

WORLD RUGBY

IN THE MATTER of the Regulations Relating
to the Game and an alleged
doping offence

BETWEEN WORLD RUGBY

A N D ALEKSEY MIKHALTSOV
("the Player")

Board Judicial Committee

T M Gresson	(New Zealand)	(Chairman)
P Thomson	(Australia)	
Prof D Gerrard	(New Zealand)	

Appearances and Attendances

Aleksey Mikhaltsov	(Player)
Artem Patsev	(Attorney for Player)

For World Rugby

Ben Rutherford	(Counsel for World Rugby)
David Ho	(Anti-Doping Manager – Compliance and Results)

DECISION OF THE BOARD JUDICIAL COMMITTEE ("BJC")

1. The BJC has determined as follows:
 - That pursuant to Regulation 21.2.1 World Rugby ("WR") has established to the comfortable satisfaction of the BJC the Player committed an anti-doping rule violation ("ADRV"); that is the presence of the Prohibited Substance Meldonium in his bodily sample.
 - That pursuant to Regulation 21.10.2.1. the Player established on a balance of probability the ADRV was neither intentional or reckless, as the term "*intentional*" is defined in Regulation 21.10.2.3.
 - Given the indicative estimation of the concentration level of the Meldonium in the Player's bodily sample was approximately 25 ng/ml

(0.025 µg/ml) and he stated he took a course of Meldonium on medical advice which was completed approximately mid October 2015, and having considered the contents of WADA's Notice – Meldonium dated 11 April 2016, the BJC was satisfied the Player has established on a balance of probability that pursuant to Regulation 21.10.4 there was no fault or negligence on his part. Accordingly, the two year period of ineligibility (as prescribed by Regulation 21.10.2.2) shall be eliminated. The Player may resume playing rugby immediately.

2. A full decision with reasons will be released in due course.

DATED this 25th day of May 2016



T M Gresson (Chairman)

P Thomson

Prof D Gerrard

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DECISION OF THE BOARD JUDICIAL COMMITTEE ("BJC")

1. Aleksey Mikhaltsov ("the Player") is a member of the Russian Men's Rugby Sevens Team, on 18 January 2016 provided a urine sample (Sample Number 3890088) during an out-of-competition test conducted on behalf of World Rugby in Portugal. The Doping Control Form which was signed by the Player noted he was taking Levomicizini (*sic*) medication. Levomycetin is an antibiotic. Subsequently, as reported on 3 February 2016, by a WADA accredited laboratory (based in Lausanne) for Doping Analyses, the Sample returned an Adverse Analytical Finding ("AAF") for the substance Meldonium ("the substance").

2. Meldonium is listed in S4 (Hormone and Metabolic Modulators) in the World Anti-Doping Agency ("WADA") 2016 List of Prohibited Substances and Methods. It is not a Specified Substance. The WADA Prohibited List is included in Schedule 2 of World Rugby Regulation 21. The substance is prohibited in-competition and out-of-competition. The Player had not applied for, and had not been granted, a therapeutic use exemption ("TUE") allowing him to use the substance.
3. Following receipt of the analysis result of the A Sample, and after a preliminary review conducted in accordance with Regulation 21.7.2 (which confirmed that an anti-doping rule violation may have been committed) the Player was provisionally suspended on 4 February 2016. Subsequently, the Player indicated he did not require analysis of the "B" sample and waived his right to a hearing. However, the waiver was subsequently withdrawn and the BJC granted the Player's application to have a hearing. World Rugby consented to the application.
4. On 19 April 2016 the Player was advised through the Russian Rugby Union ("RRU") the indicative estimate for the concentration of Meldonium in the Player's sample was approximately 25 ng/mL (0.025 µg/mL). The advice was communicated by World Rugby sending a copy of the letter dated 19 April 2016 it had received from Dr Saugy PhD of the Swiss Laboratory.
5. This BJC was appointed to consider the Player's case. With the Parties' consent the hearing proceeded by way of written submissions (with supporting evidential material) being filed and exchanged.
6. On 25 May 2016, the BJC released a short decision which stated:
 - Pursuant to Regulation 21.2.1 World Rugby had established to the comfortable satisfaction of the BJC the Player committed an anti-doping rule violation ("ADRV"); that is the presence of the Prohibited Substance Meldonium in his bodily sample.
 - Pursuant to Regulation 21.10.2.1 the Player established on a balance of probability the ADRV was neither intentional or reckless, as the term "*intentional*" is defined in Regulation 21.10.2.3.
 - Given the indicative estimation of the concentration level of the Meldonium in the Player's bodily sample was 25 ng/mL (0.025

