



INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

Annex II - Standards for Granting Therapeutic Use Exemptions

Paris, 1 January 2011

**Extract from the INTERNATIONAL STANDARD FOR THERAPEUTIC USE
EXEMPTIONS, 1 January 2011 of the World Anti-Doping Agency (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- (c) The *Athlete* is advised that the TUE has been withdrawn by the *Anti-Doping Organization*.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 the Court of Arbitration for Sport.

*[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 There may be cases when a TUE has expired or has been withdrawn and the *Prohibited Substance* subject to the TUE is still present in the *Athlete's* body.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.
 - (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 thirty (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 a 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*.

[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.]

- (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 a *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) 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 *National Anti-Doping Organizations* 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*.
- (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, for 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, 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 may be translated into other languages by *Anti-Doping Organizations*, but the English or French text shall remain on the application Form.
- 8.7** The application shall identify the *Athlete's* level of competition (e.g., International Federation's *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 the request(s) was made, the decision(s) of that body, and the decision(s) 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** There are no longer substances or methods on the *Prohibited List* that require a Declaration of Use and therefore it is not necessary to file a Declaration of Use.

10.0 Review of TUE Decisions by WADA

- 10.1** The WADA TUEC may, at any time, review the granting of a TUE to an *Athlete* in the International Federation's *Registered Testing Pool*, entered in an *International Event* as described in 7.1(b), or a *National Anti-Doping Organization's 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's *Registered Testing Pool*, entered in an *International Event* as described in 7.1(b), or *National Anti-Doping Organization's 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 the Court of Arbitration for Sport as provided in Article 13 of the *Code*.

11.0 Previously Granted Abbreviated Therapeutic Use Exemptions

- 11.1** All previously granted Abbreviated Therapeutic Use Exemptions that have not already expired or been cancelled shall expire on December 31 2009.