

WORLD RUGBY

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

BETWEEN WORLD RUGBY

A N D ALENA MIKHALTSOVA (nee
Bogacheva)
("the Player")

Board Judicial Committee

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

Appearances and Attendances

Alena Bogacheva	(Player)
Artem Patsev	(Attorney for Player)

For World Rugby

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

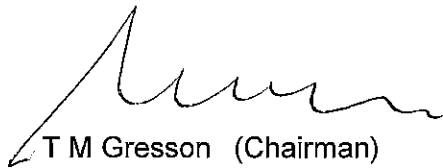
DECISION OF THE BOARD JUDICIAL COMMITTEE ("BJC")

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 her 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 0.02 µg/ml and she stated on medical advice she took a course of Meldonium which was completed on 2 October 2015, and having considered the contents of WADA's Notice – Meldonium dated 11 April 2016, the Committee 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 her 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 3rd day of May 2016



T M Gresson (Chairman)

P Thomson

Dr D Gerrard

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(nee Bogacheva)	(Player)
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David Ho	(Anti-Doping Manager – Compliance and Results)

Hearing

By way of World Rugby written submissions and correspondence

DECISION OF THE BOARD JUDICIAL COMMITTEE

1. Alena Mikhaltsova (nee Bogacheva) ("the Player") is a member of the Russian Women's Rugby Sevens Team, and having consented to be a member of World Rugby's Out of Competition Testing Pool, on 3 February 2016 provided a urine sample (Sample Number 2034826) during an out-of-competition test conducted on behalf of World Rugby in Spain. The Doping Control Form which was signed by the Player noted that she was taking no

medication and had “no comments”. Subsequently, as reported on 24 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 allowing her 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 26 February 2016. Subsequently, on 1 March 2016 the Player was advised through her Union (the Russian Rugby Union) that the indicative estimate for the concentration of Meldonium in the Player’s sample was approximately 20 ng/mL (0.02 µg/mL). The advice was communicated by World Rugby sending a copy of the letter dated 1 March 2016 it had received from Dr Saugy PhD of the Swiss Laboratory. Subsequently, the Player indicated she did not require analysis of the “B” sample.
4. This Board Judicial Committee (“BJC”) was appointed to consider the Player’s case. An organisational telephone conference hearing was held on 12 April 2016 but because of further information which became available subsequently the Player waived her right to an oral hearing. Accordingly, written submissions were filed by Counsel respectively on behalf of the Player and World Rugby and the hearing was conducted on the basis of consideration of the written material presented to the BJC.
5. On 3 May 2016, the BJC released a 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 her 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 0.02 µg/mL and she stated on medical advice she took a course of Meldonium which was completed on 2 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 her part. Accordingly, the two year period of ineligibility (as prescribed by Regulation 21.10.2.2) shall be eliminated. The Player could resume playing rugby immediately.

6. The BJC now provides its full decision.

Factual Background

7. The Player is 25 years of age. Until her provisional suspension the Player had played 32 International matches for Russia and had consented to out-of-competition testing including testing for the first quarter of 2016.
8. Meldonium (also known as Mildronate) is a drug manufactured in Latvia and is prescribed for several conditions; including heart and vascular diseases and improved exercise capacity.
9. 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.

