

# **Therapeutic Use Exemption of Prohibited Substances and Methods POLICY**

## **GENERAL PROVISIONS**

1. This policy is made in accordance with the International Standard for Therapeutic Use Exemptions (hereinafter referred to as ISTUE).

ISTUE of the World Anti-Doping Code (hereinafter referred to as WADC), is a mandatory International Standard developed as a part of the World Anti-Doping Program.

2. The purpose of the policy is to establish:

the responsibilities imposed on the National Anti-Doping Agency (hereinafter referred to as NADA) in making Therapeutic Use (hereinafter referred to as TUE) decisions;

the conditions that must be satisfied in order for the Therapeutic Use Commission (hereinafter referred to as TUEC) to be granted, permitting the presence of a Prohibited Substance in an Athlete's Sample or the Athlete's Use or Attempted Use, Possession and/or Administration or Attempted Administration of a Prohibited Substance or Prohibited Method for therapeutic reasons;

the process for an Athlete to apply for a TUE;

the process for an Athlete to get a TUE recognized by other Anti-Doping Organizations;

the process to review TUE decisions for World Anti-Doping Agency (hereinafter referred to as WADA);

the strict confidentiality provisions that apply to the TUE process.

## **THE RESPONSIBILITIES IMPOSED ON NADA IN MAKING AND COMMUNICATING TUE DECISIONS**

3. NADA's policy on the use of Prohibited Substances and Methods, which purpose is to respect the rights of the athletes is available on its official website.

4. Athletes who are not International-Level Athletes should contact NADA to apply for TUE. If NADA refuses to grant TUE, the athlete has the right to appeal exclusively to the appellate body of the national level.

An Athlete who is an International-Level Athlete must submit a request to his or her International Federation.

***Comment:*** for the avoidance of doubt, when a National Anti-Doping Organization grants a TUE to an Athlete, that TUE is valid at national level on a global basis and does not need to be formally recognized by other

*National Anti-Doping Organizations under Article 7 of International Standard on Testing and Investigations (for example, if an Athlete is granted a TUE by their National Anti-Doping Organization and then trains or competes in the country of another National Anti-Doping Organization, that TUE will be valid if the Athlete is then tested by such other National Anti-Doping Organization).*

5. A TUEC has been established at NADA to consider whether requests for the granting or recognition of TUE meet the criteria set out in paragraph 14 of these Regulations.

6. TUEC's pool should include at least four physicians with experience in the care and treatment of Athletes and a sound knowledge of clinical, sports medicine, as well as medical supervision of training loads. In cases involving special knowledge (for example, working with Athletes with impairments, if substance of method is related to their impairments), at least one TUEC member should possess general experience in the care and treatment of Athletes with impairments, or possess specific experience in treatment of athletes with impairments, and it should be in relation to the Athlete's particular impairments. Sports medicine physician should act as chair of TUEC.

7. In order to ensure a level of independence of decisions, at least a majority of the members of a TUEC should have no responsibility in NADA that appoints them. All members of the TUEC must sign a confidentiality declaration.

8. NADA has established a clear process for applying to its TUEC for a TUE that complies with the requirements of this International Standard. TUE procedure is available on the NADA's official website.

9. NADA must promptly report all decisions of its TUEC granting or denying TUE, and all decisions to recognize or refusing to recognize other Anti-Doping Organizations' TUE decisions, through ADAMS. Decisions to deny other Anti-Doping Organizations' TUE decisions shall include an explanation of the reason(s) for the denial. In respect of TUE granted, the information reported through ADAMS shall include:

Whether the Athlete was permitted to apply for a TUE retroactively under item 13 of the Policy of the Use of the Prohibited Substances and Methods and an explanation of the reason(s) why, or whether the Athlete was permitted to apply for and was granted a TUE retroactively under items 15 and 16 of the Policy of the Use of the Prohibited Substances and Methods and an explanation of the reason(s) why;

the name of the approved substance or method, the dosage(s), frequency and route of Administration permitted, the duration of the TUE (and, if different, the duration of the treatment prescribed), and any conditions imposed in connection with the TUE;

the TUE application form and the relevant clinical information establishing that the ISTUE Article 4.1 conditions have been satisfied in respect of such TUE (for access only by WADA, NADA, International Federation, and the Major Event Organization organizing an Event in which the Athlete wishes to compete).

