

THE WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD

THERAPEUTIC USE EXEMPTIONS

January 2010

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 4.0 that incorporates revisions to the International Standard for Therapeutic Use Exemptions that were approved by the World Anti-Doping Agency Executive Committee on 30 October 2009. The revised International Standard for Therapeutic Use Exemptions is effective as of 1 January 2010.

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World Anti-Doping Agency
Stock Exchange Tower
800 Place Victoria (Suite 1700)
PO Box 120
Montreal, Quebec,
Canada H4Z 1B7

URL: www.wada-ama.org

Tel: + 1 514 904 9232

Fax: + 1 514 904 8650

E-mail: info@wada-ama.org

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 official text of the *International Standard* for TUE 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 4.0) will come into effect on 1 January 2010.

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PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS

1.0 Introduction and Scope

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

The *Code* permits *Athletes* 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* where *Use* would otherwise be 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.

[Comment: 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.]

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 in the 2009 *Code* are directly relevant to 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, shall 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 shall 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*.

Possession: The actual, physical *Possession*, or the constructive *Possession* (which shall be found only if the *Person* has exclusive control over the *Prohibited Substance* or *Prohibited Method* or the premises in which a *Prohibited Substance* or *Prohibited Method* exists); provided, however, that if the *Person* does not have exclusive control over the *Prohibited Substance* or *Prohibited Method* or the premises in which a *Prohibited Substance* or *Prohibited Method* exists, constructive *Possession* shall only be found if the *Person* knew about the presence of the *Prohibited Substance* or *Prohibited Method* and intended to exercise control over it. Provided, however, there shall be no anti-doping rule violation based solely on *Possession* if, prior to receiving notification of any kind that the *Person* has committed an anti-doping rule violation, the *Person* has taken concrete action demonstrating that the *Person* never intended to have *Possession* and has renounced *Possession* by explicitly declaring it to an Anti-Doping Organization. Notwithstanding anything to the contrary in this definition, the purchase (including by any electronic or other means) of a *Prohibited Substance* or *Prohibited Method* constitutes *Possession* by the *Person* who makes the purchase.

[Comment to Possession: Under this definition, steroids found in an Athlete's car would constitute a violation unless the Athlete establishes that someone else used the car; in that event, the Anti-Doping Organization shall establish that, even though the Athlete did not have exclusive control over the car, the Athlete knew about the steroids and intended to have control over the steroids. Similarly, in the example of steroids found in a home medicine cabinet under the joint control of an Athlete and spouse, the Anti-Doping Organization shall establish that the Athlete knew the steroids were in the cabinet and that the Athlete intended to exercise control over the steroids.]

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 TUE*

Personal Information: As defined in the *International Standard for the Protection of Privacy and Personal Information*, information, including without limitation sensitive Personal Information, relating to an identified or identifiable *Participant* or relating to other *Persons* whose information is processed solely in the context of an Anti-Doping Organization's anti-doping activities.

[*Comment: It is understood that Personal Information includes, but is not limited to, information relating to an Athlete's contact details and sporting affiliations, Whereabouts, designated therapeutic use exemptions (if any), anti-doping test results, and results management (including disciplinary hearings, appeals and sanctions). Personal Information also includes personal details and contact information relating to other Persons, such as medical professionals and other Persons working with, treating or assisting an Athlete in the context of anti-doping activities.*]

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 and obtained before *Use* or *Possession* of, a substance or method that would otherwise be prohibited by the *Code*.

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*. An application for a TUE will be reviewed by a Therapeutic Use Exemption Committee (TUEC). The TUEC will be appointed by an *Anti-Doping Organization*.

4.1 A TUE will be granted only in strict accordance with the following criteria:

- a. The *Athlete* would experience a significant impairment to health if the *Prohibited Substance* or *Prohibited Method* were to be withheld in the course of treating an acute or chronic medical condition.
- b. The Therapeutic Use of the *Prohibited Substance* or *Prohibited Method* would produce no additional enhancement of performance other than that which might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition. The *Use* of any *Prohibited Substance* or *Prohibited Method* to increase "low-normal" levels of any endogenous hormone is not considered an acceptable Therapeutic intervention.
- c. There is no reasonable Therapeutic alternative to the *Use* of the otherwise *Prohibited Substance* or *Prohibited Method*.
- d. The necessity for the *Use* of the otherwise *Prohibited Substance* or *Prohibited Method* cannot be a consequence, wholly or in part, of the prior *Use*, without a TUE, of a substance or method which was prohibited at the time of *Use*.