µg/mL) and he stated on medical advice he took a course of Meldonium which was completed approximately mid October 2015, and having considered the contents of WADA's Notice – Meldonium dated 11 April 2016, the Committee was satisfied the Player had established on a balance of probability that pursuant to Regulation 21.10.4 there was no fault or negligence on his part. Accordingly, the two year period of ineligibility (as prescribed by Regulation 21.10.2.2) shall be eliminated. The Player may resume playing rugby immediately.

7. The BJC now provides its full decision.

Factual Background

8. The BJC received evidence in the form of written statements from:
 - The Player (statement dated 19 February 2016);
 - The Player's Grandmother, Ponomarenko Anatolieva (statement dated 18 May 2016);
 - Dr Alexandra Orlov (statement dated 23 March 2016);
 - Head Rugby Coach (Enisei-STM Club) Valeev Kamilievich (statement dated 23 March 2016); and
 - Team Manager, Alexei Rechnev.
9. There were some conflicts within the evidential material adduced by the Player and others on his behalf but for the purpose of this decision the central and salient facts can be briefly summarised.
9. The Player is 24 years of age. He plays for the Rugby Club Enisei-STM, Krasnoyarsk, Siberia, Russia. Until his provisional suspension the Player had played one International fifteen-a-side match and 12 International Sevens matches for Russian National Teams.
10. Meldonium (also known as Mildronate) is a drug manufactured in Latvia and is prescribed for several conditions; including heart and vascular diseases, and for improved exercise capacity.
11. Since 1 January 2016 it has been on WADA's list of banned substances because of evidence of its use by athletes with the intention of enhancing

performance. Prior to it being prohibited WADA sent the 2016 Prohibited List to all WADA stakeholders together with an explanatory note on 29 September 2015. On the same date, the documents were posted on the WADA website. Thus, the intended inclusion of Meldonium on the 2016 Prohibited List was known by all WADA Stakeholders three months prior to 1 January 2016.

12. Because he was feeling physically and psychologically exhausted from "over-training", the Player's Club Doctor (Dr Orlov) on 10 March 2015 prescribed the drug Mildronate (also known as Meldonium) with 250 mg to be taken twice daily for a period of 14 days. The prescription was repeated in June and September but on each occasion the period for taking Mildronate was reduced to one week.
13. After the last period the Player became aware WADA had indicated Meldonium would be included in the 2016 Prohibited List of banned substances. Accordingly, he was advised by his Doctor he should use Riboxin instead of Meldonium. He did not use Meldonium again; indeed he gave his unused tablets to his Grandmother, a pensioner, who lived with the Player and his Wife. Because he had ceased taking Meldonium he did not consider it was necessary to apply for a TUE.
14. When the AAF for Meldonium was conveyed to the Player, the RRU Commission on his behalf in an e-mail dated 24 March 2016 sent to Mr Ho stated:

"The player candidly admitted it and repented.

During the pendency of A. Mikhaltsov's case he was suspended from participation in all international and Russian competitions.

Mikhaltsov actively collaborated with the Commission on his case."
15. Subsequently, on 28 March 2016 the Player stated in an e-mail sent on his behalf by the RRU Commission:

"I would like to mention one more time I didn't have any intention to violate the anti-doping rules and promise never repeat again. Taking into consideration my first case like this ever I hope for the Judicial Committee will treat me with indulgence."

16. On 12 April 2016 World Rugby wrote to WADA requesting "copies of any scientific studies which WADA has available demonstrating the performance-enhancing effects and pharmacokinetics of meldonium".
17. In response WADA sent a Notice dated 11 April 2016 (headed Notice – Meldonium) it had issued and advised:
- "As indicated in the notice, several studies are currently being conducted at WADA-accredited laboratories regarding the urinary excretion of meldonium. As these studies are currently ongoing, WADA is unable to provide them at this time. However, once the results of the studies are known, WADA will make them available to its stakeholders."*

The WADA Notice

18. For the purpose of providing a full understanding of the contents of the Notice, it is reproduced in full:

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:

- 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.

not involve a Specified Substance is four years for a first violation. The period of ineligibility can be reduced in certain circumstances. In the context of this case they include:

- The Player establishing the anti-doping rule violation was not intentional (refer Regulation 21.10.2.1.1).
- The Player establishing exceptional circumstances as set out in Regulation 21.10.4 (No fault or negligence) or 21.10.5 (No significant fault or negligence).

