# INTERNATIONAL RUGBY BOARD

IN THE MATTER

of the Regulations Relating to the Game and alleged

doping offences

**BETWEEN** 

THE INTERNATIONAL

**RUGBY BOARD** 

AND

VITALY ZHIVATOV

and

**RUSHAN YAGUDIN** 

("the Players")

and

**ANDREY KOSAREV** 

("the Physiotherapist")

Respondents

### **Judicial Committee**

Tim Gresson

Gregor Nicholson

Ismail Jakoet

(New Zealand)

(Scotland)

(South Africa)

(Chairman)

### **Present**

Susan Ahern

Julie O'Mahony

Tim Ricketts

**IRB Senior Counsel IRB Junior Counsel** 

IRB - Anti-Doping Officer

Rushan Yagudin Vitaly Zhivatov

Player Player

Andrey Kosarev

**Physiotherapist** 

Artem Patsev Elena Nozhkina

Counsel for the Players Counsel for Mr Kosarev

**Howard Thomas** 

Executive Director - Russian Rugby Union

Lily Orlovska

Interpreter

#### Hearings

29<sup>th</sup> August and 8<sup>th</sup> November 2012 (GMT) (by telephone conference) and written submissions

TMG-096091-40-19-V2

# **DECISION OF THE BOARD JUDICIAL COMMITTEE**

## **Background**

- 1. Rushan Yagudin (from Krasnoyarsk) and Vitaly Zhivatov (from Moscow) ("the Players") are two young players who had been selected for the first time to play for the National Russian 7's Team which participated in the IRB 7's Series Tournament (part of the HSBC Sevens World Series) played in Hong Kong over the weekend of 23<sup>rd</sup> to 25<sup>th</sup> March 2012.
- 2. Following an eight hour flight from Moscow, they arrived in Hong Kong on 13<sup>th</sup> March 2012. Prior to the international flight, Yagudin caught a domestic flight which lasted approximately two and a half hours and then he waited at Moscow airport for approximately eight hours before the connecting international flight to Hong Kong. The time zone difference between Moscow and Hong Kong was plus four hours.
- 3. According to the Players, who were in the same hotel room, they had a poor night of broken sleep during the evening of 13<sup>th</sup>/14<sup>th</sup> March. They attributed this to what they described as "jet lag". Because there was no Team Doctor with the Russian side they approached other players and some of the support personnel with the Russian Team including Andrey Kosarev (the "Physiotherapist") for advice. The latter stated he had previously suffered from "jet lag" on many occasions and to overcome the problem, based on his experience, on the morning of 14<sup>th</sup> March 2012 he gave each of the Players a 100 mg tablet marketed under the brand name of "Phenotropil". The pills were given to the Players in the corridor outside the Physiotherapist's room following breakfast. The Players stated that after taking one pill they felt "better, (the) sleep disturbance vanished". They stated they took no more pills.
- 4. Nine days later on the 23<sup>rd</sup> March 2012 the two Players provided urine samples Code Numbers 2693322 (Yagudin) and 2693329 (Zhivatov) during In-Competition Tests conducted on behalf of the IRB. Coincidentally, they were the only two players in the Russian Team who suffered from the effects of "jet lag" and who were tested during the Tournament. When the Players provided the samples they only declared they had taken the substance

"Maximuscle" over the last seven days<sup>1</sup>. Subsequently, both samples returned Adverse Analytical Findings for the substance 4-phenylpiracetam (aka carphedon). The approximate concentration levels found in the samples were estimated to be 10,000 ng/ml and 5,000 ng/ml.

- 5. Under Regulation 21 of the IRB Anti-Doping Regulations 4-phenylpiracetam is classified as a Non Specified Stimulant under s.6(a) of the World Anti-Doping Agency's (WADA) 2012 List of Prohibited Substances and Methods. It is prohibited for use In-Competition. The WADA Prohibited List was incorporated into the Tournament's Anti-Doping Programme (TADP) which was based upon IRB Regulation 21.
- 6. There was no record of the Players having applied for therapeutic exemptions allowing them to use the substance.
- 7. Following receipt of the analysis of the A sample and after a preliminary review conducted by Dr Barry O'Driscoll (Ireland) in accordance with Clause 20.1 of the TADP (which confirmed anti-doping rule violations may have been committed), the Players were notified of their Adverse Analytical Findings and were provisionally suspended from Rugby on 18<sup>th</sup> April 2012 (Yagudin) and 19<sup>th</sup> April 2012 (Zhivatov). Subsequently, the Players indicated they did not require the "B" samples to be analysed and admitted the anti-doping rule violation which they attributed to their ingestion of the stimulant *Phenotropil* provided by the Physiotherapist.
- 8. The Players accepted they had signed the Team Member Consent Form prior to the commencement of the Tournament, on 20<sup>th</sup> March 2012. The Consent Form was attached to the Participation Agreement which included provisions relating to the TADP. Thus, the Players acknowledged they were bound by the Anti-Doping Programme. Zhivatov also acknowledged he had signed a similar Player Consent Form in relation to the IRB Junior World Rugby Trophy ("JWT") played in Georgia in 2011. He also attended the IRB Anti-Doping Outreach Programme conducted by the IRB at the JWT.

<sup>&</sup>lt;sup>1</sup> The Doping Control Form requires a Player to declare any medication and/or supplement taken in the last seven days. Clearly if the Phenotropil had been taken nine days previously the Players were not required to declare they had taken it.

- 9. The IRB sent Anti-Doping Handbooks to all participating Teams in the Hong Kong Sevens 2012. Further, the Union was sent anti-doping educational resources in March 2012.
- 10. The Physiotherapist admitted he gave Phenotropil to each of the Players on 14<sup>th</sup> March 2012. He acknowledged in a written statement he failed to search the current WADA List of banned substances and omitted to contact a qualified Doctor to ascertain whether Phenotropil contained a banned substance.
- 11. The central issue in this case required the BJC to determine whether on 14<sup>th</sup> March 2012 the *Phenotropil* was given to the Players by the Physiotherapist and thereafter taken by the Players for the purpose they all averred. We will return to this issue later when the issues in relation to sanctioning are discussed.
- 12. On 15<sup>th</sup> March 2005, a BJC found that the Physiotherapist had previously committed the following doping offences:
  - "(a) On a date between 1<sup>st</sup> March 2004 and 24<sup>th</sup> May 2004 administered a prohibited substance when he was the Physiotherapist assigned to the Russian 7's National Representative Team participating in an event organised by and subject to the Rules and Regulations of the International Rugby Board contrary to Regulation 21.1.3 of the IRB Anti Doping Regulations;
  - (b) Assisted/abetted the use of a prohibited substance by Serguei Chichkov a member of the Russian 7's National Representative Team participating in an event organised by and subject to the Rules and Regulations of the International Rugby Board contrary to Regulation 21.1.5 of the IRB Anti Doping Regulations."

The significance of these offences will be explained later in our decision. A copy of the previous BJC's decision is attached as Appendix 1.

# Phenotrophil (also known as Fenotropil, Carphedon, Phenylpiracetam)

- 13. *Phenotropil* is a medicine which was developed in Russia to boost physical stamina and mental performance. It stimulates physical activity.
- 14. Valenta Pharmaceuticals (the manufacturer of *Phenotropil*) advises the drug is currently used by Russian cosmonauts on the International Space Station to ensure peak mental and physical performance.

- 15. Counsel for the Player advised (there was no evidence of this²) *Phenotropil* can be purchased from pharmacies in Russia without a prescription for "solving sleep problems due to fatigue, depression, jet lag etc".
- 16. In section 6(a) of the WADA 2012 Prohibited List the substance is listed as 4-phenylpiracetam (carphedon). As mentioned, it is listed as a non-specified stimulant.
- 17. Photographs (which were produced and are attached as Appendices 2 and 3) of the labelling and instructions for the medical use of *Phenotropil* (both in Russian and English languages) refer to its ingredients as including *n-carbamoly methyl 4 phenyl 2 pyrrolidone*.
- 18. Both Players stated they requested the Physiotherapist to provide the instruction leaflet to them. It will be noted that the chemical description of the substance in the Prohibited List and leaflet are not identical.
- 19. The Players (who stated they checked the WADA List shortly before taking the pills) and Physiotherapist (who for the first time, and contrary to one of his earlier signed statements, asserted at the hearing he checked the Prohibited List approximately three years previously in relation to personal and family use of the drug) were unable to match the chemical descriptions of the substance. Further, the Prohibited List did not refer to the substance by the brand name (*Phenotropil*). In addition, the Players and Physiotherapist stated they relied on the statement in the leaflet "*To improve capacity for work a single dose 100-200 mg in the morning during 2 weeks* (for athletes 3 days)". The Physiotherapist stated he had previously used the drug, without any side effects. He thought it was harmless; an assurance he provided to the Players. Because of these factors they concluded the substance was not prohibited in sport.
- 20. The instruction leaflet did not refer to the drug being used for the purpose of overcoming the effects of jet lag. "Insomnia" is described as a "side action".

<sup>&</sup>lt;sup>2</sup> During the hearing the Chairman of the BJC expressed his concern that the Players' Counsel at times during the course of his submissions gave evidence about factual matters which had not otherwise been established and which could not be the subject of cross-examination.

Its pharmacological properties were described as including "improving mental performance" and "increas(ing) body's energy potential" and "improvement of physical capacity".