***Comment:*** *The full medical file, including diagnostic tests, laboratory results and values must be provided, but need not be translated into English or French. However, a translated summary of all the key information (including key diagnostic tests) must be entered into ADAMS, with sufficient information to clearly establish the diagnosis. It is strongly suggested that the summary be prepared by a physician or other person with adequate medical knowledge, in order to properly understand and summarize the medical information. More detailed/full translations may be required by the relevant Anti-Doping Organization or WADA, upon request.*

10. When a NADA grants a TUE to an Athlete, it must warn him/her in writing that:

that TUE is valid at national level only;

that if the Athlete becomes an International-Level Athlete or competes in an International Event, that TUE will not be valid for those purposes unless it is recognized by the relevant International Federation or Major Event Organization. Thereafter, the NADA should help the Athlete to determine when he/she needs to submit the TUE to an International Federation or Major Event Organization for recognition, and should guide and support the Athlete through the TUE recognition process.

11. If a National Anti-Doping Organization grants a TUE to an Athlete and the Athlete subsequently becomes an International-Level Athlete or competes in an International Event, the TUE will not be valid unless and until the relevant International Federation recognizes that TUE. If an International Federation grants a TUE to an International-Level Athlete and the Athlete then competes in an International Event organized by a Major Event Organization, the TUE will not be valid unless and until the relevant Major Event Organization recognizes that TUE. As a result, if the International Federation or Major Event Organization (as applicable) declines to recognize that TUE, then (subject to the Athlete's rights of review and appeal) that TUE may not be relied upon to excuse the presence, Use, Possession or Administration of the Prohibited Substance or Prohibited Method mentioned in the TUE vis-à-vis that International Federation or Major Event Organization.

## **TUE CONDITIONS**

12. An Athlete who needs to Use a Prohibited Substance or Prohibited

Method for Therapeutic reasons must obtain a TUE prior to Using or Possessing the substance or method in question.

13. An Athlete may also be granted retroactive TUE, (therefore, approving of the therapeutic use of already used Prohibited Substance or Prohibited Method) if:

emergency treatment or treatment of an acute medical condition was necessary;

there was insufficient time or opportunity for the Athlete to submit, or other exceptional circumstances preventing an Athlete from submitting a TUE (or circumstances preventing the TUEC to consider, an application for the TUE prior to Sample collection);

If NADA chooses to collect a Sample from an Athlete who is not an International-Level Athlete or National-Level Athlete, and that Athlete is Using a Prohibited Substance or Prohibited Method for Therapeutic reasons, NADA must permit the Athlete to apply for a retroactive TUE;

the Athlete Used Out-of-Competition, for Therapeutic reasons, a Prohibited Substance that is only prohibited In-Competition. This seeks to address situations where, for Therapeutic reasons, an Athlete Uses a substance Out-of-Competition that is only prohibited In-Competition, but there is a risk that the substance will remain in their system In-Competition. In such situations, NADA must permit the Athlete to apply for a retroactive TUE (where the Athlete has not applied in advance). This also seeks to prevent NADA from having to assess advance TUE applications that may not be necessary.

***Comment:*** Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions, in case an application for a retroactive TUE is necessary following Sample collection.

14. An Athlete may be granted a TUE if (and only if) he/she can show, on the balance of probabilities, that each of the following conditions is met:

the Prohibited Substance or Prohibited Method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence;

the Therapeutic Use of the Prohibited Substance or Prohibited Method will not, on the balance of probabilities, produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the medical condition;

there is no reasonable permitted Therapeutic alternative between The Prohibited Substance or Prohibited Method and other medical treatment;

the necessity for the Use of the Prohibited Substance or Prohibited

Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method which was prohibited at the time of such Use.

