

THE WORLD ANTI-DOPING CODE

# INTERNATIONAL STANDARD

# THERAPEUTIC USE EXEMPTIONS

January 2009



## International Standard for Therapeutic Use Exemptions

The International Standard for Therapeutic Use Exemptions was first adopted in 2004 and became effective in 2005. The enclosed represents version 3.0 that incorporates revisions to the International Standard for Therapeutic Use Exemptions that were approved by the World Anti-Doping Agency Executive Committee on 10 May and 20 September 2008. The revised International Standard for Therapeutic Use Exemptions is effective as of 1 January 2009.

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## 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 WADA expert reference group reviewed, discussed and prepared the document following wide consultation and consideration of submissions.

The official text of the *International Standard* for Therapeutic Use Exemption shall be maintained by WADA and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

The *International Standard* for TUE (version 3.0) will come into effect on 1 January 2009.

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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 (TUE) 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* has adopted 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. *Athletes* who have been identified as included in their International Federation's *Registered Testing Pool* may only obtain therapeutic use exemptions in accordance with the rules of their International Federation. Each International Federation shall publish a list of those *International Events* for which a therapeutic use exemption from the International Federation is required. Each *National Anti-Doping Organization* shall ensure, for all *Athletes* within its jurisdiction that have not been included in an International Federation *Registered Testing Pool*, 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* for Therapeutic Use Exemptions. International Federations and *National Anti-Doping Organizations* shall promptly report to *WADA* through *ADAMS* the granting of any therapeutic use exemption except as regards national-level *Athletes* who are not included in the *National Anti-Doping Organization's Registered Testing Pool*.

*WADA*, on its own initiative, may review at any time the granting of a therapeutic use exemption to any *International-Level Athlete* or national-level *Athlete* who is included in his or her *National Anti-Doping Organization's Registered Testing Pool*. Further, upon the request of any such *Athlete* who 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.

If, contrary to the requirement of this Article, an International Federation does not have a process in place where *Athletes* may request therapeutic use exemptions, an *International-Level Athlete* may request *WADA* to review the application as if it had been denied.

Presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (Article 2.1), *Use* or *Attempted Use* of a *Prohibited Substance* or a

*Prohibited Method* (Article 2.2), *Possession of Prohibited Substances and Prohibited Methods* (Article 2.6) or *Administration or Attempted Administration of a Prohibited Substance or Prohibited Method* (Article 2.8) consistent with the provisions of an applicable therapeutic use exemption issued pursuant to the *International Standard for Therapeutic Use Exemptions* shall not be considered an anti-doping rule violation.

#### **Code Article 13.4 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 exclusively to *CAS* by the *Athlete* or the *Anti-Doping Organization* whose decision was reversed. Decisions by *Anti-Doping Organizations* other than *WADA* 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*.

When an *Anti-Doping Organization* fails to take action on a properly submitted therapeutic use exemption application within a reasonable time, the *Anti-Doping Organization's* failure to decide may be considered a denial for purposes of the appeal rights provided in this Article.

#### **Code Article 14.5 Doping Control Information Clearinghouse**

*WADA* shall act as a central clearinghouse for *Doping Control Testing* data and results for *International-Level Athletes* and national-level *Athletes* who 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. This information will be made 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*.

To enable it to serve as a clearinghouse for *Doping Control Testing* data, *WADA* has developed a database management tool, *ADAMS*, that reflects emerging data privacy principles. In particular, *WADA* has developed *ADAMS* to be consistent with data privacy statutes and norms applicable to *WADA* and other organizations using *ADAMS*.

Private information regarding an *Athlete*, *Athlete Support Personnel*, or others involved in anti-doping activities shall be maintained by *WADA*,

which is supervised by Canadian privacy authorities, in strict confidence and in accordance with the *International Standard* for the protection of privacy. WADA shall, at least annually, publish statistical reports summarizing the information that it receives, ensuring at all times that the privacy of *Athletes* is fully respected and make itself available for discussions with national and regional data privacy authorities.

## **Code Article 15.4 Mutual Recognition**

15.4.1 Subject to the right to appeal provided in Article 13, *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*.

*[Comment to Article 15.4.1: There has in the past been some confusion in the interpretation of this Article with regard to therapeutic use exemptions. Unless provided otherwise by the rules of an International Federation or an agreement with an International Federation, National Anti-Doping Organizations do not have "authority" to grant therapeutic use exemptions to International-Level Athletes.]*

15.4.2 *Signatories* shall 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*.

*[Comment to Article 15.4.2: Where the decision of a body that has not accepted the Code is in some respects Code compliant and in other respects not Code compliant, Signatories should attempt to apply the decision in harmony with the principles of the Code. For example, if in a process consistent with the Code a non-Signatory has found an Athlete to have committed an anti-doping rule violation on account of the presence of a Prohibited Substance in his body but the period of Ineligibility applied is shorter than the period provided for in the Code, then all Signatories should recognize the finding of an anti-doping rule violation and the Athlete's National Anti-Doping Organization should conduct a hearing consistent with Article 8 to determine whether the longer period of Ineligibility provided in the Code should be imposed.]*

## **3.0 Terms and Definitions**

### **3.1 Defined Terms from the Code**

**ADAMS:** The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their anti-doping operations in conjunction with data protection legislation.

**Adverse Analytical Finding:** A report from a laboratory or other WADA-approved entity that, consistent with the *International Standard* for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including

elevated quantities of endogenous substances) or evidence of the *Use of a Prohibited Method*.

