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Case No. 2019-02

August 12, 2019

Final decision in the matter of

International Skating Union,

Avenue Juste-Olivier 17, 1006 Lausanne, Switzerland, represented by its Legal Advisor, Prof. Dr. Michael Geistlinger,

- Complainant -

against

Mr. Vitali MIKHAILOV BELARUS

- Alleged Offender -

and

Skating Union of Belarus

- Interested ISU Member -

Regarding the Violation of the ISU Anti-Doping Rules

I. History of the Procedure

On June 12, 2019, the ISU filed a complaint against the Alleged Offender, together with 14 exhibits. On June 14, 2019 the Alleged Offender and the Interested Member were invited by the ISU Disciplinary Commission to file a statement of reply within 21 days upon receipt of the complaint. Both, the Alleged Offender and the Interested Member filed a statement of reply on June 27, 2019.

II. Procedural Matters

According to Article 25.10 of the ISU Constitution and Article 8.1.1 of the ISU Anti-Doping Rules the ISU Disciplinary Commission has jurisdiction in doping cases arising out of ISU Testing or of Testing at International Events. The present case arises out of testing of the Alleged Offender at the 2019 ISU World Allround Speed Skating Championships, i.e. of testing at an International Event.

Prior to this event, on November 20, 2018, the skater, had signed the "Declaration for Competitors and Officials entering ISU Events" for the season 2018/2019. This Declaration states:

"I, the undersigned,

I) accept the ISU Constitution, which establishes an ISU Disciplinary Commission (Article 24) and recognizes the Court of Arbitration for Sport (CAS), in Lausanne, Switzerland as the arbitration tribunal authorized to issue final and binding awards involving the ISU, its Members and all participants in ISU activities, excluding all recourse to ordinary courts (Articles 25 & 26);....

VI) am familiar with the ISU Code of Ethics (ISU Communication 1717 or any update of this Communication) as well as ISU Anti-Doping Rules (ISU Communication 1922 & 2100 or any update of these Communications) and also with the current List of Prohibited Substances and Methods and I declare that I will fully comply with such Rules."

Therefore, the ISU Disciplinary Commission has jurisdiction to hear and decide this case.

III. Facts

The Alleged Offender is an International Level Skater and member of the Skating Union of Belarus. He participated at the 2019 ISU World Allround Speed Skating Championships in Calgary, Canada, on March 2-3, 2019. He finished 18th in the 500m Men Allround, 14th in the 5000m Men Allround, 19th in the 1500m Men Allround and 19^{th} of the Overall Classification.

An In-Competition Anti-Doping test was carried out on March 2, 2019. The ISU was notified by Canadian WADA-accredited Anti-Doping Laboratory Laval Quebec, of an Adverse Analytical Finding regarding the Alleged Offender's Sample number 4316162. The adverse finding was that the sample contained higenamine.

Higenamine is a prohibited substance, designated as a beta-2 agonist.

The ISU informed the Alleged Offender and the Skating Union of Belarus of the Adverse Analytical Finding and of the Alleged Offender's right to provide a written explanation to the ISU Director General or to dispute that an anti-doping rule violation had occurred within 15 days and to request that the B Sample be analysed. The Alleged Offender was asked to provide a copy of the description of ingredients for the Preworkout Allmax supplement which he had declared using on the Doping Control Form.

The Alleged Offender was further advised that according to Articles 10.6.3 and 10.6.1 ISU Anti-Doing Rules, he had the opportunity to promptly admit the anti-doping rule violation, consequently to request a reduction of the period of ineligibility and to cooperate and provide substantial assistance in discovering or establishing anti-doping rule violations.

On April 8, 2019, the President of the Skating Union of Belarus informed the ISU

"that Mr. Vitaly Mikhailov has bought the pre-workout complex Impact Igniter by non-acquaintance. The sports man has indicated this workout complex in his anti-doping form. Mr. Mikhailov fully admitted that he purchased this complex by non-acquaintance and by mistake."

An attached letter of Explanation by the Alleged Offender, stated that

"on February 24, 2019, being at a training camp before the World Championships in Calgary, (Canada) at the GNC sports nutrition store in the CF Market Mall, I bought the pre-workout complex IMPACT IGNITER of the ALLMAX brand for the first time, since this is a major brand in the sports nutrition industry. I did not imagine that it could contain a prohibited substance. Therefore, when taking the doping test 03/03/2019, I wrote this dietary supplement in my anti-doping form."

The Alleged Offender explained that it was only after he was informed that the prohibited substance higenamine was found in his body, that he checked the listed components of ALLMAX IMPACT IGNITER and saw that higenamine was included. He indicated he was surprised, given that a large Canadian store sold product containing a prohibited substance. He was not aware of the existence of higenamine, despite the fact that he periodically studied the list of prohibited substances.

The Alleged Offender co-operated fully and apologized for his misunderstanding. He assured the ISU that he did not want to violate the doping rules and stated that he could not understand how this could have happened.