- 21. At the behest of the BJC Counsel for the Players and IRB were given the opportunity of obtaining expert forensic pharmacological evidence in relation to the central issue namely, the period of time *Carphedon* can remain in the bodily system.
- 22. The Players' Counsel consulted Professor Viktor Chistyakov (Doctor in Pharmaceutical Sciences – Pharm D) of Moscow. He has acquired over 32 years of research experience in pharmaceuticals. He is also the author and co-author of a number of books and articles relating to Pharmacokinetic studies.
- 23. Professor Chistyakov conducted a study relating to the <u>theory</u> of pharmacology and pharmacokinetics over a period of seven days between the 19<sup>th</sup> to 26<sup>th</sup> October 2012. The Professor emphasised his research did not involve or seek to replicate the "particular circumstances of the discovery of this substance in this athletes system".
- 24. In relation to Phenotrophil he noted "published information (instructions for medical use) after oral use of the drug, it is rapidly absorbed from the gastrointestinal track, distributed in various organs and tissues, and usually comes through the brain barrier". However, there is a lack of "experimentally confirmed data of removal 4-phenylpiracetam from the human system. Thus it is impossible to calculate the time of circulation and its rate of excretion".
- 25. In his second report Professor Chistyakov expressed the view "because of the pharmacokinetic characteristics of specific drugs, such as the ability to intrahepatic recycling (for carphedon it is shown in the pre-clinical pharmacokinetic studies in animals), the drug may stay in a human system relatively long period of time after a single dose. In this regard, without experimentally confirmed data of removal 4-phenylpiracetam for the human system, it is impossible to calculate time of circulation and its rate of excretion ..."

- 26. Professor Chistyakov referred to an article by the authors P E Kholodov and V V Dorohov Pharmaceutical Chemistry Journal 19 (4), 65-69 (1985). Following their research they concluded that an oral dose of 100 mg/kg of *Phenotropil* given to rats was completely eliminated within three days (94% of the drug having been eliminated within the first 24 hours). *Phenotropil* does not metabolise in the body but is eliminated "intactly". In referring to his research Professor Chistyakov concluded there was the possibility *Phenotropil* "may remain in a human body for more than 10 days after administration of a single dose, with the possibility of its detection depending on the sensitivity of the used method". (Emphasis added)
- 27. Counsel for the IRB produced reports from Doctor Daniel Eichner, Executive Director of the Sports Medicine Research and Testing Laboratory in Salt Lake City. It is clear from Doctor Eichner's curriculum vitae that he has extensive anti-doping experience including being the Science Director at the United States Anti Doping Agency, Chief Scientific Officer for the Australian Sports Anti-Doping Authority. He qualified with a Bachelor of Science from the Australian National University with first class honours and subsequently completed his PhD in medical science at the same university.
- 28. Doctor Eichner also commented that there is a dearth of information as to the pharmacokinetic properties of *Carphedon* in particular empirical information as to how long the substance remains in the human body. He confirmed that he provided approximate concentrations as the *Carphedon* found in the Players' urine is a 100% synthetic product and no level is permitted. Thus, a comprehensive quantification was not performed on the samples and the estimates were based on the approximate concentrations found in the urine and the alleged 100 mg administered 10 days prior to testing. Doctor Eichner's laboratory found the levels in each of the samples of urine was not consistent with an individual ingesting 100 mgs of *Carphedon* ten days prior to being tested. It will be noted the sample collection according to the Players and Physiotherapist was nine (plus) days after the time of administration. In our view ultimately this part-day difference is not material.
- 29. In relation to the period of time required before *Carphedon* was excreted from the body Doctor Eichner stated:

"The Sports Medicine Research and Testing Laboratory (SMRTL) conducted analyses on samples 2693322 and 2693329 on behalf of the International Rugby Board. Both samples were found to be adverse for 4-phenylipiracetam, a metabolite for the prohibited substance, Carphedon. The approximate concentrations found in the samples were 10,000 ng/mL and 5,000 ng/mL respectively.

The athletes in question claim to have administered one 100 mg tablet of Phenotropil 10 days prior to testing. As stimulants, including Carphedon, are excreted fairly quickly, it is highly unlikely that such large concentrations of 4-phenylipiracetam would still be found in the urine 10 days post administration. Indeed, Semenov et al found that Carphedon was detectable until 96 hours post administration (Semenov, Tolotov, Sizoi, Recent Advances in Doping Analysis, 1999). I cannot think of any circumstance that would suggest 10,000 ng/ml or 5,000 ng/mL of 4-phenylipiracetam would be found in the urine 10 days after administration of one 100 mg tablet of Phenotropil." (Emphasis added)

- 30. Subsequently in discussing some of Professor Chistyakov's comments, Doctor Eichner again rejected the notion that *Carphedon* can remain in the body for more than 10 days after administration of 100 mg single dose and if, by chance, there was still a detectable amount in the urine 10 days post administration then he would have expected the levels to be trace amounts in the picogram/mL range (more than 10,000 times less than what was found). Again, he noted the levels found in the Players' urine were not consistent with an individual ingesting 100 mg of *Carphedon* 10 days prior to being tested.
- 31. Doctor Eichner also commented that the paper Professor Chistyakov referred to (supra paragraph 26) stated 100% of the drug is completely "illuminated" in 72 hours and that is "very" consistent with the metabolism of other stimulants.

# The Tournament Anti-Doping Programme - IRB Regulation 21

The TADP, which is based upon the IRB Anti-Doping Regulations, prescribes the framework under which all players can be subjected to Doping Control and the procedures for any alleged infringements of the Programmes. The Regulations (and the TADP) also adopt the mandatory provisions of the World Anti-Doping Code ("the Code")<sup>3</sup>.

 $<sup>^3</sup>$  The WADA Code can be found on the WADA website at <a href="http://www.wada-ama.org/documents/world\_anti-doping\_program/WADP-The-Code/WADA\_Anti-Doping\_CODE\_2009\_EN.pdf">http://www.wada-ama.org/documents/world\_anti-doping\_program/WADP-The-Code/WADA\_Anti-Doping\_CODE\_2009\_EN.pdf</a>

- 33. Both the TADP, Regulations and Code are based on the principles of personal responsibility and strict liability for the presence of Prohibited Substances or the use of Prohibited Methods.
- 34. Pursuant to Clause 2.1<sup>4</sup> of the TADP the "presence of a Prohibited Substance or its Metabolites or Markers in a Player's Sample" constitutes an anti-doping rule violation. A violation does not require intent, fault, negligence or knowing use on the part of the Player.
- 35. Pursuant to Clause 2.6(b)<sup>5</sup> of the TADP possession by any Player Support Personnel (eg. the Team Physiotherapist) within an In-Competition period of any prohibited substance in connection with a Player, Match, Series of Matches and/or Tournament or training constitutes an Anti-Doping Violation unless the Player Support Personnel can establish the possession was pursuant to a therapeutic use exemption granted to a Player or other acceptable justification.
- 36. Pursuant to Clause 2.7<sup>6</sup> of the TADP Trafficking or attempted Trafficking in any prohibited substance constitutes an anti-doping violation. The definition of "*Trafficking*" includes "*giving*" a Prohibited Substance by Player Support Personnel to a third party.
- 37. Pursuant to Clause 2.8<sup>7</sup> of the TADP administration to any Player while In-Competition of any Prohibited Substance or assisting, encouraging, aiding, abetting or any other type of complicity to commit an anti-doping rule violation, constitutes anti-doping violations<sup>8</sup>.
- 38. In relation to the principle of personal responsibility Clause 6 of the TADP<sup>9</sup> provides:
  - 6.1 It is each Player's responsibility to ensure that:
    - (a) no Prohibited Substance is found to be present in his body and that Prohibited Methods are not used;
    - (b) he does not commit any other anti-doping rule violation;

<sup>&</sup>lt;sup>4</sup> The equivalent of IRB Regulation 21.2.1

The equivalent of IRB Regulation 21.2.6(b)

The equivalent of IRB Regulation 21.2.7

<sup>7</sup> The equivalent of IRB Regulation 21.2.6

<sup>&</sup>lt;sup>8</sup> As an aside, the BJC recommends consideration should be given by the IRB to amending Regulation 21.2.8. It contains unnecessary tautology (eg. assisting/aiding, encouraging/abetting) and although it implicitly refers to another person being involved in an anti-doping violation, that is not explicitly stated to be the case.

The equivalent of IRB Regulation 21.6

- (c) .
- (d) he informs Player Support Personnel, including, but not limited to, their doctors of their obligation not to use Prohibited Substances and Prohibited Methods and to take responsibility to ensure that any medical treatment received by them does not violate any of the provisions of the Regulations.
- 6.3 It is the sole responsibility of each Player, Player Support Personnel and Person to acquaint themselves and comply with all of the provisions of these Anti-Doping Regulations including the Guidelines."

# **Hearing Process**

- 39. A Board Judicial Committee ("BJC") was appointed to consider this matter. The substantive hearing was scheduled to commence on 29<sup>th</sup> August 2012 but it had to be adjourned due to the unfortunate and unavoidable unavailability of one of its members. Thereafter it proceeded by way of a telephone conference on the 8<sup>th</sup> November. The BJC issued several minutes giving directions as to several matters relating to presentation of evidence and submissions by Counsel which arose throughout the hearing process. These minutes will form part of the record. All counsel filed comprehensive and helpful submissions which were appreciated by the BJC.
- 40. The minutes included directions (which were not opposed by any party) relating to the joinder of charges and respondents on the basis that given the commonality of evidence and witnesses, it was appropriate and conducive to the interests of justice to convene a single hearing.