4.2 The TUE will be cancelled, if:

- a. The *Athlete* does not promptly comply with any requirements or conditions imposed by the *Anti-Doping Organization* granting the exemption.
- b. The term for which the TUE was granted has expired.
- c. The *Athlete* is advised that the TUE has been withdrawn by the *Anti-Doping Organization*.
- d. A decision granting a TUE has been reversed by WADA or CAS.

[Comment: Each TUE will have a specified duration as decided upon by the TUEC. There may be cases when a TUE has expired or has been withdrawn and the Prohibited Substance subject to the TUE is still present in the Athlete's body. In such cases, the Anti-Doping Organization conducting the initial review of an Adverse Analytical Finding will consider whether the finding is consistent with expiry or withdrawal of the TUE.]

4.3 An application for a TUE will not be considered for retroactive approval except in cases where:

- a. Emergency treatment or treatment of an acute medical condition was necessary, 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 that permit such situations to be addressed.]

5.0 Confidentiality of Information

5.1 The collection, storage, processing, disclosure and retention of Personal Information in the TUE process by *Anti-Doping Organizations* and *WADA* shall comply with the *International Standard for the Protection of Privacy and Personal Information*.

5.2 An *Athlete* applying for a TUE shall provide written consent for the transmission of all information pertaining to the application to members of all TUECs with authority under the *Code* to review the file and, as required, other independent medical or scientific experts, and to all necessary staff involved in the management, review or appeal of TUEs, and *WADA*. The applicant shall also provide written consent for the decision of the TUEC to be distributed to other relevant *Anti-Doping Organizations* and National Federations under the provisions of the *Code*.

[Comment to 5.2: Prior to collecting Personal Information or obtaining consent from an Athlete, the Anti-Doping Organization shall communicate to the Athlete the information set forth in Article 7.1 of the International Standard for the Protection of Privacy and Personal Information.]

Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the *Athlete* concerned.

5.3 The members of the TUECs, independent experts and the staff of the *Anti-Doping Organization* involved, will conduct all of their activities in strict confidence and will sign confidentiality agreements. In particular they will keep the following information confidential:

- a. All medical information and data provided by the *Athlete* and physician(s) involved in the *Athlete's* care.
- b. All details of the application including the name of the physician(s) involved in the process.

Should the *Athlete* wish to revoke the right of any TUEC to obtain any health information on his/her behalf, the *Athlete* shall notify his/her medical practitioner in writing of the fact. As a consequence of such a decision, the *Athlete* will not receive approval for a TUE or renewal of an existing TUE.

5.4 *Anti-Doping Organizations* shall ensure that Personal Information obtained in the TUE process is retained for a period of eight (8) years, and thereafter only for as long as necessary to fulfill their obligations under the *Code* or where otherwise required by applicable law, regulation or compulsory legal process.

6.0 Therapeutic Use Exemption Committees (TUECs)

TUECs shall be constituted and act in accordance with the following guidelines:

6.1 TUECs should include at least three (3) physicians with experience in the care and treatment of *Athletes* and a sound knowledge of clinical, sports and exercise medicine. In order to ensure a level of independence of decisions, the majority of the members of any TUEC should be free of conflicts of interest or political responsibility in the *Anti-Doping Organization*. All members of a TUEC will sign a conflict of interest agreement. In applications involving *Athletes* with disabilities, at least one TUEC member shall possess specific experience with the care and treatment of *Athletes* with disabilities.

6.2 TUECs may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.

6.3 The *WADA TUEC* shall be composed following the criteria set out in Article 6.1. The *WADA TUEC* is established to review the granting or denial of TUEs for *International-Level Athletes*, *Athletes* entered in an International event as described under 7.1(b), or *Athletes* in their *National Anti-Doping Organization's Registered Testing Pool* as set forth in Article 4.4 of the *Code*. In normal circumstances, the *WADA TUEC* shall render a decision within 30 days of receipt of all requested information.

7.0 Responsibilities of International Federations and National Anti-Doping Organizations

7.1 Each International Federation shall:

- a. Establish a TUEC as provided in Article 6.
- b. Publish a list of *International Events* for which a TUE granted pursuant to the International Federation's rules is required.
- c. Establish and publish a TUE process whereby any *Athlete* who is in the International Federation's *Registered Testing Pool* or who is entered in an *International Event* described in Article 7.1(b) may request a TUE for a documented medical condition requiring the *Use of a Prohibited Substance* or a *Prohibited Method*. Such TUE process shall comply with Article 4.4 of the *Code*, this *International Standard* and the *International Standard for the Protection of Privacy and Personal Information*.
- d. Publish any rule pursuant to which the International Federation will accept TUEs granted by other *Anti-Doping Organizations*.
- e. Promptly report to *WADA*, through *ADAMS*, the granting of all TUEs, including the approved substance or method, dosage, frequency and route

of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.