In parallel, the ISU sought expert advice from the chair of its Medical Commission and Prof. Martial Saugy regarding why the Canadian Anti-Doping Laboratory had reported a result of higenamine at a level below 10 ng/mL as an Adverse Analytical Finding. Further, the ISU asked why the laboratory had not followed para 4.0 of the WADA Technical Document – TD2018MRPL (MINIMUM REQUIRED PERFORMANCE LEVELS FOR DETECTION AND IDENTIFICATION OF NON-THRESHOLD SUBSTANCES".

This provision states that

"A confirmed identification of a Non-Threshold Substance at any concentration shall be reported as an Adverse Analytical Finding, with the following exceptions:

 Salmeterol and higenamine should not be reported at levels below 10 ng/mL (i.e. 50 % of the MRPL for beta-2 agonists)." Both experts referred to the standing laboratory practice that a level of 7ng/mL should not have been reported, even where the athlete had indicated the use of a nutrition supplement containing a prohibited substance on his Doping Control Form.

There is no discretion for a laboratory to deviate from Rule 4.0. A value of 7 ng/mL should not have been reported. However, the chief laboratory analyst, after having consulted WADA, decided to report the case as Adverse Analytical Finding to the ISU.

Professor Saugy, whom the ISU nominated as expert witness, stated that

"higenamine is found in several species of plants and has been used in Japanese traditional medicine to treat cough and breathing difficulties. It has been shown in a publication with an animalmodel that it has certainly beta2-agonist effect, although this is still debated in the scientific community. Regarding the method, no doubt that with the present technologies, it is no problem to measure higenamine at lower levels than 10 ng/ml, as it is the case for salmeterol. Regarding the effect of the substance on the performance, very little (in fact nothing has been published) is known on higenamine (as well as for salmeterol). It is then reasonable to admit that the 10 ng/ml reporting limit has been set, because of the lack of effect at this concentration; even if it always difficult to make a relation between urinary concentration of a product and an effect on the body. And also because higenamine can be part of traditional medicine and is present in plants, as a matter of precaution, it was important to put this limit. So to my point of view, the 7 ng/ml found in the urine of this athlete is below the official reporting limit. Indeed, it SHOULD have not been reported by the laboratory. But it SHALL not be ADRV for the athlete."

As a consequence of the ISU experts' opinions, on April 29, 2019, the ISU Anti-Doping Manager sent the following email to WADA:

"This is to inform you that the ISU after having consulted Professor Saugy and the chair of its Medical Commission Doctor Jane Moran intends to close the case of ISU AAF 4316162 BLR SS (Higenamine concentration around 7 ng/mL (gs: 1.008) by laboratory Montreal) as no ADRV for the following reasons:

- According to para 4.0 of the WADA Technical Document TD2018MRPL (MINIMUM REQUIRED PERFORMANCE LEVELS FOR DETECTION AND IDENTIFICATION OF NON-THRESHOLD SUBSTANCES) ("4.0 Reporting of Non-Threshold Substances A confirmed identification of a Non-Threshold Substance at any concentration shall be reported as an Adverse Analytical Finding, with the following exceptions:
- Salmeterol and higenamine should not be reported at levels below 10 ng/mL (i.e. 50 % of the MRPL for beta-2 agonists)".
- The laboratory deviated from the above document because of the indication of the Skater on the DCF that he had used Preworkout Allmax.
- The Skater confirmed this fact when having been confronted by the ISU with the laboratory report and showed to the ISU that the list of ingredients of Allmax clearly mentions the substance higenamine (please, see attachments).

• According to Professor Saugy, the reasons for having established a reporting limit of 10 ng/mL for higenamine are the lack of effect of the substance below the concentration of 10 ng/mL, even if it is always difficult to make a relation between urinary concentration of a product and an effect on the body, and the fact that higenamine can be part of traditional medicine and is present in plants. Thus, as a matter of precaution, it was important to put this limit."

During a telephone conversation on May 16, 2019, WADA informed the ISU Anti-Doping Manager that the case must be considered an anti-doping rule violation regardless of whether or not the concentration was below the limit, which was not a threshold limit because the Skater had admitted to take a forbidden substance. WADA claimed that the 10ng/mL reporting limit for higenamine had been set to avoid natural contamination being declared as ADRV. Since the laboratory had seen the admission by declaration on the Doping Control Form that the presence of higenamine was not due to natural contamination, WADA considered the laboratory entitled to report and advised it to report the presence of the substance as an Adverse Analytical Finding, even though other laboratories would not have done so.

Three different products of Preworkout Allmax were available, one of which contained higenamine. Thus, it was only when the Skater confirmed which product he had purchased, did it become clear that he made a voluntary intake of a supplement that contained higenamine and, therefore, an anti-doping rule violation.