15. In exceptional circumstances and notwithstanding any other provision in this International Standard for Therapeutic Use Exemptions, an Athlete may apply for and be granted retroactive approval for their Therapeutic Use of a Prohibited Substance or Prohibited Method if, considering the purpose of the World Anti-Doping Code, it would be manifestly unfair not to grant a retroactive TUE. For International-Level Athletes and National-Level Athletes, NADA may grant an Athlete's application for a retroactive TUE only with the prior approval of WADA (and WADA may in its absolute discretion agree with or reject the NADA's decision).

16. For Athletes who are not International-Level Athletes or National-Level Athletes, NADA may grant an Athlete's application for a retroactive TUE without first consulting WADA. However, WADA may at any time review NADA's decision to grant a retroactive TUE pursuant to this Article, and may in its absolute discretion, agree with or reverse the decision.

17. Any decision made by WADA and/or NADA may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.

18. All decisions of an Anti-Doping Organization, whether granting or denying a TUE, must be reported through ADAMS.

### **TUE Application Process**

19. An Athlete who needs a TUE should apply as soon as possible.

For substances prohibited In-Competition only, the Athlete should apply for a TUE at least 30 days before his/her next Competition, unless it is an emergency or exceptional situation.

20. The Athlete should apply to their NADA, International Federation and/or a Major Event Organization (as applicable), using the TUE application form provided. TUE application form template for International-Level Athletes and Athletes who are not International-Level Athletes or are not National-Level Athletes is available from the NADA's official website.

***Comment:*** *In certain situations, an Athlete may not know which National Anti-Doping Organization they should apply to for a TUE. In such circumstances, the Athlete should consult NADA, to determine if they fall within NADA's TUE jurisdiction, according to their rules.*

*Thereafter, the National Anti-Doping Organization should help the Athlete to determine when he/she needs to submit the TUE to an International Federation or Major Event Organization for recognition, and should guide and support the Athlete through the recognition process.*

21. An Athlete may not apply to more than 1 (one) Anti-Doping Organization for a TUE for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition. Nor may an Athlete have more than 1 (one) TUE at a time for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition (and any such new TUE will supersede the previous TUE, which should be canceled by the relevant anti-doping organization).

22. The Athlete must submit a TUE application form to NADA via ADAMS or email. The form must be signed by the treating physician and accompanied by a comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible) and the results of all examinations, laboratory investigations and imaging studies relevant to the application.

23. The Athlete should keep a complete copy of the TUE application form and of all materials and information submitted in support of that application.

24. When a properly drafted TUE application with clinical documentation is received, the NADA will forward the request and documentation to the TUEC Secretary, who will forward the relevant request to the TUEC Chairperson and enter this information into ADAMS within five (5) working days in Russian and English.

25. The TUE application will be considered by the TUEC only after receiving a duly completed TUE application form together with all related documents. An incomplete request form will be returned to the Athlete for completion and resubmission.

26. The TUEC may request from the Athlete or their physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the Athlete's application; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate.

27. Any costs incurred by the Athlete in making the TUE application and in supplementing it as required by the TUEC are the responsibility of the Athlete.

28. The TUEC shall decide whether or not to grant the application as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than twenty-one (21) days of receipt of a complete application. Where a TUE application is made in a reasonable time prior to an Event, the TUEC must use its best endeavors to issue its decision before the start of the Event.

29. After receiving a decision of the TUEC, the NADA will provide, within five (5) working days, notification of the TUEC's decision to the

Athlete and access to the TUE decision via WADA's ADAMS and other Anti-Doping Organizations.

30. The decision to grant a TUE will contain the dose(s), frequency of ingestion, route of administration and duration of use of the otherwise Prohibited Substance or Prohibited Method.