- f. Promptly report the granting of a TUE to the relevant *National Anti-Doping Organization* and National Federation.
- g. At WADA's request, promptly provide its entire file on any TUE which has been denied.

7.2 Each *National Anti-Doping Organization* shall:

- a. Establish a TUEC as provided in Article 6.
- b. Identify and publish those categories of *Athletes* within its jurisdiction who are required to obtain a TUE before *Using a Prohibited Substance* or a *Prohibited Method*. At a minimum, this shall include all *Athletes* in the *National Anti-Doping Organization's Registered Testing Pool* and other national-level *Athletes* as defined by the *National Anti-Doping Organization*.
- c. Establish and publish a TUE process whereby any *Athlete* who is in the *National Anti-Doping Organization's Registered Testing Pool* or who is described in 7.2(b) may request a TUE for a documented medical condition requiring the *Use of a Prohibited Substance* or a *Prohibited Method*. Such TUE process shall comply with Article 4.4 of the *Code*, this *International Standard* and the *International Standard for the Protection of Privacy and Personal Information*.

[*Comment to 7.2(b): National Anti-Doping Organizations will not grant TUEs to Athletes in an International Federation's Registered Testing Pool except in those instances where the International Federation's rules recognize or give authority to National Anti-Doping Organizations to grant TUEs to such Athletes.*]

- d. Promptly report to WADA, through ADAMS, the granting of a TUE to any *Athlete* in its *Registered Testing Pool*, and if applicable, to an *Athlete* in an International Federation's *Registered Testing Pool* or entered in an *International Event* described in Article 7.1(b), including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.
- e. At WADA's request, promptly provide its entire file on any TUE that has been denied.
- f. Promptly report the granting of a TUE to the relevant National Federation and International Federation where the rules of the International Federation authorize NADO to grant TUEs to *International-Level Athletes*.
- g. Recognize TUEs granted by International Federations to *Athletes* in the International Federation's *Registered Testing Pool* or entered in an *International Event* as described under 7.1(b).

[As used in this Article 7, the term "publish" means: An *Anti-Doping Organization* shall publish information by providing the information in a conspicuous place on its website and by sending the information to each National Federation which is subject to its rules.]

8.0 TUE Application Process

8.1 Unless the rules of their International Federation provide otherwise, the following *Athletes* shall obtain a TUE from their International Federation:

- a. *Athletes* in the International Federation's *Registered Testing Pool*; and
- b. *Athletes* participating in an *International Event* for which a TUE granted pursuant to the International Federation's rules is required.

8.2 *Athletes* not identified in Article 8.1 shall obtain a TUE from their *National Anti-Doping Organization*.

[Comment to 8.1 and 8.2: Unless the rules of an International Federation provide otherwise, an Athlete who already has a TUE from a National Anti-Doping Organization, but later becomes a member of the International Federation's Registered Testing Pool or seeks to participate in an International Event which the International Federation has identified as requiring an International Federation TUE, shall obtain a new TUE from the International Federation.]

The phrase "unless the rules of an International Federation provide otherwise" takes into account the fact that some International Federations, through their rules, are willing to recognize TUEs granted by National Anti-Doping Organizations and do not require a new TUE application at the International Federation level. Where such rules are in place, the Athlete should obtain a TUE from the Athlete's National Anti-Doping Organization.]

8.3 The *Athlete* should submit an application for a TUE no less than thirty (30) days before he/she needs the approval (for instance, an *Event*).

8.4 A TUE will only be considered following the receipt of a completed application form that shall include all relevant documents (see Annex 1 - TUE form). The application process shall be dealt with in accordance with the principles of strict medical confidentiality.

8.5 The TUE application form(s), as set out in Annex 1, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.

8.6 The TUE application form(s) may be translated into other language(s) by *Anti-Doping Organizations*, but the English or French text shall remain on the application form(s).

8.7 The application shall identify the *Athlete's* level of competition (e.g., International Federation *Registered Testing Pool*), sport and, where appropriate, discipline and specific position or role.

8.8 The application shall list any previous and/or current TUE requests, the body to whom that request was made, the decision of that body, and the decisions of any other body on review or appeal.

8.9 The application shall include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis and treatment, as well as duration of validity, should be guided by the WADA “Medical Information to Support the Decisions of TUECs”.

