior to actually placing Meldonium on the Prohibited List, Meldonium is a problem that is not going away any time soon.

QUESTION:

I understand that the ISSF is responsible for pursuing the anti-doping rule violation if an athlete tests positive during a World Cup.

WHO HAS AUTHORITY IF A SHOOTING ATHLETE TESTS POSITIVE AT THE OLYMPIC GAMES?

ANSWER:

Under the World Anti-Doping Code (the Code), “*results management and hearings shall be the responsibility of, and shall be governed by, the procedural rules of the Anti-Doping Organization that initiated and directed sample collection*”.

As you indicated, because ISSF initiates and directs sample collection at World Cups, the ISSF is responsible for results management and hearings for any positive doping controls that arise in the course of a World Cup or out-of-competition if the doping control is collected on behalf of ISSF outside competition times.

Similarly, because the International Olympic Committee (IOC) is responsible for initiating and directing sample collection during the Olympic Games, they are responsible for results management and hearing arising out of positive doping controls taken “during the period” of the Olympic Games.

However, the IOC’s responsibility and authority with regards to sanctioning is restricted to the athlete’s disqualification from the Games. Any further sanction or period of ineligibility that may be imposed as a result of a shooting athlete’s anti-doping rule violation in the course of the Olympic Games, or any other major international event for that matter, would eventually get transferred to the ISSF for sanctioning.

HOW DOES THE PROCESS WORK?

From a regulatory standpoint,

Article 7.1.1 of the Code confirms that (...) *Results management and the conduct of hearings for a test conducted by the International Olympic Committee, the International Paralympic Committee, or another Major Event Organization, or an anti-doping rule violation discovered by one of those organizations, shall be referred to the applicable International Federation in relation to Consequences beyond exclusion from the Event, Disqualification of Event results, forfeiture of any medals, points, or prizes from the Event, or recovery of costs applicable to the anti-doping rule violation.*

Therefore, just as the ISSF, as an International Federation has its own anti-doping rules and anti-doping program, so does the IOC, as a Major Event Organiser, have its own anti-doping program and anti-doping rules for each individual Olympic Games to deal with violation that occurs in the course of those same Games.

As the anti-doping program of any anti-doping organisation and Code Signatory should, the IOC Anti-Doping Programme of the Games of the XXXI Olympiad in Rio de Janeiro in August 2016 is in compliance with the Code as are the IOC Anti-Doping Rules. (The IOC Anti-Doping Rules and the Rio Olympic Games Rio 2016 Anti-Doping Programme can both be downloaded from the IOC website).

From a practical standpoint:

The IOC is responsible for the Rio 2016 Olympic Games Anti-Doping Programme,

including in- competition testing and out-of-competition testing, from the opening of the Olympic Village on 24 July 2016 up to and including the day of the closing ceremony on August 21, 2016 (the Games Period).

Rio 2016 is responsible for the implementation of the Games Doping Control Programme, which includes the infrastructure and operational provisions to enable doping control testing as well as analysis of the doping control samples to be conducted in accordance with the Code and International Standards. If this results in an adverse analytical finding or another type of possible anti-doping rule violation then the detailed results management process is the responsibility of the IOC in accordance with the Anti-Doping Rules for the Rio Olympics.

SCOPE OF THE IOC ANTI-DOPING RULES (IOC AD RULES)

The IOC AD Rules apply in connection with the Olympic Games Rio 2016. They shall, without limitation, apply to all Doping Controls over which the IOC has jurisdiction in connection with the Olympic Games Rio 2016.

The IOC AD Rules shall, without limitation, apply automatically to (a) the IOC; (b) all athletes entered in the Olympic Games Rio 2016 or who have otherwise been made subject to the authority of the IOC in connection with the Olympic Games Rio 2016 (see below); (c) all athlete support personnel supporting such athletes; (d) other persons participating in, or accredited to, the Olympic Games Rio 2016 including, without any limitation, International Federations and NOCs; and (e) any person operating (even if only temporarily) under the authority of the IOC in connection with the Olympic Games Rio 2016.

Athletes entered in the Olympic Games Rio 2016 or who have otherwise been made subject to the authority of IOC in connection with the Olympic Games Rio 2016 are bound by the IOC / Rio AD Rules as a condition of eligibility to participate in the Olympic Games Rio 2016. Athletes shall, without limitation, be subject to the authority of the IOC upon being put forward by their NOC as potential participants in the Olympic Games Rio 2016 in advance of the Period of the Olympic Games Rio 2016 and shall in particular be considered to be entered into the Olympic Games Rio 2016 upon being included in the final NOC delegation list or in any case, upon their signature of the Eligibility Conditions Form.

The athlete support personnel and other persons participating in, or accredited to, the Olympic Games Rio 2016 are bound by the IOC AD Rules as a condition of such participation or accreditation.

Persons operating (even if only temporarily) under the authority of IOC in connection with the Olympic Games Rio 2016 are bound by the IOC AD Rules as a condition of their participation or involvement in the Olympic Games Rio 2016.

Therefore, the IOC’s authority with regards to anti-doping rule violations in the course of the Olympic Games is far-reaching.

THE EXTENT OF THE IOC’S RESULTS MANAGEMENT RESPONSIBILITIES IN RELATION TO ANTI-DOPING VIOLATIONS (SEE ARTICLE 7 OF THE IOC AD RULES)

The IOC AD Rules state that the IOC shall be responsible for results management for anti-doping rule violations arising under these Rules in relation to the consequences that are specified in Articles 9, 10.1, 10.2.1 and 11.

Rio 2016 is responsible for initiating and directing all doping controls. If an athlete tests positive, in accordance with its Code Compliant AD Rules, Rio 2016 has the authority to deal with disqualification or forfeiture of medals in the course of the Olympics, by transferring that authority to an Ad Hoc anti-doping panel comprised solely of CAS arbitrators.

The CAS Ad Hoc Anti-Doping Panel shall decide based on the facts and evidence before it if the athlete (or other person) has committed an anti-doping rule violation and if the athlete (or other person) should be disqualified from the Olympic Games, including stripped of any medals he or she might have won.

The IOC AD Rules also clearly specify that the responsibility for results management and the conduct of hearings for anti-doping rule violations arising under those Rules in relation to consequences that extend beyond the Olympic Games Rio 2016 shall be referred to the applicable International Federation.

This means that if a shooting athlete tests positive during the course of the Olympic Games, the case will first go before the CAS Ad Hoc Anti-Doping Doping Panel who will decide on disqualification or other sanction relating to the Olympic Games. Then, if the anti-doping rule violation is confirmed and the athlete is disqualified, the matter will be remitted to the ISSF, who, in accordance with the ISSF Anti-Doping Rules, will follow its own disciplinary process (See Article 8 of the ISSF Anti-Doping Rules) to decide on the additional consequences that may or may not be imposed on the athlete further to the anti-doping rule violation and disqualification from the Olympic Games.

BOTTOM LINE

Both the IOC Anti-Doping Rules and the ISSF Anti-Doping Rules comply with the Code and are administered, implemented and overseen by qualified individuals and experts.

Legal matters are never easy. However, because of the world-wide harmonisation of anti-doping rules, athletes who test positive whether in the course of an ISSF World Cup or the Olympic Games can at least be sure that they will be treated fairly, justly and in a consistent and transparent way.

We thank you for your question and encourage you to submit any anti-doping related inquests you might have to doris@issf-sports.org.

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