

SCHEDULE 3(a). WADA INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS

3.2 Defined Terms from the International Standard for TUE

Personal Information: as defined in the International Standard for the protection of privacy and Personal Information, information including without limitation sensitive Personal Information, relating to an identified or identifiable participant or relating to other Persons whose information is processed solely in context of an anti-doping organisation's anti-doping activities.

[Comment: It is understood that Personal Information includes, but is not limited to, information relating to an athlete's contact details an sporting affiliations, whereabouts, designated therapeutic use exemptions (if any), anti-doping test results, and results management (including disciplinary hearings, appeals and sanctions). Personal Information also includes personal details and contact information relating to other persons, such as medical professionals and other persons working with, treating or assisting an athlete in the context of anti-doping activities.]

Therapeutic: Of or relating to the treatment of a medical condition by remedial agents or methods; or providing or assisting in a cure.

TUE: is a therapeutic use exemption approved by a Therapeutic Use Exemption Committee based on a documented medical file before the Use or Possession of, a substance or method that would otherwise be prohibited by the Code.

TUEC: Therapeutic Use Exemption Committee is the Panel established by the relevant Anti-Doping Organization.

WADA TUEC: WADA Therapeutic Use Exemption Committee is the Panel established by WADA.

PART TWO: STANDARDS FOR GRANTING THERAPEUTIC USE EXEMPTIONS

4.0 Criteria for Granting a Therapeutic Use Exemption

A Therapeutic Use Exemption (TUE) may be granted to an Athlete permitting the Use of a Prohibited Substance or Prohibited Method. An application for a TUE will be reviewed by a Therapeutic Use Exemption Committee (TUEC). The TUEC will be appointed by an Anti-Doping Organization.

- 4.1** A TUE will be granted only in strict accordance with the following criteria:
- a. The Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld in the course of treating an acute or chronic medical condition.
 - b. The Therapeutic Use of the Prohibited Substance or Prohibited Method would produce no additional enhancement of performance other than that which might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition. The Use of any Prohibited Substance or Prohibited Method to increase “low-normal” levels of any endogenous hormone is not considered an acceptable Therapeutic intervention.
 - c. There is no reasonable Therapeutic alternative to the Use of the otherwise Prohibited Substance or Prohibited Method.
 - d. The necessity for the Use of the otherwise Prohibited Substance or Prohibited Method cannot be 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 Use.
- 4.2** The TUE will be cancelled, if:
- a. The Athlete does not promptly comply with any requirements or conditions imposed by the Anti-Doping Organization granting the exemption.
 - b. The term for which the TUE was granted has expired.
 - c. The Athlete is advised that the TUE has been withdrawn by the Anti-Doping Organization.
 - d. A decision granting a TUE has been reversed by WADA or CAS.

[Comment: Each TUE will have a specified duration as decided upon by the TUEC. There may be cases when a TUE has expired or has been withdrawn and the Prohibited Substance subject to the TUE is still present in the Athlete’s body. In such cases, the Anti-Doping Organization conducting the initial review of an Adverse Analytical Finding will consider whether the finding is consistent with expiry or withdrawal of the TUE.]



- 4.3** An application for a TUE will not be considered for retroactive approval except in cases where:
- a. Emergency treatment or treatment of an acute medical condition was necessary, or
 - b. Due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a TUEC to consider, an application prior to Doping Control.

[Comment: Medical emergencies or acute medical situations requiring administration of an otherwise Prohibited Substance or Prohibited Method before an application for a TUE can be made, are uncommon. Similarly, circumstances requiring expedited consideration of an application for a TUE due to imminent competition are infrequent. Anti-Doping Organizations granting TUEs should have internal procedures that permit such situations to be addressed.]

5.0 Confidentiality of Information

- 5.1** The collection, storage, processing, disclosure and retention of Personal Information in the TUE process by Anti-Doping Organizations and WADA shall comply with the International Standard for the Protection of Privacy and Personal Information.
- 5.2** An Athlete applying for a TUE shall provide written consent for the transmission of all information pertaining to the application to members of all TUECs with authority under the Code to review the file and, as required, other independent medical or scientific experts, and to all necessary staff involved in the management, review or appeal of TUEs, and WADA. The applicant shall also provide written consent for the decision of the TUEC to be distributed to other relevant Anti-Doping Organizations and National Federations under the provisions of the Code.

[Comment to 5.2: Prior to collecting Personal Information or obtaining consent from an Athlete, the Anti-Doping Organization shall communicate to the Athlete the information set forth in Article 7.1 of the International Standard for the Protection of Privacy and Personal Information.]

Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the Athlete concerned.

- 5.3** The members of the TUECs, independent experts and the staff of the Anti-Doping Organization involved, will conduct all of their activities in strict confidence and will sign confidentiality agreements. In particular they will keep the following information confidential:
- a. All medical information and data provided by the Athlete and physician(s) involved in the Athlete's care.
 - b. All details of the application including the name of the physician(s) involved in the process.