31. The decision to refuse a TUE shall include a statement of the reasons for the refusal.

32. Each TUE will have a specified duration, as decided by the TUEC, at the end of which the TUE will expire automatically. If the Athlete needs to continue to Use the Prohibited Substance or Prohibited Method after the expiry date, he/she must submit an application for a new TUE well in advance of that expiry date, so that there is sufficient time for a decision to be made on the application before the expiry date.

33. A TUE will be withdrawn prior to expiry if the Athlete does not promptly comply with any requirements or conditions imposed by the Anti-Doping Organization granting the TUE. Alternatively a TUE may be reversed upon review by WADA or on appeal.

34. Where an Adverse Analytical Finding is issued shortly after a TUE for the Prohibited Substance in question has expired or has been withdrawn or reversed, NADA conducting the initial review of the Adverse Analytical Finding, to determine whether the finding was due to the Use of the Prohibited Substance prior to the expiry, withdrawal or reversal of the TUE. If so, such Use (and any resulting presence of the Prohibited Substance in the Athlete's Sample) is not an anti-doping rule violation.

35. If, after receiving a TUE, the Athlete would need to make a significant change in the dose, frequency, route or duration of administration of the Prohibited Substance or Prohibited Method contained in the TUE, the Athlete should contact NADA who will decide whether to request a new TUE. If the presence, Use, Possession or Administration of a Prohibited Substance or Prohibited Method does not comply with the conditions specified in the TUE, the fact that the Athlete has a TUE will not make it an anti-doping rule violation.

### **TUE Recognition Process**

36. Code Article 4.4 requires Anti-Doping Organizations to recognize TUEs granted by other Anti-Doping Organizations that satisfy the Article 4.2 conditions. Therefore, if an Athlete who becomes subject to the TUE requirements of an International Federation or Major Event Organization already has a TUE, he/she should not submit an application for a new TUE to the International Federation or Major Event Organization.

Instead:

The International Federation or Major Event Organization may publish

notice that it will automatically recognize TUE decisions made pursuant to Code Article 4.4 (or certain categories of such decisions, e.g., those made by specified Anti-Doping Organizations, or those relating to particular Prohibited Substances). Where an Athlete's TUE is granted automatically upon granting the exemption described above, no further action need be taken;

37. In the absence of such automatic recognition, the Athlete shall submit a request for recognition of the TUE to the International Federation or Major Event Organization in question, either via ADAMS or as otherwise specified by that International Federation or Major Event Organization. The request should be accompanied by a copy of the TUE and the original TUE application form and supporting materials referenced at Article 22 (unless the NADA issuing the TUE has already filed the TUE and the accompanying medical information with ADAMS).

### **Review of TUE Decisions by WADA**

38. Code Article 4.4.6 provides that WADA, in certain cases, must review TUE decisions of International Federations, and that it may review any other TUE decisions, in each case to determine compliance with the Article 13 and 14 conditions of these regulations. In relation to the Article 14 conditions, WADA shall establish a WADA TUEC that meets the requirements of Article 5.3 to carry out such reviews. In relation to the Article 13 conditions, these can be reviewed by WADA (which may, at its discretion, consult with a member(s) of a WADA TUEC).

39. Each request for review must be submitted to WADA in writing and must be accompanied by payment of the application fee established by WADA, as well as copies of all of the information specified in Article 22 of the Regulation (or, in the case of review of a TUE denial, all of the information that the Athlete submitted in connection with the original TUE application). The request must be copied to the Anti-Doping Organization whose decision would be the subject of the review, and to the Athlete (if he/she is not requesting the review).

40. Where the request is for review of a TUE decision that WADA is not obliged to review, WADA shall advise the Athlete as soon as practicable following receipt of the request whether or not it will review the TUE decision. Any decision by WADA not to review the TUE decision is final and may not be appealed. However, the TUE decision may still be appealable, as set out in Code Article 4.4.7.