10. In her written statement, the Player stated because of exhaustion from "overtraining" a Medical Practitioner at Krasnoyarsk Hospital, on 10 September 2015, prescribed for her the drug Mildronate 0.5 gs (to be taken twice daily over a period of 21 days) together with other drugs. The prescription was confirmed in a copy of a Krasnoyarsk Hospital Certificate (Number 18716) tendered to the BJC.
11. The Player stated that towards the end of September 2015, she became aware WADA had indicated Meldonium would be included in the 2016 Prohibited List of banned substances. However, this did not concern her as she had completed taking the drug and was assured by the Medical Practitioner that any trace of it would be completely eliminated from her system within "a couple of days". In these circumstances, she did not consider it necessary to apply for a TUE. She stopped taking Meldonium on 2 October 2015.
12. When advised of the AAF for Meldonium as reported by the Laboratory, the Player was "deeply concerned". She exchanged correspondence with World Rugby culminating in a letter she sent on 24 March 2016. It stated:
- “ ...
- As I've received the documentation package and additional information, I do hereby WAIVE my right to open my B-sample and do hereby REQUEST a hearing of my case before a Judicial Committee.*
- I've never used any prohibited substances and/or methods and I have been always strictly following my doctor's recommendations, so at this very moment I have no idea how could any prohibited substance enter my system.*
- That's why I cannot say that I admit an anti-doping rule violation, since I've never committed an intentional one, and now the only way for me is to study thoroughly: a) the documentation package from the laboratory in order to rebut the presumption of the ADRV, and b) every possible or even theoretical contacts of meldonium with my system in order to present the relevant evidence and to prove No Fault or Negligence on my side.*
- ...”
13. Following the Organisational Telephone Conference, World Rugby wrote to WADA requesting "copies of any scientific studies which WADA has

available demonstrating the performance-enhancing effects and pharmacokinetics of meldonium”.

14. 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

15. 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.

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.

The Player’s Application to Lift the Provisional Suspension

16. It will be noted WADA’s recommendations in the Notice vary depending on the concentration level and the date of the test. Following receipt of the WADA Notice, Mr Patsev on behalf of the Player, submitted the Provisional Suspension should be lifted prior to the BJC dealing with the substantive issues. Mr Patsev submitted this was because, based on the scientific opinion of Dr Arthur Kopylov PhD (Institute of Biomedical Chemistry of the Russian Academy of Medical Science - Moscow), the precise concentration of Meldonium could be disputed. Thus, it was “probable” there was a false positive result but in any event whatever the concentration level it was less than 0.02 µg/mL.
17. However, the BJC decided it was not necessary for it to consider the application because in dealing with the substantive issues it determined that the sanction should be eliminated thereby allowing the Player to immediately resume playing Rugby. Thus, the application to lift the Provisional Suspension became redundant.

Issues

18. As indicated, in our previous decision, there were three substantive issues which required our consideration.

Anti-Doping Rule Violation

19. Pursuant to Regulation 21.2.1 the “presence of a Prohibited Substance or its Metabolites or Markers in a Player’s Sample” constitutes an anti-doping rule violation. Regulation 21.2.1.1 provides:

“21.2.1.1 *It is each Player’s personal duty to ensure that no Prohibited Substance enters his or her body. Players are responsible for any Prohibited Substance or its Metabolites or Markers found to be present in their Samples. Accordingly, it is not necessary that intent, Fault, negligence or knowing Use on the Player’s part be demonstrated in order to establish an anti-doping rule violation under Regulation 21.2.1”*

20. Regulation 21.2.1.2 provides:

“21.2.1.2 *Sufficient proof of an anti-doping rule violation under Regulation 21.2.1 is established by any of the following: presence of a Prohibited Substance or its Metabolites or Markers in the Player’s A Sample where the Player waives analysis of the B Sample and the B Sample is not analysed; or, where the Player’s B Sample is analysed and the analysis of the Player’s B Sample confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the Player’s A Sample; or, where the Player’s B Sample is split into two bottles and the analysis of the second bottle confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the first bottle. [See Comment 2]*”

21. Pursuant to Regulation 21.3.1 World Rugby has the burden of establishing an anti-doping rule violation to the comfortable satisfaction of the BJC.

22. As mentioned, the AAF for Meldonium was reported by a WADA accredited laboratory based in Switzerland. In this respect Regulation 21.3.2.2 is relevant. It creates a presumption that WADA accredited laboratories are presumed to have conducted sample analysis in accordance with the International Standard for Laboratories. The Regulation states:

“21.3.2.2 *WADA-accredited laboratories, and other laboratories approved by WADA, are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The Player or other Person may rebut this presumption by establishing that a departure from the International Standard for Laboratories occurred which could reasonably have caused the Adverse Analytical Finding. If the Player or other Person rebuts the preceding presumption by showing that a departure from the International Standard for Laboratories occurred which*

could reasonably have caused the Adverse Analytical Finding, then World Rugby shall have the burden to establish that such departure did not cause the Adverse Analytical Finding.”

