

ANNEX II

STANDARDS FOR GRANTING THERAPEUTIC USE EXEMPTIONS

Extract from “INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS” of the World Anti-Doping Agency (WADA); in force 1 January 2005

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* contained in the *Prohibited List*. 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*. An exemption will be granted only in strict accordance with the following criteria:

[Comment: This standard applies to all Athletes as defined by and subject to the Code i.e. able-bodied athletes and athletes with disabilities. This Standard will be applied according to an individual's circumstances. For example, an exemption that is appropriate for an athlete with a disability may be inappropriate for other athletes.]

- 4.1 The *Athlete* should submit an application for a **TUE** no less than 21 days before participating in an *Event*.
- 4.2 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.
- 4.3 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.
- 4.4 There is no reasonable therapeutic alternative to the use of the otherwise *Prohibited Substance* or *Prohibited Method*.
- 4.5 The necessity for the use of the otherwise *Prohibited Substance* or *Prohibited Method* cannot be a consequence, wholly or in part, of prior non-therapeutic use of any substance from the *Prohibited List*.
- 4.6 The **TUE** will be cancelled by the granting body, 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 - (c) the *Athlete* is advised that the **TUE** has been withdrawn by the *Anti-Doping Organization*.

[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 finding will consider whether the finding is consistent with expiry or withdrawal of the TUE.]

- 4.7 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 which permit such situations to be addressed.]

5.0. Confidentiality of information

- 5.1 The applicant must provide written consent for the transmission of all information pertaining to the application to members of the TUEC and, as required, other independent medical or scientific experts, or to all necessary staff involved in the management, review or appeal of TUEs.

Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the *Athlete* involved in the *Athlete's* care. The applicant must also provide written consent for the decisions of the TUEC to be distributed to other relevant *Anti-Doping Organizations* under the provisions of the *Code*.

- 5.2 The members of the TUECs and the administration of the *Anti-Doping Organization* involved will conduct all of their activities in strict confidence. All members of a TUEC and all staff involved 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 the TUEC or the WADA TUEC to obtain any health information on his/her behalf, the *Athlete* must 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.

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 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, a majority of the members of the TUEC should not have any official 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 must 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 on its own initiative TUE decisions granted by *Anti-Doping Organizations*. As specified in Article 4.4 of the *Code*, the WADA TUEC, upon request by *Athletes* who have been denied TUEs by an *Anti-Doping Organization* will review such decisions with the power to reverse them.

7.0 *Therapeutic use exemption (TUE) application process*

- 7.1 A TUE will only be considered following the receipt of a completed application form that must include all relevant documents (see Appendix 1 – TUE form). The application process must be dealt with in accordance with the principles of strict medical confidentiality.
- 7.2 The TUE application form(s), as set out in Appendix 1, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.
- 7.3 The TUE application form(s) may be translated into other language(s) by *Anti-Doping Organizations*, but English or French must remain on the application form(s).
- 7.4 An *Athlete* may not apply to more than one *Anti-Doping Organization* for a TUE. The application must identify the *Athlete's* sport and, where appropriate, discipline and specific position or role.
- 7.5 The application must list any previous and/or current requests for permission to use an otherwise *Prohibited Substance* or *Prohibited Method*, the body to whom that request was made, and the decision of that body.
- 7.6 The application must include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application.
- 7.7 Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* will be undertaken at the expense of the applicant or his/her national sport governing body.

- 7.8 The application must 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.
- 7.9 The dose, frequency, route and duration of administration of the otherwise *Prohibited Substance* or *Prohibited Method* in question must be specified.
- 7.10 Decisions of the TUEC, should be completed within 30 days of receipt of all relevant documentation and will be conveyed in writing to the *Athlete* by the relevant *Anti-Doping Organization*. Where a TUE has been granted to an *Athlete* in the *Anti-Doping Organization Registered Testing Pool*, the *Athlete* and WADA will be provided promptly with an approval which includes information pertaining to the duration of the exemption and any conditions associated with the TUE.
- 7.11 (a) Upon receiving a request by an *Athlete* for review, as specified in Article 4.4 of the Code, the WADA TUEC will, as specified in Article 4.4 of the Code, be able to reverse a decision on a TUE granted by an *Anti-Doping Organization*. The *Athlete* shall provide to the WADA TUEC all the information for a TUE as submitted initially to the *Anti-Doping Organization* accompanied by an application fee. Until the review process has been completed, the original decision remains in effect. The process should not take longer than 30 days following receipt of the information by WADA.
- (b) WADA can undertake a review at any time. The WADA TUEC will complete its review within 30 days.
- 7.12 If the decision regarding the granting of a TUE is reversed on review, the reversal shall not apply retroactively and shall not disqualify the *Athlete's* results during the period that the TUE had been granted and shall take effect no later than 14 days following notification of the decision to the *Athlete*.
- 8.0 *Abbreviated therapeutic use exemption (ATUE) application process*
- 8.1 It is acknowledged that some substances included on the *List of Prohibited Substances* are used to treat medical conditions frequently encountered in the *Athlete* population. In such cases, a full application as detailed in section 4 and section 7 is unnecessary. Accordingly an abbreviated process of the TUE is established.
- 8.2 The *Prohibited Substances* or *Prohibited Methods* which may be permitted by this abbreviated process are strictly limited to the following:
- Beta-2 agonists (formoterol, salbutamol, salmeterol and terbutaline) by inhalation, and glucocorticosteroids by non-systemic routes.
- 8.3 To use one of the substances above, the *Athlete* shall provide to the *Anti-Doping Organization* a medical notification justifying the therapeutic necessity. Such medical notification, as contained in Appendix 2, shall describe the diagnosis, name of the drug, dosage, route of administration and duration of the treatment. When applicable any tests undertaken in order to establish the diagnosis should be included (without the actual results or details).

- 8.4 The abbreviated process includes:
- (a) approval for use of *Prohibited Substances* subject to the abbreviated process is effective upon receipt of a complete notification by the *Anti-Doping Organization*. Incomplete notifications must be returned to the applicant;
 - (b) on receipt of a complete notification, the *Anti-Doping Organization* shall promptly advise the *Athlete*. As appropriate, the *Athlete's* IF, NF and NADO shall also be advised. The *Anti-Doping Organization* shall advise WADA only upon receipt of a notification from an *International-level Athlete*;
 - (c) a notification for an ATUE will not be considered for retroactive approval except:
 - if emergency treatment or treatment of an acute medical condition was necessary; or
 - due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a TUEC to receive, an application prior to *Doping Control*.
- 8.5 (a) A review by the TUEC or the WADA TUEC can be initiated at any time during the duration of an ATUE.
- (b) If an *Athlete* requests a review of a subsequent denial of an ATUE, the WADA TUEC will have the ability to request from the *Athlete* additional medical information as deemed necessary, the expenses of which should be met by the *Athlete*.
- 8.6 An ATUE may be cancelled by the TUEC or WADA TUEC at any time. The *Athlete*, his/her IF and all relevant *Anti-Doping Organizations* shall be notified immediately.
- 8.7 The cancellation shall take effect immediately following notification of the decision to the *Athlete*. The *Athlete* will nevertheless be able to apply under section 7 for a TUE.
- 9.0 *Clearing house*
- 9.1 *Anti-Doping Organizations* are required to provide WADA with all TUEs, and all supporting documentation, issued under section 7.
- 9.2 With respect to ATUEs, *Anti-Doping Organizations* shall provide WADA with medical applications submitted by *International-level Athletes* issued under section 8.4
- 9.3 The Clearing house shall guarantee strict confidentiality of all the medical information.