



## **The World Anti-Doping Code**

# **INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS**

## PREAMBLE

The World Anti-Doping Code *International Standard* for Therapeutic Use Exemptions (TUE) is a level 2 mandatory *International Standard* developed as part of the World Anti-Doping Program.

The basis for the development of the *International Standard* for TUE has been a review of various procedures and protocols of International Federations, the IOC, National Anti-Doping Organizations and relevant sections in the revised International Standard for Doping Control (ISDC). A broad WADA expert reference group reviewed, discussed and prepared the document.

Version 1.0 of the *International Standard* for TUE was circulated to *Signatories* and governments for review and comments in November 2002. Version 2.0 was based on the comments and proposals received from *Signatories* and governments. Draft version 2.1 was developed based on the comments received on version 2.0 and integrated some of the principles discussed during the drafting process of the International Standard on the 2004 Prohibited List.

All *Signatories* and governments were consulted and had the opportunity to review and provide comments to version 2.3. Revisions were made based on input from *Signatories* and governments. The *International Standard* for TUE was submitted for approval to the WADA Executive Committee in September 2003.

The *International Standard 3.0* for TUE will come into effect on January 1<sup>st</sup>, 2004.

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# PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS

## 1.0 Introduction and Scope

The purpose of the *International Standard* for TUE is to ensure that the process of granting therapeutic use exemptions is harmonized across sports and countries.

The *Code* permits *Athletes* and their physicians to apply for Therapeutic Use Exemptions i.e. permission to use, for therapeutic purposes, substances or methods contained in the *List of Prohibited Substances or Methods* whose use is otherwise prohibited.

The *International Standard* for TUE includes criteria for granting a TUE, confidentiality of information, the formation of Therapeutic Use Exemptions Committees and the TUE application process.

This standard applies to all *Athletes* as defined by and subject to the *Code* i.e. able-bodied *Athletes* and *Athletes* with disabilities.

The World Anti-Doping Program encompasses all of the elements needed in order to ensure optimal harmonization and best practice in international and national anti-doping programs. The main elements are: the *Code* (Level 1), *International Standards* (Level 2), and Models of Best Practice (Level 3).

In the introduction to the *Code*, the purpose and implementation of the *International Standards* are summarized as follows:

*“International Standards for different technical and operational areas within the anti-doping program will be developed in consultation with the Signatories and governments and approved by WADA. The purpose of the International Standards is harmonization among Anti-Doping Organizations responsible for specific technical and operational parts of the anti-doping programs. Adherence to the International Standards is mandatory for compliance with the Code. The International Standards may be revised from time to time by the WADA Executive Committee after reasonable consultation with the Signatories and governments. Unless provided otherwise in the Code, International Standards and all revisions shall become effective on the date specified in the International Standard or revision. ”*

Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the *International Standard* were performed properly.

Definitions specified in the *Code* are written in italics. Additional definitions specific to the *International Standard* for TUE are underlined.

## 2.0 Code Provisions

The following articles of the *Code* directly address the *International Standard* for TUE:

### **Code Article 4.4 Therapeutic Use.**

WADA shall adopt an *International Standard* for the process of granting therapeutic use exemptions.

Each International Federation shall ensure, for *International-Level Athletes* or any other *Athlete* who is entered in an *International Event*, that a process is in place whereby *Athletes* with documented medical conditions requiring the *Use of a Prohibited Substance* or a *Prohibited Method* may request a therapeutic use exemption. Each *National Anti-Doping Organization* shall ensure, for all *Athletes* within its jurisdiction that are not *International-Level Athletes*, that a process is in place whereby *Athletes* with documented medical conditions requiring the *Use of a Prohibited Substance or a Prohibited Method* may request a therapeutic use exemption. Such requests shall be evaluated in accordance with the *International Standard* on therapeutic use. *International Federations* and *National Anti-Doping Organizations* shall promptly report to WADA the granting of therapeutic use exemptions to any *International-Level Athlete* or national-level *Athlete* that is included in his or her *National Anti-Doping Organization's Registered Testing Pool*.

WADA, on its own initiative, may review the granting of a therapeutic use exemption to any *International-Level Athlete* or national-level *Athlete* that is included in his or her *National Anti-Doping Organization's Registered Testing Pool*. Further, upon the request of any such *Athlete* that has been denied a therapeutic use exemption, WADA may review such denial. If WADA determines that such granting or denial of a therapeutic use exemption did not comply with the *International Standard* for therapeutic use exemptions, WADA may reverse the decision.”

### **Code Article 13.3 Appeals from Decisions Granting or Denying a Therapeutic Use Exemption.**

Decisions by WADA reversing the grant or denial of a therapeutic use exemption may be appealed to CAS by the *Athlete* or the *Anti-Doping Organization* whose decision was reversed. Decisions by *Anti-Doping Organizations* denying therapeutic use exemptions, which are not reversed by WADA, may be appealed by *International-Level Athletes* to CAS and by other *Athletes* to the national level reviewing body described in Article 13.2.2. If the national level reviewing body reverses the decision to deny a therapeutic use exemption, that decision may be appealed to CAS by WADA.”