23. As mentioned, Mr Patsev, initially submitted that, based on the opinion of Dr Kopylov (who at the Moscow premises of the Institute of Biomedical Chemistry conducted a study of the empirical data considered by the Swiss Laboratory) the AAF reported for the sample was a false positive result. However, Dr Kopylov’s view was discounted by Dr Saugy who described the former’s analysis as “*theoretical*” which failed to:

“... take into account the matrix effect of the biological sample which is in all our procedures corrected by the use of an internal standard.”

And further:

“It can be seen in the attached file how we did estimate the Meldonium concentration with control spiked urine at 20 ng/ml.

By comparing the signal of the internal standards for both the sample and the spiked urine respectively (6112105 vs 13965385), we easily understand that the estimated concentration is really close to 20 after the use of the correction by the internal standard, which is the state of the art procedure in such a case.

We must again emphasize the fact that this procedure is not quantitative, but qualitative. The LOD which is announced is also an estimated quantity.

What finally defines an adverse analytical finding when a qualitative method is applied is the specificity of the result. That is defined in the WADA TD2015 IDCR.

...”

24. In addressing this conflict between the experts, Mr Rutherford succinctly submitted:

“... the mere presentation of a hypothesis, flawed as it has been demonstrated to be, by a scientist (it is noted, not one attached to a WADA-accredited laboratory) is insufficient to displace the presumption of the laboratory having conducted its analysis appropriately in accordance with Internal Standards given its status as a WADA-accredited laboratory in accordance with Regulation 21.3.2.2. ... the admission by the Player of having taken meldonium during September and October is in all probability the source of the meldonium in her Sample as opposed to some sort of error by the laboratory as Dr Kopylov asserts.”

We agree. We note, also, Mr Patsev in his response to Mr Rutherford's submissions (which appended Dr Saugy's letter) did not advance his submission any further.

25. Accordingly, the BJC determined World Rugby had established to the required standard the anti-doping rule violation; that is the presence of the Prohibited Substance Meldonium in the Player's bodily sample.

Sanction

26. The period of ineligibility to be imposed for a violation of Regulation 21.2.1 (Presence of Prohibited Substance or its Metabolites or Markers) that does 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), 21.10.5 (No significant fault or negligence).

27. 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.

28. 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."

29. We were satisfied that based on her explanation (refer paras 11 and 12 supra) pursuant to Regulation 21.10.2.1 the Player established on a balance of probability the ADRV was neither intentional or reckless. She did not take the Meldonium for the purpose of "*cheating*"; that is, she took the Meldonium not for the purpose of committing an ADRV. Further, given the assurance she received from the Medical Practitioner at Krasnoyarsk Hospital and the

fact, she ceased taking Meldonium on 2 October 2015, it is seriously questionable whether she could have reasonably apprehended there would be minute quantities of the substance in her system after 1 January 2016 and there was a significant risk it might constitute an ADRV.

30. 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

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

32. 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.

33. 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.

34. We carefully considered Mr Patsev’s submissions as to whether the Player established there was no fault or negligence on her 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 0.02 µg/mL;
- (ii) The doping test occurred on 3 February 2016; and
- (iii) On the Doctor’s advice the Meldonium was taken for 21 days during September/October 2015.

¹ Included in Appendix 2

35. Further, the BJC adopted WADA's indication that a finding of no fault or negligence, in these circumstances could be made. Accordingly, we concluded for the reasons previously mentioned (refer para 29 supra), the Player could not have reasonably known or suspected that minute quantities of the substance would still be present in her body after 1 January 2016 and, as stated in our decision dated 3 May 2016, we were satisfied she had established there was no fault or negligence on her part. As a result, the two year period of ineligibility was eliminated and the Player was permitted to resume playing Rugby immediately.

Costs

36. 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 exercise our discretion written submissions should be provided to the BJC via Mr Ho by 17:00 GMT on 24 May 2016.

Review

37. 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 1st day of June 2016



T M Gresson (Chairman)

P Thomson

Prof D Gerrard