Should the Athlete wish to revoke the right of any TUEC to obtain any health information on his/her behalf, the Athlete shall notify his/her medical practitioner in writing of the fact. As a consequence of such a decision, the Athlete will not receive approval for a TUE or renewal of an existing TUE.

- 5.4** Anti-Doping Organizations shall ensure that Personal Information obtained in the TUE process is retained for a period of eight (8) years, and thereafter only for as long as necessary to fulfill their obligations under the Code or where otherwise required by applicable law, regulation or compulsory legal process.

6.0 Therapeutic Use Exemption Committees (TUECs)

TUECs shall be constituted and act in accordance with the following guidelines:

- 6.1** TUECs should include at least three (3) physicians with experience in the care and treatment of Athletes and a sound knowledge of clinical, sports and exercise medicine. In order to ensure a level of independence of decisions, the majority of the members of any TUEC should be free of conflicts of interest or political responsibility in the Anti-Doping Organization. All members of a TUEC will sign a conflict of interest agreement. In applications involving Athletes with disabilities, at least one TUEC member shall possess specific experience with the care and treatment of Athletes with disabilities.
- 6.2** TUECs may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.
- 6.3** The WADA TUEC shall be composed following the criteria set out in Article 6.1. The WADA TUEC is established to review the granting or denial of TUEs for International-Level Athletes, Athletes entered in an International event as described under 7.1(b), or Athletes in their National Anti-Doping Organization's Registered Testing Pool as set forth in Article 4.4 of the Code. In normal circumstances, the WADA TUEC shall render a decision within 30 days of receipt of all requested information.



7.0 Responsibilities of International Federations and National Anti-Doping Organizations

7.1 Each International Federation shall:

- a. Establish a TUEC as provided in Article 6.
- b. Publish a list of International Events for which a TUE granted pursuant to the International Federation's rules is required.
- c. Establish and publish a TUE process whereby any Athlete who is in the International Federation's Registered Testing Pool or who is entered in an International Event described in Article 7.1(b) may request a TUE for a documented medical condition requiring the Use of a Prohibited Substance or a Prohibited Method. Such TUE process shall comply with Article 4.4 of the Code, this International Standard and the International Standard for the Protection of Privacy and Personal Information.
- d. Publish any rule pursuant to which the International Federation will accept TUEs granted by other Anti-Doping Organizations.
- e. Promptly report to WADA, through ADAMS, the granting of all TUEs, including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.
- f. Promptly report the granting of a TUE to the relevant National Anti-Doping Organization and National Federation.
- g. At WADA's request, promptly provide its entire file on any TUE which has been denied.

7.2 Each National Anti-Doping Organization shall:

- a. Establish a TUEC as provided in Article 6.
- b. Identify and publish those categories of Athletes within its jurisdiction who are required to obtain a TUE before Using a Prohibited Substance or a Prohibited Method. At a minimum, this shall include all Athletes in the National Anti-Doping Organization's Registered Testing Pool and other national-level Athletes as defined by the National Anti-Doping Organization.
- c. Establish and publish a TUE process whereby any Athlete who is in the National Anti-Doping Organization's Registered Testing Pool or who is described in 7.2(b) may request a TUE for a documented medical condition requiring the Use of a Prohibited Substance or a

Prohibited Method. Such TUE process shall comply with Article 4.4 of the Code, this International Standard and the International Standard for the Protection of Privacy and Personal Information.

[Comment to 7.2(b): National Anti-Doping Organizations will not grant TUEs to Athletes in an International Federation's Registered Testing Pool except in those instances where the International Federation's rules recognize or give authority to National Anti-Doping Organizations to grant TUEs to such Athletes.]

- d. Promptly report to WADA, through ADAMS, the granting of a TUE to any Athlete in its Registered Testing Pool, and if applicable, to an Athlete in an International Federation's Registered Testing Pool or entered in an International Event described in Article 7.1(b), including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.
- e. At WADA's request, promptly provide its entire file on any TUE that has been denied.
- f. Promptly report the granting of a TUE to the relevant National Federation and International Federation where the rules of the International Federation authorize NADO to grant TUEs to International-Level Athletes.
- g. Recognize TUEs granted by International Federations to Athletes in the International Federation's Registered Testing Pool or entered in an International Event as described under 7.1(b).

[As used in this Article 7, the term "publish" means: An Anti-Doping Organization shall publish information by providing the information in a conspicuous place on its website and by sending the information to each National Federation which is subject to its rules.]

8.0 TUE Application Process

8.1 Unless the rules of their International Federation provide otherwise, the following Athletes shall obtain a TUE from their International Federation:

- a. Athletes in the International Federation's Registered Testing Pool; and
- b. Athletes participating in an International Event for which a TUE granted pursuant to the International Federation's rules is required.



8.2 Athletes not identified in Article 8.1 shall obtain a TUE from their National Anti-Doping Organization.

[Comment to 8.1 and 8.2: Unless the rules of an International Federation provide otherwise, an Athlete who already has a TUE from a National Anti-Doping Organization, but later becomes a member of the International Federation's Registered Testing Pool or seeks to participate in an International Event which the International Federation has identified as requiring an International Federation TUE, shall obtain a new TUE from the International Federation.