**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:** Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization*, including but not limited to those *Persons* in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and therapeutic use exemptions, must be applied to international- and national-level competitors. Some *National Anti-Doping Organizations* may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national caliber competitors. *National Anti-Doping Organizations* are not required, however, to apply all aspects of the *Code* to such *Persons*. Specific national rules may be established for *Doping Control* for non-international-level or non-national-level competitors without being in conflict with the *Code*. Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempted Administration*) and 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* is an *Athlete*.

*[Comment: This definition makes it clear that all international- and national-caliber Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes must be included in a National Anti-Doping Organization's Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-caliber Athletes to competitors at lower levels of competition. Competitors at all levels of competition should receive the benefit of anti-doping information and education.]*

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

**Competition:** A single race, match, game or singular athletic contest. For example, a basketball game or the finals of the Olympic 100-meter race in

athletics. For stage races and other athletic contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

***Doping Control:*** All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, therapeutic use exemptions, results management and hearings.

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

***Event Period:*** The time between the beginning and end of an *Event*, as established by the ruling body of the *Event*.

***In-Competition:*** Unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, "*In-Competition*" means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

***International Event:*** An *Event* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization*, or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event*.

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

***International Standard:*** 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. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard*.

**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. This includes an entity which may be designated by multiple countries to serve as regional *Anti-Doping Organization* for such countries. 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.

**National Event:** A sport *Event* involving international- or national-level *Athletes* that is not an *International Event*.

**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 *National Anti-Doping Organization's* test distribution plan. Each International Federation shall publish a list which identifies those *Athletes* included in its *Registered Testing Pool* either by name or by clearly defined, specific criteria.

**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.

**Use:** The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

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

### 3.2 Defined Terms from the *International Standard for TUEs*

**Retroactive TUE:** Therapeutic use exemption approved by a Therapeutic Use Exemption Committee based on a documented medical file after a laboratory has reported an *Adverse Analytical Finding* (AAF).

**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 approved by a Therapeutic Use Exemption Committee based on a documented medical file before the *Use* of the substance in sports.

**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 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** The *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 Organisations* 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:

- (i) The date on which they are cancelled by the competent TUEC following review in accordance with art. 8.6 of the 2005 TUE Standard ;
- (ii) Their expiry date as mentioned on the ATUE ;
- (iii) 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.

## ANNEX 2:

### Therapeutic use exemption application form

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#### Identification of Anti-Doping Organization

(Logo or Name of the ADO)

Application form

# Therapeutic Use Exemptions TUE

Please complete all sections in capital letters or typing

## 1. Athlete Information

Surname: ..... Given Names: .....

Female  Male  Date of Birth(d/m/y).....

Address: .....

City: ..... Country: ..... Postcode: .....

Tel.:..... E-mail:

.....

*(with international code)*

Sport:..... Discipline/Position: .....

International or National Sport Organization:

.....

If athlete with disability, indicate disability: .....

**2. Medical information**

**Diagnosis with sufficient medical information** (see note 1):

.....

.....

.....

.....

**If a permitted medication can be used to treat the medical condition, provide clinical justification for the requested use of the prohibited medication**

.....

.....

.....

*3. Medication details*

Prohibited substance(s): <i>Generic name</i>	Dose	Route	Frequency
1.			
2.			
3.			

<b>Intended duration of treatment:</b> <i>(Please tick appropriate box)</i>	once only <input type="checkbox"/>	emergency <input type="checkbox"/>
	or duration (week/month): .....	

<p><b>Have you submitted any previous TUE application:</b>    yes <input type="checkbox"/>    no <input type="checkbox"/></p> <p>For which substance?</p> <p>.....</p> <p>To whom?.....When?.....</p> <p>Decision:    Approved <input type="checkbox"/>                      Not approved <input type="checkbox"/></p>
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#### 4. Medical practitioner's declaration

**I certify that the above-mentioned treatment is medically appropriate and that the use of alternative medication not on the prohibited list would be unsatisfactory for this condition.**

Name: .....

Medical specialty: .....

Address: .....

Tel.: .....

Fax: .....

E-mail: .....

Signature of Medical Practitioner: ..... Date: .....

#### 5. Athlete's declaration

I, ..... certify that the information under 1. is accurate and that I am requesting approval to use a Substance or Method from the WADA Prohibited List. I authorize the release of personal medical information to the Anti-Doping Organization (ADO) as well as to WADA staff, to the WADA TUEC (Therapeutic Use Exemption Committee) and to other ADO under the provisions of the Code. I understand that if I ever wish to revoke the right of these organizations to obtain my health information on my behalf, I must notify my medical practitioner and my ADO in writing of that fact.

**Athlete's signature:** ..... **Date:** .....

**Parent's/Guardian's signature:** ..... **Date:** .....

(if the athlete is a minor or has a disability preventing him/her to sign this form, a parent or guardian shall sign together with or on behalf of the athlete)

6. Note:

<b>Note 1</b>	<b>Diagnosis</b> <i>Evidence confirming the diagnosis must be attached and forwarded with this application. The medical evidence should include a comprehensive medical history and the results of all relevant examinations, laboratory investigations and imaging studies. Copies of the original reports or letters should be included when possible. Evidence should be as objective as possible in the clinical circumstances and in the case of non-demonstrable conditions independent supporting medical opinion will assist this application.</i>
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**Incomplete Applications will be returned and will need to be resubmitted.**

**Please submit the completed form to the ADO and keep a copy for your records.**