# **Anti-Doping Violations Established**

- 41. Pursuant to Clause 3.1<sup>10</sup> of the TADP, the Board has the burden of establishing anti-doping rule violations to the comfortable satisfaction of the BJC.
- 42. As indicated, it is common ground the Players took the banned substance 4phenylpiracetam (carphedon). Thus, they accepted and did not challenge
  the analytical findings. Accordingly, the BJC finds the IRB has established to
  the required standard the anti-doping rule violations; that is the presence of

<sup>&</sup>lt;sup>10</sup> The equivalent of IRB Regulation 21.3.1

the Prohibited Substance *4-phenylpiracetam* (carphedon) in the Players' bodily samples.

- 43. In relation to the Physiotherapist, issues were raised by counsel and members of the BJC as to whether there was an unnecessary duplication of charges.
- 44. The Physiotherapist faced charges of being in possession of the banned substance "Carphedon", trafficking (ie. giving the substance to each of the Players) and administering it, (ie. being a party to the Players subsequent use of the banned substance). The elements of these charges are described in paragraphs 35 to 37 (supra).
- 45. Counsel for the Physiotherapist (Ms Nozhkina) submitted the possession charge was ill-founded because:
  - The Physiotherapist was not a player
  - He was in possession of the Carphedon for a legitimate purpose (ie.
    for personal and families use when they were suffering from the
    effects of jet lag)
  - The charge duplicated the more serious trafficking and administration charges.
- 46. In relation to the administration and trafficking charges, Ms Nozhkina submitted there was duplication of charges. She submitted the two offences occurred at the same time and "... it is impossible to commit two offences at the same time".
- 47. Returning to the possession charge, because of the extended meaning which is given to the term "possession by player support personnel" we accept Mrs Ahern's submission that the necessary causal link had been established in that the Physiotherapist as a member of the Team's support personnel at the Tournament was in possession of the substance which he gave to the Players for their use which was prohibited. Thus, technically the charge was established, but the more serious charge of trafficking (which the Physiotherapist admitted) arose from the same factual matrix. Further, as will be explained later, for sanctioning purposes the least serious possession

charge was subsumed by the more serious administration and trafficking charges.

- 48. In relation to the trafficking and administration charges, although the Regulation does not contain a specific definition of the term "administration", Clause 2.8 (Regulation 21.2.8) states that an anti-doping violation is committed if there is "... assisting, encouraging, aiding, abetting ... or any other type of complicity involving an anti-doping rule violation". This wording relates to a different situation from that contemplated by the term "trafficking" ie. giving. It creates a different offence of being a party to an offence. In this respect, the Physiotherapist clearly has been a party to both Players anti-doping violations in that by his actions of discussing the suitability of the Phenotropil and then giving the substance to the Players, he has assisted and encouraged each of them to commit anti-doping violations ie. to take the Phenotropil tablets which contained the banned substance Carphedon.
- 49. Accordingly, we are satisfied the administration charge also has been established, but again for the purpose of sanctioning we intend adopting the approach suggested by Counsel for the IRB and treating the charges of possession, trafficking and administration as one violation rather than imposing cumulative or concurrent sanctions. In this regard, we intend adopting the approach of the BJC in the case of IRB v Telea<sup>11</sup> by invoking Clause 22.10(d) (Regulation 21.22.10D) which contemplates the situation whereby additional anti-doping rule violations may be committed prior to a player/person receiving notice of the first offence. In such a case "the violation shall be considered as a single first violation, and the sanction imposed shall be based on the violation that carries the more severe sanction". For reasons which will become apparent the Physiotherapist's trafficking violation in this case clearly carries the more severe sanction.

# Sanctioning - The Players

50. The sanction for the presence of a prohibited substances, including 4-phenylpiracetam (Carphedon) is a mandatory sanction of two years period of ineligibility. However, the mandatory sanction is subject to the Players' establishing (on a balance of probability – Regulation 21.3.1) a basis for

<sup>11</sup> http://www.irbkeeprugbyclean.com/downloads/cases/35/Telea\_decision

eliminating or reducing the period of ineligibility based on exceptional circumstances as set out in Regulation 21.22.4 and 21.22.5. Under the former if a player can establish he "bears no fault or negligence for the violation" and can establish how the prohibited substance entered his system, the period of ineligibility can be eliminated. Under the latter where there is no significant fault or negligence on the part of the player then the period of ineligibility may be reduced to a period of not less than one half of the minimum period of ineligibility. Again, this provision requires the player to establish how the prohibited substance entered his system.

51. The TADP (Regulation 21) contains the following definitions:

### No Fault or Negligence

The Player's establishing that he did not know or suspect, and could not reasonably have known or suspected even with the exercise of utmost caution, that he had used or been administered the Prohibited Substance or Prohibited Method.

# No Significant Fault or Negligence

The Player's establishing that his fault or negligence, when viewed in totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to an antidoping rule violation.

On behalf of the Players it was submitted they were not at fault or negligent 52. in relation to the positive testing for Carphedon and the otherwise applicable period of ineligibility should be eliminated. As mentioned, they claimed as a result of discussing their "sleeping problem" with the Physiotherapist on 14th March 2012 he gave each of them one Phenotropil tablet for the purpose of overcoming the effects of "Jet lag". The Players and Physiotheapist's accounts were partially supported by statements from Andrey Sorokin (Assistant Coach) and Alexandra Tsvetkov (Assistant Manager) each of whom confirmed on the morning of 14th March 2012 in the Hotel Restaurant they overheard the Players and Physiotherapist discuss the problems associated with "jet lag". They observed the three of them leave the restaurant and subsequently the Physiotherapist informed Tsvetkov and Sorokin he had given "a drug to the Players to fight jet lag". Another player, Vladimir Ostronsiko stated the Players asked him about jet lag and the drug Phenotropil. He told them he had never suffered from it, nor had heard of the drug but he advised them to check the "drug medical paper and compare with the WADA List".

53. However, as both Counsel acknowledged, the resolution of this case significantly turned on the expert scientific evidence of Professor Chistyakov and Doctor Eichner and in relation to the fundamental issue; namely whether the approximate concentration levels (10,000 ng/ml or 5,000 ng/ml) of 4-phenylpiracetam would be found in the Players' urine ten days after the administration of 100 mg tablet of *Phenotropil*.

### **Submissions**

- 54. Counsel for the Players relied on the expert opinion of Professor Chistyakov who, as mentioned, confirmed general research indicated the substance *Carphedon* can remain in the human system for more than ten days after the administration of a single dose. Thus, Counsel rejected Doctor Eichner's opinion that 10,000 ng/ml or 5,000 ng/ml of *4-phenylpiracetam* would not be found in the urine ten days after administration of a 100 mg tablet of *Phenotropil*.
- 55. In his comprehensive submissions Mr Patsev referred to a number of factors which he submitted raised issues regarding to the validity of Doctor Eichner's conclusions. They included:
  - The indicated concentrations of the banned substance found in the samples were not actual figures but were only approximations.
  - There was no indication which method was used by the Salt Lake City laboratory to analyse the samples for the purpose of calculating the amounts of *Carphedon* in each of the samples.
  - The lack of published pharmacokinetic information relating to the length of time the drug *Carphedon* is metabolised. Because of this he submitted (and this was based on his discussions with Professor Chistyakov) confirmed data on the pharmacokinetics of "nootropics" (which we were informed is a class of substance which includes *Carphedon*) is of assistance as the data confirms a substance from the "nootropics" group can remain in the human system for a "long time" after a single dose.
- 56. Mr Patsev referred to some matters which were not referred to by Professor Chistyakov in his written reports. For example, the reference to pharmacokinetic concentration time curve for drugs with similar

characteristics as Phenotropil, is an "inverted parabola which curve decreases sharply but approaching the horizontal axis starts decreasing slowly. Therefore it indicates the fact that in the first day the level of substance removal from the body is very high and proofs that the level of removal from the body doesn't stay at the same rate in time. On the contrary – the further removal of these drugs from a human body is very low, and complete removal can take one month (30 days or more)."

- Counsel for the IRB referred to the evidence of Doctor Eichner and was critical of Mr Patsev's submissions referring to evidential matters which were not included in Professor Chistyakov's reports. She also noted in relation to Professor Chistyakov's conclusion (*Phenotropil* can circulate in a human body for more than ten days after a single dose), there were no reference either to the volume of the drug which must be consumed in order to achieve this outcome or to the volumes remaining in any samples being beyond trace amounts. Moreover, she submitted (based on the 100 mg ingestion of *Phenotropil* and its levels found in the Players' urine) Doctor Eichner completely discounted the notion that the *Carphedon* was administered ten days prior to testing.
- 58. Finally, Counsel referred to Doctor Eichner's comment the Salt Lake City WADA Accredited Laboratory "can detect up to 50 ng/ml (probably lower but this is 10% of MRPL below which we would not report an adverse finding for the stimulant)". In relation to the specific circumstances of the case she submitted the concentrations were quite strong and "were thousands of times greater than Dr Eichner would have expected to find if in fact 100 mg of Phenotrpil was consumed by the Players 10 days before they were tested".