The phrase "unless the rules of an International Federation provide otherwise" takes into account the fact that some International Federations, through their rules, are willing to recognize TUEs granted by National Anti-Doping Organizations and do not require a new TUE application at the International Federation level. Where such rules are in place, the Athlete should obtain a TUE from the Athlete's National Anti-Doping Organization.]

8.3 The Athlete should submit an application for a TUE no less than thirty (30) days before he/she needs the approval (for instance, an Event).

8.4 A TUE will only be considered following the receipt of a completed application form that shall include all relevant documents (see Annex 1 - TUE form). The application process shall be dealt with in accordance with the principles of strict medical confidentiality.

8.5 The TUE application form(s), as set out in Annex 1, can be modified by Anti-Doping Organizations to include additional requests for information, but no sections or items shall be removed.

8.6 The TUE application form(s) may be translated into other language(s) by Anti-Doping Organizations, but the English or French text shall remain on the application form(s).

8.7 The application shall identify the Athlete's level of competition (e.g., International Federation Registered Testing Pool), sport and, where appropriate, discipline and specific position or role.

8.8 The application shall list any previous and/or current TUE requests, the body to whom that request was made, the decision of that body, and the decisions of any other body on review or appeal.

8.9 The application shall include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis and treatment, as well as duration of validity, should be guided by the WADA "Medical Information to Support the Decisions of TUECs".

- 8.10** Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the Anti-Doping Organization before approval will be undertaken at the expense of the applicant.

[Comment to 8.10: In some cases, the applicant's National Federation may elect to pay this expense.]

- 8.11** The application shall include a statement by an appropriately qualified physician attesting to the necessity of the otherwise Prohibited Substance or Prohibited Method in the treatment of the Athlete and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.

- 8.12** The substance or method, dose, frequency, route and duration of administration of the otherwise Prohibited Substance or Prohibited Method in question shall be specified. In case of change, a new application shall be submitted.

- 8.13** In normal circumstances, decisions of the TUEC should be completed within thirty (30) days of receipt of all relevant documentation and will be conveyed in writing to the Athlete by the relevant Anti-Doping Organization. In case of a TUE application made in a reasonable time limit prior to an Event the TUEC should use its best endeavors to complete the TUE process before the start of the Event.

[Comment to 8.13: When an Anti-Doping Organization has failed to act on an Athlete's TUE application within a reasonable time, the Athlete may seek review by WADA as if the application was denied.]

9.0 Declaration of Use

- 9.1** The Prohibited List identifies certain substances and methods that are not prohibited but for which an Athlete is required to file a declaration of Use. An Athlete should satisfy this requirement by declaring the Use on a Doping Control Form and when available by filing a declaration of Use through ADAMS.

- 9.2** An Athlete's failure to declare Use on a Doping Control Form and through ADAMS when available, as stated in Article 9.1, shall not be an anti-doping rule violation.

[Comment to 9.2: The rules of Anti-Doping Organizations with jurisdiction over an Athlete may impose consequences other than an anti-doping rule violation for a failure to declare.]



10.0 Review of TUE Decisions by WADA

10.1 The WADA TUEC may, at any time, review the grant of a TUE to an Athlete in the International Federation Registered Testing Pool, entered in an International Event as described in 7.1(b), or a National Anti-Doping Organization Registered Testing Pool. In addition to the information to be provided as set forth in Articles 7.1 and 7.2, the WADA TUEC may also seek additional information from the Athlete, including further studies as described in Article 8.10. If a decision granting a TUE is reversed by WADA upon review, the reversal shall not apply retroactively and shall not disqualify the Athlete's results during the period for which the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the Athlete.

10.2 An Athlete in an International Federation Registered Testing Pool, entered in an International Event as described in 7.1(b), or National Anti-Doping Organization Registered Testing Pool may request that WADA review the denial of a TUE by submitting a written request for review to WADA within twenty-one (21) days of the date of the denial. An Athlete submitting such a request for review to WADA shall pay an application fee as established by WADA and shall provide to the WADA TUEC copies of all information that the Athlete submitted to the Anti-Doping Organization in connection with the TUE application. The WADA TUEC will assess the request based on the file that was available to the Anti-Doping Organization that has denied the TUE but may, for the sake of clarification, seek additional information from the Athlete, including further studies as described in Article 8.10. Until the WADA review process has been completed, the original TUE denial remains in effect. If WADA reverses the denial of a TUE, the TUE shall immediately go into effect in accordance with the conditions set forth in the WADA decision.

10.3 Decisions by WADA to affirm or reverse the TUE decisions of an Anti-Doping Organization may be appealed to CAS as provided in Article 13 of the Code.

11.0 Previously Granted Abbreviated Therapeutic Use Exemptions (ATUEs)

11.1 All previously granted ATUEs that have not already expired or been cancelled shall expire on December 31, 2009.