41. Where the request is for review of a TUE decision of an International Federation that WADA is obliged to review, WADA may nevertheless refer the decision back to the International Federation:

42. for clarification (for example, if the reasons are not clearly set out



in the decision);

43. for re-consideration by the International Federation (for example, if the TUE was only denied because medical tests or other information required to demonstrate satisfaction of the Article 4.2 conditions were missing).

44. Where a request for review is referred to the WADA TUEC, the WADA TUEC may seek additional information from the Anti-Doping Organization and/or the Athlete, (including further studies) as described in Article 22, and/or it may obtain the assistance of other medical or scientific experts as it deems appropriate.

45. WADA shall reverse any grant of a TUE that does not comply with the Article 13 and 14 conditions (as applicable). Where the TUE reversed was a prospective TUE (rather than a retroactive TUE), such reversal shall take effect upon the date specified by WADA (which shall not be earlier than the date of WADA's notification to the Athlete). The reversal shall not apply retroactively and the Athlete's results prior to such notification shall not be Disqualified. Where the TUE reversed was a retroactive TUE, however, the reversal shall also be retroactive.

46. WADA shall reverse any denial of a TUE where the TUE application met the Article 13 and 14 of these regulations, i.e., it shall grant the TUE.

47. Where WADA reviews a decision of an International Federation that has been referred to it pursuant to Code Article 4.4.3 (i.e., a mandatory review), it may require whichever Anti-Doping Organization "loses" the review (i.e., the Anti-Doping Organization whose view it does not uphold) (a) to reimburse the application fee to the party that referred the decision to WADA (if applicable); and/or (b) to pay the costs incurred by WADA in respect of that review, to the extent they are not covered by the application fee.

48. Where WADA reverses a TUE decision that WADA has decided in its discretion to review, WADA may require the Anti-Doping Organization that made the decision to pay the costs incurred by WADA in respect of that review.

49. If applicable, WADA shall communicate the reasoned decision of the WADA TUEC promptly to the Athlete and to their National Anti-Doping Organization and International Federation (and, if applicable, the Major Event Organization).

### **Confidentiality of Information**

50. The Processing of Personal Information during the TUE process by NADA shall comply with the International Standard for the Protection of Privacy and Personal Information and the Local Provisions for the Protection

of the Privacy and Personal Information of Athletes, Athlete Support Personnel and Other Persons.

51. An Athlete applying for a grant of a TUE or the recognition of a TUE agrees to the following:

52. All information pertaining to the application will be transmitted to members of all TUECs with authority under this International Standard to review the file and, as required, other independent medical or scientific experts, and to all necessary staff (including WADA staff) involved in the management, review or appeal of TUE applications;

53. The Athlete must authorize their physician(s) to release to any relevant TUEC upon request any health information that any such TUEC deems necessary in order to consider and determine the Athlete's application;

54. The decision on the application will be made available to all Anti-Doping Organizations with Testing authority and/or Results Management authority over the Athlete.

55. The TUE application shall be dealt with in accordance with the principles of strict medical confidentiality. The members of all relevant TUECs, any consulted independent experts and the relevant staff of the Anti-Doping Organization shall conduct all of their activities relating to the process in strict confidence and shall sign appropriate confidentiality agreements. In particular, they shall keep the following information confidential:

56. All medical information provided by the Athlete and physician(s) involved in the Athlete's care;

57. All details of the application, including the name of the physician(s) involved in the process.

58. Should the Athlete wish to revoke the right of a TUEC to obtain any health information on their behalf, the Athlete shall notify their physician in writing of such revocation; provided that, as a result of that revocation, the Athlete's application for a TUE or for recognition of an existing TUE will be deemed withdrawn without approval/recognition having been granted.

59. NADA shall only use information submitted by an Athlete in connection with a TUE application to evaluate the application and in the context of potential anti-doping rule violation investigations and proceedings.