#### Discussion

59. We have carefully considered the reports of Professor Chistyakov and Doctor Eichner and as the former has noted there are some important areas of commonality between them. Both agree there is a dearth of information as to the pharmacokinetic properties of "Carphedon". The Professor formed the view that Carphedon can remain in the human for a "relatively long time" but, as he acknowledged this view was not based on an exact replication of

the Players' circumstances which involved 100 mg doses and the approximate concentration levels found in their urine samples.

- octor Eichner did not dispute the view *Carphedon* could ("by chance") remain in the human body after ten days. However, he considered if a detectable amount of the prohibited substance was found ten days after ingestion it would be a "trace amount" in the picogram range; ie. more than 10,000 times less than what was detected in the Players' samples. Again, in this respect there appeared to be agreement between the two experts because Professor Chistyakov (on our reading of his reports) did not refute this statement. As mentioned, his general research indicated there was a possibility after a period of ten days some detectable traces may be present. In this regard, he emphasised (and essentially Doctor Eichner made the same observation) this depended on the sensitivity of the method used in the detection of the substance.
- 61. In relation to the sensitivity of the method used, as mentioned Doctor Eichner noted it was possible for his laboratory to detect traces up to 50 ng/ml. Thus, for this reason in our view the concentration levels (10,000 ng/ml and 5,000 ng/ml) of the banned substance in the samples being approximations was not as significant an issue as Mr Patsev submitted.
- 62. Doctor Eichner's view (which was based on the approximate quantities found after the ingestion of a 100 mg tablet) the substance would be completely eliminated from the body within 72 hours is supported (allowing for the difference in mammals) by the specific research conducted on rats by the Scientists Kholdov and Dorohov. Again, Professor Chistyakov properly referred the BJC to their conclusion, "Phenotropil from the body of rats at an oral dose of 100 mg/kg is completely eliminated within 3 days (but 94% of drugs comes out in the first 24 hours). Phenotropil doesn't metabolize in the body and comes out off the body intactly."
- 63. For these reasons we conclude, despite the evidence of the Players and supporting witnesses, we cannot be satisfied the Players' positive tests for the banned substance *Carphedon* were as a result of taking the substance nine days previously. Indeed, on our analysis the forensic evidence indicates it is more likely the stimulant was ingested by each of the Players

up to three days before the first day of the Tournament (23<sup>rd</sup> March 2012). It follows this conclusion gives rise to the irresistible inference that because of its properties (enhancement of mental and physical performance) and the failure to admit taking it during this period, the *Carphedon* was taken within 72 hours of the commencement of the Tournament for a more sinister purpose, namely to enhance performances.

64. Accordingly, we are unable to conclude the Players have proved on a balance of probabilities there was no fault or negligence on their part and we have no alternative but to impose the mandatory sanction of two years ineligibility on each of the Players.

## **Sanctioning - Kosarev**

65. As mentioned a BJC on 15<sup>th</sup> March 2005 had previously found the Physiotherapist had committed anti-doping offences. It was alleged each of the offences was committed on a date between 1<sup>st</sup> March 2004 and 24<sup>th</sup> May 2004. In this respect Clause 22.10E (Regulation 21.22.10E) is relevant. It states:

"Multiple Anti-Doping Rule Violations During Eight-Year Period For the purposes of Regulation 21.22, each anti-doping rule violation must take place within the same eight-year period in order to be considered multiple violations."

- 66. For the purpose of the previous 2005 hearing and in particular sanctioning, the agreed summary of facts provided to the BJC included the following:
  - "1. The Player was at all material times a member of the Russian 7's National Representative Team.
  - 2. The Physiotherapist was at all material times the Physiotherapist for the Russian 7's National Representative Team.
  - 3. ...
     4. ...
     5. ...
  - 6. On the <u>24<sup>th</sup> May 2004 the player signed the Declaration of Medication form certifying the information contained therein was accurate and that he had used a prohibited substance namely Retabolili intra muscularly in one single dose on the 15<sup>th</sup> March 2004. (Emphasis added)</u>

- 7. The said <u>Declaration of Medication form was also signed on the 24<sup>th</sup> May 2004 by the Physiotherapist as "the prescribing Physician" certifying that the prohibited substance had been administered as the correct treatment for the medical condition suffered by the Player, namely "Atrophy of muscles of a thigh after a trauma". (Emphasis added)</u>
- 8. The said declaration of medication form was forwarded to Dr. Ismail Jakoet, Chairman of the International Rugby Board TUE Committee who found from his investigations that Retabolili is nandrolone decanoate which is an androgenic anabolic steroid and did not fit the abbreviated TUE process.

9. to 18. ..."

- 67. In determining the application of the eight year limitation period for multiple anti-doping violations, the relevant dates were the dates the actual violations occurred and not the sample collection dates, declaration dates or charge dates. It was noted the IRB alleged anti-doping violations were committed by the Physiotherapist between 1st March 2004 and 24th May 2004 thereby covering a period of 14 days (1st to 14th March 2004) which was outside the limitation period. However, the agreed facts in that case, which in part were based on a declaration made on 24 May 2004, indicated the administration of the prohibited substance occurred on 15th March 2004. submissions on the eight year limitation period, Counsel for Kosarev confirmed the offence date of 15th March 2004 for the 2004 administration violations. However, contrary to Counsel's submission we consider the offences between 2004 and 2012 do fall within the eight year limitation period by one day, ie. 15th March 2004 to 14th March 2012. Thus, the relevant provisions relating to multiple violations apply.
- 68. Clause 22.10 TADP (Regulation 21.22.10) prescribes the applicable sanctions for multiple violations:

### Multiple Violations

# A. Second Anti-Doping Rule Violation

For a Player's or other Person's first anti-doping rule violation, the period of Ineligibility is set forth in Regulation 21.22.1 and 21.22.2 (subject to elimination, reduction or suspension under Regulation 21.22.3 or 21.22.4, 21.22.5, 21.22.6, 21.22.7 and/or 21.22.8, or to an increase under Regulation 21.22.9). For a second anti-doping

rule violation the period of Ineligibility shall be within the range set forth in the table below.

Second Violation	RS	FFMT	NSF	St	AS	TRA
First Violation						
RS	1-4	2-4	2-4	4-6	8-10	10- life
FFMT	1-4	4-8	4-8	6-8	10- life	Life
NSF	1-4	4-8	4-8	6-8	10- life	Life
St	2-4	6-8	6-8	8-life	life	Life
AS	4-5	10-life	10- life	life	life	Life
TRA	8-life	Life	Life	life	life	Life

Definitions for the purposes of the second anti-doping rule violation table:

**RS** (Reduced sanction for Specified Substance under Regulation 21.22.3): The anti-doping rule violation was or should be sanctioned by a reduced sanction under Regulation 21.22.3 because it involved a Specified Substance and the other conditions under Regulation 21.22.3 were met.

**FFMT** (Filing Failure and/or Missed Tests): The anti-doping rule violation was or should be sanctioned under Regulation 21.22.2(c).

**NSF** (Reduced sanction for No Significant Fault or Negligence): The anti-doping rule violation was or should be sanctioned by a reduced sanction under Regulation 21.22.5 because No Significant Fault or Negligence under Regulation 21.22.5 was proved by the Player.

**St** (Standard sanction under Regulation 21.22.1 or 21.22.2(a)): The anti-doping rule violation was or should be sanctioned by the standard sanction or two years under Regulation 21.22.1 or 21.22.2(a).

**AS** (Aggravated sanction): The anti-doping rule violation was or should be sanctioned by an aggravated sanction under Regulation 21.22.9 because the Anti-Doping Organisation established the conditions set forth under Regulation 21.22.9.

**TRA** (Trafficking or Attempted Trafficking and Administration or Attempted Administration): The anti-doping rule violation was or should be sanctioned by a sanction under Regulation 21.22.2(b)."

69. In 2004 the BJC concluded there was No Significant Fault (NSF) on the part of the Physiotherapist and reduced the sanction from a period of four year's

ineligibility to two year's ineligibility. This was the maximum reduction permitted under the Regulations.

- 70. In the context of this case, it can be seen from the table the following sanctions are potentially applicable:
  - If we concluded the sanctions for the Physiotherapist's most recent violations should be reduced on a No Significant Fault basis a period of ineligibility of between four to eight years.
  - Otherwise, a lifetime ban.
- 71. As noted, we have rejected the Players' evidence the banned substance was used by them for the purpose of overcoming the effects of jet lag nine days prior to testing. Indeed, as mentioned, in our view the evidence gives rise to the strong inference the substance was taken for an alternative and (indeed more sinister) purpose, namely to enhance performance up to 72 hours before the matches commenced on the first day of the Tournament. However, we acknowledge that contrary to the Player's accounts, there is the possibility (albeit unlikely) the Physiotherapist may have given the Phenotropil nine days previously on 14th March 2012 to the Players for what they described to him as "jet lag" and the pills were taken by them within 72 hours prior to the commencement of the Tournament. whether the Carphedon tablets were given to the Players nine days or up to 72 hours prior to the commencement of the Tournament, contrary to Ms Nozhkina's submission we are unable to conclude the Physiotherapist has satisfied the requirements of establishing there was No Significant Fault on his part.
- 72. In his statement dated 26<sup>th</sup> July 2012 the Physiotherapist stated:

"I admit my guilt and failure to proper check the drug that I dispensed to the two players. I should have conducted a thorough research against the WADA, IRB and RusADA list of banned substances, and I should have contacted a professional doctor in sport medicine or a professional in chemistry to determine the possible presence of a prohibited substance in Phenotropil. But, as I stated before, after reading the pack and medicine manual of Phenotropil I had no clues at all that this drug might contain any of the substances prohibited in sport". (Emphasis added)

73. He also stated following his previous violations "my words are far from trustworthy". In this respect, regrettably we have to agree. We found parts

of his evidence far from convincing. There was a serious internal discrepancy in that during the hearing he stated he previously checked the WADA Prohibited List for the *Phenotropil* when it was for his own or family's use. Apart from the fact, it is curious he carried out the exercise for this purpose (namely to check specifically if it was prohibited in sport when seemingly it was not being used in a sport environment), it is more significant, this was not mentioned in either of his two written statements.