The ISU Disciplinary Commission received a statement of 11 July 2019 from Dr. Jane Moran, Chair of the ISU Medical Commission, relating to her former emails. Dr Moran confirmed that the threshold for higenamine was 10mg/ml, but it was reported by the INRS lab in Montreal because higenamine is a prohibited substance at any level and the Athlete declared it on the doping Control Form. Hence, the lab was clear that the positive result was from a supplement and not a plant or organic source and therefore reported it below the threshold.

Dr. Moran notes that had the Athlete not reported the supplement on the DCF, the finding would not have been reported as it was below the reporting level.

An expert opinion from Professor Martial Saugy, Director of REDs, University of Lausanne, dated July 16, 2019 was received by the ISU DC by email on July 16, 2019 from the ISU relating to his earlier correspondence with ISU.

Professor Saugy's Conclusion:

- the 7 ng/ml of Higenamine found in the athlete's urine is below the official reporting limit as defined in the WADA TD2018MRPL. Therefore, as indicated in this technical document, it SHOULD have not been reported by the laboratory.
- If Higenamine is considered as a stimulant, the 7 ng/ml reported by the laboratory are far below the actual reporting limit for stimulants (50 ng/ml).

IV. Law

The Minimum Required Performance Levels for Detection and Identification of Non-Threshold Substances are set out in the WADA Technical Document – TD2018MRPL (MINIMUM REQUIRED PERFORMANCE LEVELS FOR DETECTION AND IDENTIFICATION OF NON-THRESHOLD SUBSTANCES".

The introductory paragraph to this Technical Document notes that some laboratories have the ability to detect substances at lower levels than do other laboratories:

It is recognized that some Laboratories will be able to identify lower concentrations of Prohibited Substances than other Laboratories. While such individual capabilities are encouraged in order to improve the overall system, it is also recognized that there are Minimum Required Performance Levels (MRPL) at which all Laboratories **shall** operate (Table 1) (emphasis added).

Rule 1.0 gives the Minimum Required Performance Levels (MRPL). It states that:

The MRPL is intended to harmonize the analytical performance of methods applied to the detection of Non-Threshold Substances. The MRPL is a mandatory analytical parameter of technical performance established by WADA with which the Laboratories shall comply when testing for the presence of a particular Prohibited Substance, its Metabolite(s) or Marker(s). The MRPL is the minimum concentration of a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Method that Laboratories shall be able to reliably detect and identify in routine daily operations.

• The MRPL is not a threshold (T) nor is it a Limit of Detection (LOD). Adverse Analytical Findings may result from concentrations below the established MRPL values......

However, Rule 4.0 includes that:

- "A confirmed identification of a Non-Threshold Substance <u>at any concentration</u> shall be reported as an Adverse Analytical Finding, <u>with the following exceptions</u>:
- Salmeterol and higenamine should not be reported at levels below 10 ng/mL (i.e. 50 % of the MRPL for beta-2 agonists)."

The Complainant asked the Panel to impose a reprimand on the Alleged Offender, and to declare the results obtained in the 2019 ISU World Allround Speed Skating Championships to be disqualified, with all resulting consequences, including forfeiture of any medals, points and prizes.

The Alleged Offender and Skating Union of Belarus accept that a technical violation of the Anti-Doping Rules has occurred, the circumstances of the case are such that careful consideration is required. Attention is drawn to the honest declaration of the substance of the DCF and level of higenamine found supporting a lack of negative intent. More active measures to prevent similar situations arising on the future would be put in place. The Panel has considered this case and finds that:

Rule 4.0 of the WADA Technical Document – TD2018MRPL is not discretionary for this substance. Hence, a value of 7 ng/mL of higenamine should not have been reported as an Adverse Analytical Finding. Given that this level should not have been reported, no weight can be given to a sanction flowing from it. The correct result is that no Adverse Analytical Finding (pursuant to the WADA Technical Document) was found. The result was only reported due to the admission of the Skater by declaration that he had used a supplement on the DCF. This supplement was later confirmed as stating it contained higenamine in the list of ingredients. Hence, the laboratory found that the presence of higenamine was not a positive test from a plant or organise source but from a supplement. Therefore, higenamine was reported at below the reporting threshold of 10ng/ml. In this case the athlete was placed in jeopardy by the honest and correct declaration of use of a nutritional supplement declared on his Doping Control Form. That supplement contained a prohibited substance that manifested in his urine sample at a level below the MRPL. The MRPL is presumably set after consideration of the possibility of natural sources or contamination effects, and due to scientific uncertainty of any performance enhancing effects below this level.

V. Decision

Based on the above considerations the ISU Disciplinary Commission rules as follows:

- 1. The Complaint is dismissed.
- 2. The Complainant bears the costs of the proceedings.

Volker Waldeck

Dr. Allan Böhm

Allan Both

Susan Petricevic

The present decision is subject to appeal to the Court of Arbitration for Sport, Avenue de Beaumont 2, CH-1012 Lausanne, Switzerland, within 21 days upon receipt of the decision, in accordance with Article 25 Paragraph 12 and Article 26 of the ISU Constitution 2018.