

ANNEX II



THE WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS

1 January 2009

**Extract from the INTERNATIONAL STANDARD FOR THERAPEUTIC USE
EXEMPTIONS, 1 January 2009 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* 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 can apply 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 twenty-one (21) days before he/she needs the approval (for instance 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 analytical 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*, or
- (c) the conditions set forth under 7.13 apply.

[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* concerned. 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 (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 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 Annex 2 – 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 Annex 2, 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. The arguments related to the diagnosis and treatment, as well as duration of validity, should follow the *WADA* "Medical Information to Support the Decisions of TUECs". For asthma, the specific requirement(s) set out in Annex 1 must be fulfilled.
- 7.7 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 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. In case of change, a new application should be submitted.
- 7.10 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*. 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, the *WADA* TUEC will, as specified in Article 4.4 of the *Code*, be able to reverse a decision on a TUE denied 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 thirty (30) days following receipt of all the information by *WADA*.
- (b) *WADA* can, on its own initiative, undertake a review at any time.

7.12 If the decision regarding the granting of 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 that the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the *Athlete*.

7.13 *Use of inhaled Beta-2 Agonists:*

- The *Use* of inhaled formoterol, salbutamol, salmeterol, terbutaline reflects current clinical practice. The *Use* of these substances should be declared on *ADAMS* where reasonably feasible and in accordance with the *Code* as soon as the product is used and must as well be declared on the *Doping Control* form at the time of *Testing*. Failure to declare will be taken into account in the result management process in particular in case of application for a Retroactive TUE.
- *Athletes* using the substances listed above by inhalation must have a medical file justifying this *Use* and meeting the minimum requirements outlined in Annex 1.

Depending upon the category of the *Athlete*, the medical file will be evaluated as follows:

- For all *Athletes* included in an International Federation *Registered Testing Pool* a regular TUE approved before the *Use* of the substance.
- For *Athletes* participating in an *International Event* but who are not included in an International Federation *Registered Testing Pool* either a TUE, or a Retroactive TUE in the case of an *Adverse Analytical Finding*, in accordance with the rule of the International Federation or of the *Major Event Organization*.
- For national-level *Athletes* who are not included in an International Federation *Registered Testing Pool*, whether or not they are part of a national *Registered Testing Pool*, either a TUE, or a Retroactive TUE in the case of an *Adverse Analytical Finding*, in accordance with the rules of the *National Anti-Doping Organization*.
- No Retroactive TUE will be granted if the requirements of Annex 1 are not met meaning that any *Adverse Analytical Finding* reported by the laboratory in these circumstances will result in an anti-doping rule violation.
- Any *Athlete* may apply for a TUE at any time if they wish.
- Any *Athlete* who has applied for a TUE or a Retroactive TUE and who was denied such TUE may not use the substance without the prior granting of a TUE (no Retroactive TUE will be permitted).

8.0 Declaration of *Use* 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. For monitoring purposes, these substances, for which the route of administration is not prohibited, will require a simple declaration of use. These are strictly limited to:

Glucocorticosteroids used by non systemic routes, namely intraarticular, periarticular, peritendinous, epidural intradermal injections and inhaled route.

8.2 For the mentioned substances, the declaration of *Use* should be done through *ADAMS* where reasonably feasible and in accordance with the *Code* by the *Athlete* at the same time as the *Use* starts. This declaration should mention the diagnosis, the name of the substance, the dose undertaken, the name and the contact details of the physician.

In addition, the *Athlete* must declare the *Use* of the substance in question on the *Doping Control* form.

9.0 Clearinghouse

9.1 *Anti-Doping Organizations* are required to provide *WADA* with all TUEs approved for *Athletes* who are part of a national or international *Registered Testing Pool*, and all supporting documentation, in accordance with section 7.

9.2 The declarations of use should be available to *WADA (ADAMS)*.

9.3 The clearinghouse shall guarantee strict confidentiality of all the medical information.

10.0 Transitional Provision

Abbreviated Therapeutic Use Exemptions (ATUEs) delivered prior to December 31 2008, shall remain governed by the 2005 TUE Standard.

These ATUEs shall remain valid after January 1 2009, until the earliest of:

- (a) The date on which they are cancelled by the competent TUEC following review in accordance with art. 8.6 of the 2005 TUE Standard;
- (b) Their expiry date as mentioned on the ATUE;
- (c) December 31 2009.

Annex 1: Minimal requirements for the medical file to be used for the TUE process in the case of asthma and its clinical variants

The file must reflect current best medical practice to include:

- (1) A complete medical history;
- (2) A comprehensive report of the clinical examination with specific focus on the respiratory system;
- (3) A report of spirometry with the measure of the Forced Expiratory Volume in 1 second (FEV1);
- (4) If airway obstruction is present, the spirometry will be repeated after inhalation of a short acting Beta-2 Agonist to demonstrate the reversibility of bronchoconstriction;
- (5) In the absence of reversible airway obstruction, a bronchial provocation test is required to establish the presence of airway hyper-responsiveness;
- (6) Exact name, speciality, address (including telephone, e-mail, fax) of examining physician.