- 74. In our view even if we adopt the most favourable view of the Physiotherapist's conduct (ie. he gave the Players the tablets for their "jet lag" on 14<sup>th</sup> March 2012, nine days prior to the first day of competition) factors such as his previous violations, his considerable experience of being associated with the Russian National Teams, his awareness of his responsibilities in relation to anti-doping, his failure to obtain medical advice about "Carphedon" before giving it to each of the Players, and his general lack of caution all point to gross negligence on his part.
- 75. Accordingly, the BJC is satisfied that in respect of the 2012 violations a lifetime ban must be imposed. As discussed we are minded to treat all the Physiotherapist's violations in relation to this case as one violation.

## **Decisions**

- 76. For the reasons outlined, the sanctions imposed for each of the Player's anti-doping violations are periods of ineligibility of two years commencing from 18<sup>th</sup> April 2012 (Yagudin) and 19<sup>th</sup> April 2012 (Zhivatov) being the dates the Players' provisional suspensions commenced and concluding (but inclusive of) 18<sup>th</sup> and 19<sup>th</sup> April 2014 respectively.
- 77. The sanction which is imposed for the Physiotherapist's anti-doping violations is a lifetime period of ineligibility.
- 78. The Players' and Physiotherapist's attention is drawn to the TADP definition "Consequences of Anti-Doping Rule Violations" and TAP Clause 22.13 (Regulation 21.22.13) headed "Status During Ineligibility".

## **Costs**

79. If the IRB wishes us to exercise our discretion in relation to costs pursuant to Regulation 21.21.10, written submissions should be provided to the BJC via Mr Ricketts by 17:00 Dublin time on 14 February 2013, with any responding written submissions from the Players to be provided by no later than 17:00 Dublin time on 28 February 2013.

## Review

80. This decision is final, subject to a referral to a Post Hearing Review Body (Regulation 21.25) or an appeal, where the circumstances permit, to the Court of Arbitration for Sport (Regulation 21.27). In this regard, attention is also directed to Regulation 21.24.2, 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 21st day of January 2013

T M Gresson G Nicholson I Jakoet

# IN THE MATTER OF A BOARD JUDICIAL COMMITTEE HEARING CONCERNING

Serguei Chichkov ("The Player") Andrey Kosarev ("The Physiotherapist") Dr. Elena Stepanova ("The Physician") Known jointly as the Respondents

DATE:

15<sup>th</sup> February 2005

VENUE:

Huguenot House, 35-38 St. Stephens Green, Dublin 2

COMMITTEE: Brian McLoughlin - Chairman

Professor Lorne Crerar

Dr. Barry O'Driscoll

PRESENT:

Susan Ahern - Legal Counsel for the IRB

Tim Ricketts - Anti Doping Officer for the IRB

Interpreter

By way of Conference Call:-

Dr. Rifkit Sattarov - Russian Team Manager

Serguei Chichkov - The Player

Andrey Kosarev - The Physiotherapist

Dr. Elana Stepanova - The Physician

### PURPOSE:

To consider the hearing of a complaint that the Player:

On the 24th May 2004 admitted orally or in writing having used or taken advantage of a prohibited substance, when he was a member of the Russian 7's National Representative Team participating in an event organised by and subject to the Rules and Regulations of the International Rugby Board contrary to Regulation 21.1.1(c) of the IRB Anti Doping Regulations.

To consider the hearing of a complaint that the Physiotherapist:

(a) On a date between the 1st March 2004 and 24th May 2004 administered a prohibited substance when he was the Physiotherapist assigned to the Russian 7's National Representative Team participating in an event organised by and subject to the Rules and Regulations of the

- International Rugby Board contrary to Regulation 21.1.3. of the IRB Anti Doping Regulations;
- (b) Assisted/abetted the use of a prohibited substance by Serguei
  Chichkov a member of the Russian 7's National Representative Team
  participating in an event organised by and subject to the Rules and
  Regulations of the International Rugby Board contrary to Regulation
  21.1.5. of the IRB Anti Doping Regulations;

To consider the hearing of a complaint that the Physician:

- (a) On a date between the 1<sup>st</sup> March 2004 and 24<sup>th</sup> May 2004, distributed, supplied, administered a prohibited substance to Andrey Kosarev and Serguei Chichkov members of the Russian 7's National Representative Team participating in an event organised by and subject to the Rules and Regulations of the International Rugby Board contrary to Regulation 21.1.3. of the IRB Anti Doping Regulations;
- (b) Assisted/abetted the use of a prohibited substance by Serguei Chichkov a member of the Russian 7's National Representative Team participating in an event organised by and subject to the Rules and Regulations of the International Rugby Board contrary to Regulation 21.1.5. of the IRB Anti Doping Regulations;

## INTRODUCTION:

The Board Judicial Committee was appointed by the International Rugby Board pursuant to the provisions of Regulation 21.1.8 of the IRB Anti Doping Regulations to investigate the complaint.

The Chairman having introduced the Tribunal Members, explained the procedures to be followed and referred to the Notice to Admit Facts dated the 3<sup>rd</sup> November 2004 which had been circularised to each of the Respondents and to which a reply had been received from Rifkit Sattarov the Russian National Rugby 7's Team Manager by e.mail dated the 22<sup>nd</sup> November 2004 accepting the validity of the said facts and setting out mitigating circumstances in relation to the Player.

written submissions had been received from the Respondents other than the said e.mail of the 22<sup>nd</sup> November 2004.

### EVIDENCE AS TO FACT:

The Committee considered the following;

## STATEMENTS:

- (a) Statement of Tim Ricketts dated 27th May 2004
- (b) Statement of Mark Egan IRB 7's Manager dated 27th May 2004
- (c) 2 Statements of Ismail Jakoet both dated 27th May 2004
- (d) e.mail of Rifkit Sattarov of the 22<sup>nd</sup> November 2004 EXHIBITS:
- (a) IRB 7's 2003/2004 Union Consent and Agreement Form signed by V. Petrenchouk on behalf of the Russian Union and dated 14<sup>th</sup> May 2004
- (b) IRB 7's 2003/2004 Player Consent and Agreement Form signed by the Player
- (c) IRB Abbreviated Therapeutic Use Exemption Declaration of Medication Form signed by the Player and the Physiotherapist on the 24<sup>th</sup> May 2004

Prior to the Hearing the following set of facts were agreed by Rifkit Sattarov, Team Manager of the Russian National Rugby 7's on behalf of the Respondents by the said e.mail of the 22<sup>nd</sup> November 2004.

- 1. The Player was at all material times a member of the Russian 7's National Representative Team.
- 2. The Physiotherapist was at all material times the Physiotherapist for the Russian 7's National Representative Team.
- 3. The Physician was at all material times the Club Physician to Vvapodmoskovje and the Player respectively.
- 4. On the 14<sup>th</sup> May 2004 V. Petrenchouk for and on behalf of the Russian Rugby Union and its team squad and officials signed the IRB 7's 2003/2004 Union Consent and Agreement form.
- 5. The player signed the IRB 7's 2003/2004 Player Consent and Agreement form.
- 6. On the 24<sup>th</sup> May 2004 the player signed the Declaration of Medication form certifying the information contained therein was accurate and that he had used a

Offence may have deen committed by the Player and as a result, the player was to IRB Anti-Doping Regulations and as a consequence was of the view that a Doping and is a prohibited substance according to the list of prohibited substances in the 10. Mr. Ricketts informed the Russian delegation that Retabolili is an anabolic steroid

advice of the Physician. the Physiotherapist acknowledged that it was he who injected the player on the Players Club of which he is the Physio prescribed the substance to the player and Player with the substance he responded that the Team Physician of the questioned as to whether he was the prescribing Physician who provided the that it had no ramifications for medication taken in the future and when submitted in good faith to be open about what substances the player had taken so the meeting. The Physiotherapist said the Declaration of Medication form was Mr. Ricketts and the provisions of the IRB Anti-Doping Regulations outlined to In the course of the meeting the Declaration of Medication form was produced by Sergei Guneyev – Assisting Translator

Alex Roshchyn – Team Liaison Officer and Translator

The Physiotherapist

The Player

Rifkit Sattarov – Russian Team Manager

Tim Ricketts – IRB Anti-Doping Manager

Mark Egan – IRB 7's Manager

Medication form at which the following persons were present;