23. The Player has the burden of establishing both of these matters. Pursuant to Regulation 21.3.1 the standard of proof shall be by a balance of probability.

24. Regulation 21.10.2.3 defines the term “*intentional*” as used in Regulation 21.10.2.1.1. The definition embraces intentional and reckless conduct. The Regulation provides:

“... the term “intentional” is meant to identify those Players who cheat. The term therefore requires that the Player or other Person engaged in conduct which he or she knew constituted an anti-doping rule violation or knew that there was a significant risk that the conduct might constitute or result in an anti-doping rule violation and manifestly disregarded that risk.”

25. We were satisfied that based on his explanation (refer paras 11 and 14 supra) pursuant to Regulation 21.10.2.1 the Player established on a balance of probability the ADRV was neither intentional or reckless. He did not take Meldonium for the purpose of “*cheating*”; that is, he took Meldonium not for the purpose of committing an ADRV. Further, given the fact he ceased taking Meldonium by mid October 2015, it is seriously questionable whether he could have reasonably apprehended there would be minute quantities of the substance in his system after 1 January 2016 and there was a significant risk it might constitute an ADRV.

26. Given these findings, pursuant to Regulation 21.10.2.2, the BJC reduced the period of ineligibility from four years to two years.

No Fault or Negligence

27. Regulation 21.10.4 provides if a Player can establish No Fault or Negligence then the otherwise applicable period of ineligibility shall be eliminated.

28. No Fault or Negligence is defined in Appendix 1 of Regulation 21 as follows:
- “No Fault or Negligence: The Player or other Person’s establishing that he or she did not know or suspect, and could not reasonably have known or suspected even with the exercise of utmost caution, that he or she had Used or been administered the Prohibited Substance or Prohibited Method or otherwise violated an anti-doping rule. Except in the case of a Minor, for any violation of Regulation 21.2.1, the Player must also establish how the Prohibited Substance entered his or her system.*
29. Further, Comment 30¹ in relation to Regulation 21.10.4 stipulates there must be exceptional circumstances before there can be a finding of no fault or negligence.
30. We carefully considered Mr Patsev’s submissions as to whether the Player established there was no fault or negligence on his part and noted World Rugby properly indicated it was unable to refute the Player’s evidence in relation to the background circumstances surrounding the AAF for the substance. On this basis, we determined the Player’s case came within paragraph numbered 3 of the WADA Notice (supra) in that:
- (i) The concentration level was approximately 25 ng/mL (0.025 µg/mL);
 - (ii) The doping test occurred on 18 January 2016; and
 - (iii) On the Doctor’s advice Meldonium was taken for seven days during September/October 2015.
31. Further, the BJC adopted WADA’s indication a finding of no fault or negligence, in these circumstances could be made. Accordingly, we concluded for the reasons previously mentioned the Player could not have reasonably known or suspected that minute quantities of the substance would still be present in his body after 1 January 2016 and, as stated in our decision dated 25 May 2016, we were satisfied he had established there was no fault or negligence on his part. As a result, the two year period of ineligibility was eliminated and the Player was permitted to resume playing Rugby immediately.

Costs

32. The BJC’s preliminary view is that it is not appropriate costs are awarded to either World Rugby or the Player. However if either party wishes us to

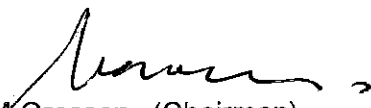
¹ Included in Appendix 2

exercise our discretion written submissions should be provided to the BJC via Mr Ho by 17:00 GMT on 10 June 2016.

Review

33. This decision is final, subject to referral to a Post Hearing Review Body (Regulation 21.13.8.1) or an appeal, where the circumstances permit to the Court of Arbitration for Sport (Regulation 21.13.2.1). In this regard, attention is also directed to Regulation 21.13.8.2, which sets out the process for referral to a Post Hearing Review Body, including the time within which the process must be initiated.

DATED this 2nd day of June 2016


T M Gresson (Chairman)

P Thomson

Prof D Gerrard