### **Code Article 14.5 Doping Control Information Clearing House.**

WADA shall act as a central clearing house for *Doping Control Testing* data and results for *International-Level Athletes* and national-level *Athletes* that have been included in their *National Anti-Doping Organization's Registered Testing Pool*. To facilitate coordinated test distribution planning and to avoid unnecessary duplication in *Testing* by the various *Anti-Doping Organizations*, each *Anti-Doping Organization* shall report all *In-Competition* and *Out-of-Competition* tests on such *Athletes* to the WADA clearinghouse as soon as possible after such tests have been conducted.

WADA shall make this information accessible to the *Athlete*, the *Athlete's* National Federation, *National Olympic Committee* or *National Paralympic Committee*, *National Anti-Doping Organization*, *International Federation*, and the *International Olympic Committee* or *International Paralympic Committee*. Private information regarding an *Athlete* shall be maintained by WADA in strict confidence. WADA shall, at least annually, publish statistical reports summarizing such information.

#### **Code Article 15.4 Mutual Recognition.**

Subject to the right to appeal provided in Article 13, the *Testing*, therapeutic use exemptions and hearing results or other final adjudications of any *Signatory* which are consistent with the *Code* and are within that *Signatory's* authority, shall be recognized and respected by all other *Signatories*. *Signatories* may recognize the same actions of other bodies which have not accepted the *Code* if the rules of those bodies are otherwise consistent with the *Code*.”

### **3.0 Terms and definitions**

#### **3.1 Defined terms from the Code**

***Anti-Doping Organization:*** A *Signatory* that is responsible for adopting rules for, initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the *International Olympic Committee*, the *International Paralympic Committee*, other *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, *International Federations*, and *National Anti-Doping Organizations*.

***Athlete:*** For purposes of *Doping Control*, any *Person* who participates in sport at the international level (as defined by each *International Federation*) or national level (as defined by each *National Anti-Doping Organization*) and any additional *Person* who participates in sport at a lower level if designated by the *Person's National Anti-Doping Organization*. For purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code*.

***Code:*** The World Anti-Doping Code.

***Doping Control:*** The process including test distribution planning, *Sample* collection and handling, laboratory analysis, results management, hearings and appeals.

***Event:*** A series of individual Competitions conducted together under one ruling body (e.g., the *Olympic Games*, *FINA World Championships* or *Pan American Games*).

***In-Competition:*** For purposes of differentiating between *In-competition* and *Out-of-Competition Testing*, unless provided otherwise in the rules of an *International Federation* or other relevant *Anti-Doping Organization*, an *In-*

*Competition* test is a test where an *Athlete* is selected for *testing* in connection with a specific *Competition*.

***International-Level Athletes:*** *Athletes* designated by one or more International Federations as being within the *Registered Testing Pool* for an International Federation.

***International Standards:*** A standard adopted by WADA in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly.

***National Anti-Doping Organization:*** The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of test results, and the conduct of hearings, all at the national level. If this designation has not been made by the competent public authority (ies), the entity shall be the country's National Olympic Committee or its designee.

***Out-of-Competition:*** Any *Doping Control* which is not *In-Competition*.

***Prohibited List:*** The List identifying the *Prohibited Substances* and *Prohibited Methods*.

***Prohibited Method:*** Any method so described on the *Prohibited List*.

***Prohibited Substance:*** Any substance so described on the *Prohibited List*.

***Registered Testing Pool:*** The pool of top level *Athletes* established separately by each International Federation and *National Anti-Doping Organization* who are subject to both *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or Organization's test distribution plan.

***Signatories:*** Those entities signing the *Code* and agreeing to comply with the *Code*, including the International Olympic Committee, International Federations, International Paralympic Committee, *National Olympic Committees*, National Paralympic Committees, *Major Event Organizations*, *National Anti-Doping Organizations*, and WADA.

***Testing:*** The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

***WADA:*** The World Anti-Doping Agency

### **3.2 Defined terms from the *International Standard* for TUE**

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

**TUE:** Therapeutic Use Exemption

**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* 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 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 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 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 promptly provided 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 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 name of the drug, dosage, route of administration and duration of the treatment.

The diagnosis and when applicable any tests undertaken in order to establish that 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. The *Anti-Doping Organization* shall advise promptly the *Athlete's* IF, NF and NADO (as appropriate) and *WADA* on receipt of the notification.
- c. A notification for a TUE will not be considered for retroactive approval except:
  - In 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 the TUE.

b. If an *Athlete* requests a review of a denial of TUE, 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** A TUE 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 Clearinghouse**

**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 the abbreviated TUE, *Anti-Doping Organizations* shall provide *WADA* with medical applications submitted by *Athletes* issued under section 8.

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