- On the  $27^{th}$  May 2004 a meeting was held relating to the Declaration of anabolic steroid and did not fit the abbreviated TUE process. investigations that Retabolili is nandrolone decanoate which is an androgenic
- Chairman of the International Rugby Board TUE Committee who found from his 8. The said declaration of medication form was forwarded to Dr. Ismail Jakoet,
- ', pumpaj condition suffered by the Player, namely, "Atrophy of muscles of a thigh after asubstance had been administered as the correct treatment for the medical the Physiotherapist as "the prescribing Physician" certifying that the prohibited
- The said Declaration of Medication form was also signed on the 24th May 2004 by 15m March 2004.
- orthibited substance namely Retabolili intra muscularly in one single dose on the

- the 27<sup>th</sup> May 2004. of IRB regulation 21 were given to the Player and team Manager by letter dated Tournament and copies of the Medical declaration form and the relevant sections be suspended with immediate effect from participation in the IRB 7's Bordeaux
- 11. The Player was notified of the results of the investigation and a copy was sent to investigation Yuri Nikolaev President Rugby Union of Russian following consideration of the
- 12. suspended pending the outcome of the hearing (IRB Regulation 21.16) substance and notifying him of the IRBs intention to appoint a Board Judicial Committee in accordance with the said regulations. He was provisionally he may have committed a Doping Offence namely, breach of regulation 21.1.1 (c) The Player was notified by letter dated the 28th July 2004 that the IRB Anti-Doping Investigation had now concluded and it been determined by the IRB that admission orally or in writing having used or taken advantage of a prohibited
- 13. The Physiotherapist was notified of the results of the investigation and a copy was determined by the IRB that he may have committed Doping Offences namely: 2004 that the IRB Anti-Doping Investigation had now concluded and it had been of the investigation, the Physiotherapist was notified by letter dated the 28th July sent to Yuri Nikolaev President Rugby Union of Russia. Following consideration
- (A) breach of Regulation 21.1.3 administering a prohibited substance
- (B) breach of Regulation 21.1.5 assisting/abetting the use of prohibited substance by the player.
- provisionally suspended. Committee in due course in accordance with the regulations. He was And notifying him that there would be an appointment of the Board Judicial
- 14. By letter dated the 16<sup>th</sup> June 2004 the IRB notified the Physician of the AntitoYuri Nikolaev President Rugby Union of Russian. either of these said letters and a follow up later dated the 24<sup>th</sup> June 2004 was sent Yuri Nikolaev President Rugby Union of Russian. No response was received to no later than 1700 hours on Wednesday 23<sup>rd</sup> June 2004. This letter was copied to Doping Investigation and requested a statement from her in respect of the matter
- 15. On the 13<sup>th</sup> July 2004 a further letter was sent to Yuri Nikolaev requesting a reply.
- 16. By email dated the 27<sup>th</sup> July 2004, Rifkit Sattarov, General Manager of the Russian Team Rugby 7's apologised for the delay in responding to the letter from

the IRB dated the 16th June 2004 and inter alia set out the position in relation to the injury to the Player and the rehabilitation programme recommended by the Physician stating that they had carried out their own internal investigation and that the Physician had set out the injuries suffered by the player, the treatment to be administered and therapy to be followed. After a period of 2 months when the player had not responded to the therapy, the prohibited substance set out in the player had not responded to the therapy, the prohibited substance set out in the player had not responded to the therapy, the prohibited substance set out in the player had not responded to the therapy, it is prohibited substance set out in the player had not responded to the therapy.

- I. The player was "discharged of participation in the International Competitions, including competitions organised by IRB and FIRA AER up to" the decision of the IRB.
- 2. The Physiotherapist was "discharged of participation in the International Competitions, including competitions organised by IRB and FIRA AER up to"
- the decision of the IRB.

  3. The Physician was dismissed from her post.
- 17. By letter dated the 28<sup>th</sup> July 2004 the Physician was notified of the information furnished to them by the Russian Rugby Union and requesting her comments within 7 days (that is by close of business 4<sup>th</sup> August 2004). No response was
- received to this letter. Is, By letter dated the  $5^{th}$  August 2004, the Physician was notified that the IRB had arranged for a Board Judicial Committee to proceed with the case, alleging
- breaches of the following regulations, namely; (A) Regulation 21.1.3 supplying a prohibited substance (B) Regulation 21.1.5 assisting/abetting the use of a prohibited substance.

As no formal admission of liability was made by or on behalf of the Respondents they were notified that the matter would proceed to a Hearing before a Board Judicial Committee.

# RAL EVIDENCE GIVEN AT THE HEARING:

- The complaint was read out to the Player and he admitted the complaint but stated that he did not know it was a prohibited substance.
- 2. The complaints against the Physiotherapist were read out and he admitted the complaints.
- 3. The complaints were read out to the Physician and she admitted the complaints.

The following circumstances were outlined by and on behalf of each of the Respondents, namely, on behalf of the Player it was stated;

- 1. He did not know it was a prohibited substance
- 2. He had a doping test and nothing was revealed
- 3. He had taken the substance on the advice of his Physician after intensive treatment for his injury had failed.
- 4. He did not understand the form he completed as it was in English

On behalf of the Physiotherapist it was stated;

- Acknowledged that he had signed the Declaration of Medication Form but stated that he did not know when he signed the Form that the substance was a banned substance and believed it was part of the ongoing treatment recommended by the Physician.
- 2. No prescription was received from the Physician.
- 3. The Physician handed the substance to him and he injected it into the Player
- 4. The total responsibility for the medication was with the Physician. He had been working with her for 2 years.
- 5. It was not a substance regularly used
- 6. He would inject patients on a daily basis and in 75% of the cases he would not know what the substance was.

# n behalf of the Physician it was stated;

- 1. She admitted it was a banned substance
- 2. She told the Physiotherapist where to inject the substance
- 3. It was usually the practice to notify the Physiotherapist of the substance but in this instance she did not
- 4. She confirmed that she knew it was a banned substance contrary to what she had stated in her e.mail of the 6<sup>th</sup> August 2004
- 5. She accepted total responsibility for the complaints that had been made against both the Player and the Physiotherapist

The Committee were satisfied that doping offences had been committed as alleged and invited submissions on sanction from the respective parties.

# SUBMISSIONS RELATING TO SANCTIONS:

Mr. Sattarov stated that his e.mail of the 22<sup>nd</sup> November 2004 set out the position in relation to the Player and since then they check every substance and will be very careful in the future and will be more strict. As soon as they became aware of the breach they took all steps to deal with the matter and they suspended the Physician from May 2004 and payments that were due to her for April, May and June of 2004 were withheld and a new Physician appointed. The Physician's employment with the Union was terminated.

The Physiotherapist was suspended from all games for one month but in fact is still provisionally suspended by virtue of the IRB Ruling on the matter as indeed is the Player.

Susan Ahern, Legal Counsel for the IRB emphasised the strict liability provision of Regulation 21.3.1 and that in her opinion none of the Respondents were entitled to rely on the "no fault of negligence" provision contained in Regulation 21.20.1

# **NCTIONS:**

The Player:

The Committee then considered the matter of sanctions and in relation to the Player found that the strict liability provision at 21.3.1 in the Regulations applied to the complaint made against the Player and therefore lack of intent was not a defence open to the Player.

In addition the complaint to which the Player had been found guilty was under Regulation 21.1.1 (c) and thus the Player was not entitled to the benefits of the "no fault of negligence" provision contained in the Regulations at 21.20.1.

Pursuant to the provisions of 21.19 of the Regulations the Board were of the view that the offence came within the scope of a doping offence for which a sanction is not otherwise provided in the Regulations and taking into account the mitigating circumstances outlined on his behalf during the course of the Hearing the Committee decided to suspend the Player from the 27<sup>th</sup> May 2004 up to and including the 1<sup>st</sup> April 2005.

# The Physiotherapist:

The Physiotherapist was found to have committed the offence contrary to the provisions of Regulation 21.1.3 of the IRB Anti Doping Regulations. Regulation 21.19.3 sets out the Sanction to be imposed for such an offence (minimum of 4 years to a lifetime ban) and Regulation 21.20.2 deals with "no significant fault of negligence" which, inter alia, includes the administration of a prohibited substance or prohibited method under Regulation 21.1.3.

The Committee is satisfied that on the balance of probabilities the Physiotherapist bears "no significant fault of negligence" and in the circumstances in compliance with the provisions of Regulation 21.20.2 are disposed to reducing the Sanction by not less than one half of the minimum Sanction otherwise applicable and thus suspend the Physiotherapist for a period of 2 years from  $27^{th}$  May 2004

In all the circumstances the Committee have decided to Dismiss the complaint made pursuant to Regulation 21.1.5 of the IRB Anti Doping Regulations

The Physician:

The Physician was found to have committed both offences alleged against her and notwithstanding the mitigating circumstances that there were no previous complaints made against her and her admission of the offences albeit late in the day the Committee were of the view that there were aggravating factors in that she;

- 1. Knowingly distributed and supplied a banned substance;
- 2. Knowingly assisted and abetted the use of a prohibited substance;
- 3. Failed to notify either the Player or the Physiotherapist of the nature of the substance;
- 4. In the course of correspondence between the parties, namely, a e.mail of the 6<sup>th</sup> August 2004 it was stated on her behalf that she did know that the substance was prohibited

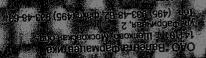
Sanctions for offences committed under Regulations 21.1.3 and 21.1.5 are provided for at Regulation 21.19.3 (a minimum of 4 years to a lifetime ban). The Committee were of the view that pursuant to the provisions of 20.20.2 a lifetime ban could be interpreted to be a period of 16 years and in the event that the person involved in a violation pursuant to Regulation 21.1.3 established a case for a reduced Sanction where otherwise applicable is a lifetime ban the reduced period would be no less than 8 years. However this is not the position in this case but using the provision as a guideline the Committee are of the view that a 10 year ban is appropriate in respect of the complaint found to be proved pursuant to Regulation 21.1.3 and are disposed to taking into account the complaint proved pursuant to Regulation 21.1.5.

# RIGHT OF APPEAL:

The Respondents are advised of their entitlement to Appeal against the finding and/or sanction proposed to an Appeal Committee and shall have 14 days from the date of the notification of the decision of the Judicial Committee in which to Appeal, the provisions of which are set out at Regulation 21.21.2 in the IRB Anti Doping Regulations.

Dated this 15 <sup>th</sup> day of March, 2005
SIGNED
BRIAN McLOUGHLIN - CHAIRMAN
FOR AND ON BEHALF OF BOARD JUDICIAL COMMITTER







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#### **INSTRUCTIONS** for medical use of **PHENOTROPIL®**

Registration number: P/V 002784/01

Trade name: PHENOTROPIL ®

Chemical name: N-carbamoyl-methyl-4-phenyl-2-pyrrolidone

Dosage form: tablets

Ingredients:

active agent: phenotropil (N-carbamoyl-methyl-4-phenyl-2-pyrrolidone) – 50 mg or 100 mg

additive agents:

for 50 mg doses: lactose monohydrate (milk sugar) - 80,50 mg, potato starch - 18,00 mg, calcium stearate - 1.50 ma

for 100 mg doses: lactose monohydrate (milk sugar) - 51,52 mg, potato starch - 46,48 mg, calcium stearate - 2,00 mg

Description

flat-faced tablets, color varies from white to white with yellow and cream, tints

Pharmacotherapeutic group: nootropics

ATC code: N06BX

## Pharmacological properties

Pharmacodynamics.

Phenotropil ® is a nootropic drug that has a pronounced antiamnestic effect, has a direct activating effect on the integrative activity of the brain, contributes to the consolidation of memory, improves concentration and mental performance, facilitates the learning process, increases the rate of information transfer between the hemispheres of the brain, increases the resistance of fabrics the brain to hypoxia and toxic effects, has anticonvulsant activity and anxiolytic activity, regulates the activation and inhibition of the central nervous system and improves mood.

Phenotropil ® positively influences on the metabolic processes and brain blood circulation, stimulates the redox processes, increases body's energy potential at the expense of glucose utilization, improves regional blood flow in the ischemic brain regions. Increases the content of noradrenaline, dopamine and serotonin in brain, does not affect the content of gamma aminobutyric acid (GABA), is not associated with either GABA A or GABA B receptors, has no evident influence on spontaneous electrobiological activity of the brain.

Phenotropil ® has no effect on breathing and the cardiovascular system, has an indistinct diuretic effect, has an anorectics effect if taken as a course of treatment.

Stimulating effect of Phenotropil ® is in its capacity to make a moderately apparent effect on motor reaction, improvement of physical capacity for work, in evident antagonism to cataleptic influence of neuroleptics, as well as in hypnotic action weakening of ethanol and hexenal.

The psychostimulant action of Phenotropil ® prevails in ideational sphere. A moderate psychostimulant effect of the medicine combines with the anxiolytic activity, puts in a good mood, has some analgesic effect and increases pain threshold.

The adaptogenic effect of Phenotropil ® declares itself in the increased organism resistance to stress under conditions of excessive mental and physical activity, in case of fatigue, hypokinesia and immobilization, in case of low temperature.

Taking the drug causes eyesight improvement, which declares itself in sharpness, brightness and visual fields improvement.

Phenotropil ® improves inferior limbs' blood supply.

Phenotropil ® stimulates antibodies generation as a reaction to antigen introduction, which points out its immunopotentiating properties, but at the same time it doesn't favour the development of delayed-type hypersensivity and doesn't change the allergic inflammatory reaction of skin, caused by foreign protein

If Phenotropil ® is taken as a course of treatment there are no drug dependence, tolerance, withdrawal

Phenotropil ® produces its effect from a single dose which is important when the drug is taken in extreme

Phenotropil ® has no teratogenic, mutagenic, carcinogenic and embryotoxic properties. The toxicity is low; the fatal dose makes 800 mg/kg.

Pharmacokinetics.

Phenotropil ® is quickly absorbed into different organs and tissues, easily goes through blood-brain barrier. Absolute bioavailability of the drug taken perorally makes 100 %. Maximal concentration in blood is reached after an hour, half-life period makes 3 – 5 hours. Phenotropil ® is not metabolized in organism and is immutable when leaves organism. About 40 % of the drug is excreted in the urine and 60 % is excreted in the bile and sweat.

## Indications for use

Central nervous system diseases of different genesis, especially those connected with vascular diseases and derangement of brain metabolism, intoxication, (particularly in case of posttraumatic state and in case of chronic cerebrovascular insufficiency), accompanied by the deterioration of intellectual-mental functions, reduction of motor activity;

Neurotic state, which declares itself in flaccidity, increased exhaustion, reduced psychomotor activity, disturbance of attention, impaired memory;

Derangement of learning process;

Mild and moderate depressions:

Psychoorganic syndromes, which declare themselves in intellectual-mental disorders and apathy abulia syndrome, as well as flaccid apathy state when there is schizophrenia; Convulsive state;

Obesity (of alimentary-constitutional genesis);

Prevention of hypoxia, increase of resistance to stress, correction of the functional state of organism in extreme professional conditions to prevent the development of fatigue and improve mental and physical capacity for work, daily biorhythm correction, the inversion of the sleep-wake cycle; Chronic alcoholism (to reduce asthenia, depression, intellectual-mental disorders).

### Contraindications

Individual intolerance.

#### Safety tips

Phenotropil ® is to be taken with caution by sick people with serious organic lesions of liver and kidneys, severe hypertension, by people sick of atherosclerosis and those who have had panic attacks, severe raptoid state or acute psychotic state, especially with psychomotor agitation, because of possible exacerbation of anxiety, panic, hallucinations and delirium, as well as by sick people inclined to allergic reactions to nootropic drugs of pyrrolidone group.

## Application during pregnancy and lactation

Phenotropil ® is not to be prescribed during pregnancy and lactation because of the lack of clinical research

## Application in pediatrics

It is not recommended to prescribe Phenotropil ® to children, because there is no data of children's use of the drug.

# Dosage and method of administration

It is recommended to ingest Phenotropil ® immediately after meals. Doses vary according to the peculiarities of state of a sick person. Average single dose makes 150 mg (from 100 mg to 250 mg), average daily dose makes 250 mg (from 200 mg to 300 mg). Maximal permissible dose is 750 mg a day. It is recommended to divide a daily dose into 2 parts. A daily dose up to 100 mg is to be taken once in the morning, and a daily dose of more than 100 mg is to be divided into 2 parts. Treatment duration can vary from 2 weeks to 3 months. Average treatment duration makes 30 days. If necessary the course of treatment can be repeated in a month.

To improve capacity for work – a single dose of 100-200 mg in the morning during 2 weeks (for athletes – 3

Recommended treatment duration for those who suffer alimentary-constitutional obesity makes 30-60 days with a dose of 100-200 mg once a day (in the morning). It is not recommended to take Phenotropil ® after 3 p.m.

### Side action

Insomnia (if the drug is taken after 3 p.m.). During first 1-3 days of treatment some people can have psychomotor agitation, hyperemia of skin, the sense of warmth, high blood pressure. Overdose

# No cases of overdose were reported.

Treatment: symptomatic therapy.

## Interaction with other drugs

Phenotropil ® can potentize other drugs which stimulate central nervous system, antidepressants and nootropic drugs.

# Special instructions

In case of excessive psycho-emotional exhaustion on the background of chronic stress and fatigue, chronic insomnia, a single first day dose of Phenotropil ® can cause sharp sleep requirement. Such outpatients are to be recommended to start the course of treatment on nonworking days.

## Presentation

Tablets 50 or 100 mg.

10 tablets in blisters of PVC film and aluminum foil.

Each jar, 1 or 3 stripes package, along with instructions for use in a stack of cardboard.

## Recommendations on storage

Keep in dry and shadowed, with temperature not higher than 30°C.

Keep out of children.

#### **Expiration date**

5 years. Do not use after expiry date.

# Pharmacy purchasing terms

On prescription.

# Consumer claims are to be addressed to the manufacturer:

JSC «Valenta Farmatsevtika»

2, Fabrichnaya str., town of Shchelkovo, Moscow region, 141101.

Tel. (495) 933-48-62, fax (495) 933-48-63.

# ИНСТРУКЦИЯ кому применёнию препарата ФЕНОТРОЛИЛ® по медицинско

Регистрационный номер: Р.// 002784/01 Торговое название: ФЕНОТРОПИЛ⊛ Химическое название: N-карбамоилметил-4-фенил-2-пирролидон Пекарственная форма: таблетки

Лекарственная форма: таолетки Состав: *активное вещество:* фенотропип ( N-карбамоилметил-4-фенил-2-пирролидон) - 50 мг или 100 мг

ампивнов вещество: фенотропип ( N-карбамоилметил-4-фенил-2-пирропидон) - 50 мг или 100 мг олля дозировки 50мг: лактозы моногидрат (сахар молочный) - 80,50 мг, крахмал картофельный - 18,00 мг, кальция стварат - 1,50 мг. для дозировки 100мг: лактозы моногидрат (сахар молочный) - 51,52 мг, крахмал картофельный - 46,48 Олисание

мг, кальции стеарат - 2,00 мг. Олисание: таблетки плоскоцилиндрической формы от белого до белого с желтоватым или кремоватым оттенком таблетки плоскоцилиндрической формы от белого до бело швета. Фармакотерапевтическая группа: ноотропное средство Код АТХ: NG6BX Фармакологические свойства Фармакодинамика

фармакологические своиства фармакологические своиства фармакойнамижа фармакойнамижа фармакойнамижа фенотропил - ноотролный препарат, обладает выраженным антиамнестическим действием, оказывает прямое активирующее влияние на интегративную деятельность головного мозга, пособствует консолидации памяти, улучшает концентрацию внимания и умственную деятельность, облечает процесс обучения, повышает скорость передачи информации между полушариями обладает противосудорожным действием и анхисиолитической активностью, регулирует процессы обладает противосудорожным действием и анхисиолитической активностью, регулирует процессы еННОТРОПИЛ оказывает положительное влияние на обменные процессы и кровообращение мозга, стимулирует окислительно-восстановительные процессы, повышает энергетический потенциал участках мозга. Повышает осдержание норадреналина, дофамина и сертонина в мозге, не влияет на заметного влияния на спонтанную биоэпектрическую активность мозга.

ФЕНОТРОПИЛ не оказывает влияния на дыхание и сердечно-оссудистую систему, проявляет невыраженный диуретический эффект, обладает анорексигенной активностью при курсовом применении.

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Стимулирующее действие ФЕНОТРОПИЛА проявляется в его способности оказывать умеренно выраженный эффект в отношении двигательных реакций, в повышении физической работоспособности, в выраженном антагонизме каталептическому действию нейролептиков, а также в сслаблении выраженности снотворного действия этанола и гексенала. Психостимулирующее ФЕНОТРОПИЛА преобладает в идеаторной сфере.

Умеренный психостимулирующий эффект препарата сочетается с анксиолитической активностью, улучшает настроение, оказывает некоторый анальгезирующий эффект, повышая порог болевой чувствительности.

умеренным психостимулирующий эффект препарата сочетается с анксиолитической активностью, улучшает настроение, оказывает некоторый анальгезирующий эффект, повышая порог болевой Адаптогенное действие ФЕНОТРОПИЛА проявляется в повышении устойчивости организма к стрессу в условиях чрезмерных психических и физических нагрузок, при утомлении, гипокинезии и иммобилизации, при низких температурах. На фоне приема ФЕНОТРОПИЛА отмечено улучшение зрения, которое проявляется в увеличении остроты, яркости и полей эрения. ФЕНОТРОПИЛ улучшает кровоснабжение нижних конечностей. ФЕНОТРОПИЛ тумулирует выработку антител в ответ на введение антигена, что указывает на его иммуностимулирующие свойства, но в то же время он не способствует развитию кожи, вызванную введением чужеродного белка. При курсовом применении ФЕНОТРОПИЛА не развивается лекарственная зависимость, Действие ФЕНОТРОПИЛА проявляется с однократной дозы, что важно при применении препарата в жетремальных условиях. ФЕНОТРОПИЛ не обладает тератогенными, мутагенными, канцерогенными и эмбриотоксичными свойствами. Токсичность - низка, летальная доза в остром эксперименте составляет в 800 мг/кг.

своиствами, поксичность - низка, летальная доза в остром эксперименте составляет осо миль. Фармакокомнетика ФЕНОТРОПИЛ быстро всасывается, проникает в различные органы и ткани, легко проходит через гематоэнцефалический барьер. Абсолютная биодоступность препарата при пероральном приеме составляет 100 %. Максимальная концентрация в крови достигается через 1 час, период полувыведения составляет 3-5 часов. ФЕНОТРОПИЛ не метабопизируется в организме и выводится из организма в неизменном виде. Примерно 40 % препарата выводится с мочой и 60 % препарата выводится с желчью и потом.

томазания к применению заболевания применению системы различного генеза, особенно связанные с сосудистыми заболеваниями и нарушениями обменных процессов в мозге, интоксикацией в частности при посттраематических состояниях и явлениях хронической цереброваскулярной недостаточности), сопровождающиеся ухудшением интеллектуально-мнестических функций, снижением двигательной активности.

Невротические состояния, проявляющиеся вялостью, повышенной истощаемостью, снижением психомоторной активности, нарушением внимания, ухудшением памяти. Нарушения процессов обучения. Депрессии легкой и средней степени тяжести. Психорганические синдромы, проявляющиеся интеллектуально-мнестическими нарушениями и апатико-абулическими явлениями, а также вялоапатические состояния при шизофрении. Судсрожные состояния. Ожирение (алиментарно-конституционального генеза). Профилактика гипоксии, повышение устойчивости к стрессу, коррекция функционального состояния организма в экстремальных условиях профессиональной деятельности с целью предупреждения развития утомления и повышения умственной и физической работоспособности, коррекция суточного биоритма, инверсия цикла «сон-бодрствоявание»; Хронический алкоголизм (с целью уменьшения явлений астении, депрессии, интеллектуально-мнестических нарушений). Противопоказания Индимилуальная непереносимость. С осторожностью

Противопоказания
Индивидуальная непереносимость.
С осторожностью
ФЕНОТРОПИЛ применяют с осторожностью у больных с тяжелыйм органическими поражениями печени и
почек, тяжелым течением артериальной гипертонии, у больных атероскперозом, также у больных,
перенасших ранее панические атаки, острые психотические состояния, протекающие с психомоторным
возбуждением - вспедствие возможности обострения тревоги, паники, галлюцинаций и бреда, а также у
больных, склонных к аллергическим реакциям на ноотролные препараты группы пирролидона.
Применение при беременности и в период лактации
ФЕНОТРОПИЛ не спедует назначать при беременности и кормлении грудью из-за отсутствия данных
клинических исспедований.
Применение в педиатрии
Не рекомендуется назначение ФЕНОТРОПИЛА детям, в связи с отсутствием данных применения
препарата у детей.
Способ применения и дозы
ФЕНОТРОПИЛ применяют внутрь, сразу после еды. Доза препарата и продолжительность лечения
должны определяться врачом. Дозы варьируют в зависимости от особенностей состояния больного.
Средняя разовая доза составляет 150 мг (от 100 мг до 250 мг); средняя суточняя доза составляет 250 мг (от
200 мг до 300 мг). Максимальная допустимая доза составляет - 750 мг в сутки. Рекомендуется разделять
суточную дозу на 2 приема. Суточную дозу до 100 мг принимать однократно в утренние часы, а свыше 100
мг разделить суточную дозу на два приема. Продолжительность лечения может варьировать от 2-х недель
до 3-х месяцев. Средняя продолжительность лечения составляет 30 дней. При необходимости курс может
быть повторен через месяц.
Пля повышения работоспособности - 100-200 мг однократно в утренние часы, в течение 2-х недель
быть повторен через месяц.
Пля повышения работоспособности - 100-200 мг однократно в утренние часы, в течение 2-х недель
быть повторен через месяц.
Пля повышения работоспособности - 100-200 мг однократно в утренние часы, в течение 2-х недель (для
портоменов - 3 дня).
Рекомендуемая длительность лечения для больных с алиментарно-конституциональным ожирением
составляет 30-60 дней в доз

Бессонникца (в случае приема препарата позднее 15 часоа). У некоторых больных в первые 1-3 дня приема препарата может возникнуть психомоторное возбуждение, гиперемия кожных покровов, ощущение тепла, повышение артериального давления.

Передозировка

Передозировка Случаев передозировки не отмечалось. 

Лечение: симптоматическая терапия. 
Взаимодействие с другими лекарственными средствами 
ФЕНОТРОПИЛ может усиливать действие препаратов, стимулирующих центральную нервную систему, 
антидепрессантов и ноотропных препаратов. 
Особые указания 
При чрезмерном психоэмоциональном истощении на фоне хронического стресса и утомления, 
хронической бессонницы, однократный прием ФЕНОТРОПИЛА в первые сутки может вызвать резкую 
потребность в сне. Таким больным в амбулаторных условиях следует рекомендовать начинать курсовой 
прием препарата в нерабочие дни.

потребность в сне. Таким оольным в амоулаторных условиях следует рекомендовать начинать курсовой прием препарата в нерабочие дни. Форма выпуска
Таблетки, 50 или 100 мг.
По 10 таблеток в контурной ячейковой упаковке из пленки поливинилхлоридной и фольги алюминиевой.
1 или 3 контурные ячейковые упаковки вместе с инструкцией по применению помещают в пачку из картона.

условия хранения В сухом защищенном от света мёсте, при температуре не выше 30 °C. Хранить в недоступных для детей местах. Срок годности 5 лет. Не рекомендуется использование после истечения срока годности. Условия отпуска из аптек

порецепту. Претензии от покупателей принимает предприятие-изготовитель: ОАО «Валента Фармацевтика», 141101 г.Щелково, Московская область, ул. Фабричная, 2. Тел. (495) 933-48-62, факс (495) 933-48-63.