8.10 Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* before approval will be undertaken at the expense of the applicant.

[Comment to 8.10: In some cases, the applicant’s National Federation may elect to pay this expense.]

8.11 The application shall include a statement by an appropriately qualified physician attesting to the necessity of the otherwise *Prohibited Substance* or *Prohibited Method* in the treatment of the *Athlete* and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.

8.12 The substance or method, dose, frequency, route and duration of administration of the otherwise *Prohibited Substance* or *Prohibited Method* in question shall be specified. In case of change, a new application shall be submitted.

8.13 In normal circumstances, decisions of the TUEC should be completed within thirty (30) days of receipt of all relevant documentation and will be conveyed in writing to the *Athlete* by the relevant *Anti-Doping Organization*. In case of a TUE application made in a reasonable time limit prior to an *Event* the TUEC should use its best endeavors to complete the TUE process before the start of the *Event*.

[Comment to 8.13: When an Anti-Doping Organization has failed to act on an Athlete’s TUE application within a reasonable time, the Athlete may seek review by WADA as if the application was denied.]

9.0 Declaration of Use

9.1 The *Prohibited List* identifies certain substances and methods that are not prohibited but for which an *Athlete* is required to file a declaration of *Use*. An *Athlete* should satisfy this requirement by declaring the *Use* on a *Doping Control Form* and when available by filing a declaration of *Use* through *ADAMS*.

9.2 An *Athlete’s* failure to declare *Use* on a *Doping Control Form* and through *ADAMS* when available, as stated in Article 9.1, shall not be an anti-doping rule violation.

*[Comment to 9.2: The rules of Anti-Doping Organizations with jurisdiction over an Athlete may impose consequences **other than** an anti-doping rule violation for a failure to declare.]*

10.0 Review of TUE Decisions by WADA

10.1 The *WADA TUEC* may, at any time, review the grant of a TUE to an *Athlete* in the *International Federation Registered Testing Pool*, entered in an *International Event* as described in 7.1(b), or a *National Anti-Doping Organization Registered Testing Pool*. In addition to the information to be provided as set forth in Articles 7.1 and 7.2, the *WADA TUEC* may also seek additional information from the *Athlete*, including further studies as described in Article 8.10. If a decision granting a TUE is reversed by *WADA* upon review, the reversal shall not apply retroactively and shall not disqualify the *Athlete’s* results during the period for which

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

10.2 An *Athlete* in an International Federation *Registered Testing Pool*, entered in an *International Event* as described in 7.1(b), or *National Anti-Doping Organization Registered Testing Pool* may request that *WADA* review the denial of a TUE by submitting a written request for review to *WADA* within twenty-one (21) days of the date of the denial. An *Athlete* submitting such a request for review to *WADA* shall pay an application fee as established by *WADA* and shall provide to the *WADA TUEC* copies of all information that the *Athlete* submitted to the *Anti-Doping Organization* in connection with the TUE application. The *WADA TUEC* will assess the request based on the file that was available to the *Anti-Doping Organization* that has denied the TUE but may, for the sake of clarification, seek additional information from the *Athlete*, including further studies as described in Article 8.10. Until the *WADA* review process has been completed, the original TUE denial remains in effect. If *WADA* reverses the denial of a TUE, the TUE shall immediately go into effect in accordance with the conditions set forth in the *WADA* decision.

10.3 Decisions by *WADA* to affirm or reverse the TUE decisions of an *Anti-Doping Organization* may be appealed to *CAS* as provided in Article 13 of the *Code*.

11.0 Previously Granted Abbreviated Therapeutic Use Exemptions (ATUEs)

11.1 All previously granted ATUEs that have not already expired or been cancelled shall expire on December 31, 2009.

ANNEX 1:

Therapeutic use exemption application form

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: _____

Please mark the appropriate box:

I am part of an International Federation Registered Testing Pool

I am part of a National Anti-Doping Organization Testing Pool

I am participating in an International Federation event for which a TUE granted pursuant to the International Federation's rules is required¹ - Name of the competition: _____

None of the above

If athlete with disability, indicate disability: _____

¹ Refer to your International Federation for the list of designated events

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): <u>Generic name</u>	Dose	Route	Frequency
1.			
2.			
3.			

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

Have you submitted any previous TUE application: **yes** **no**

For which substance?

To whom? _____ When? _____

Decision: Approved Not approved

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 authorized staff, to the WADA TUEC (Therapeutic Use Exemption Committee) and to other ADO TUECs and authorized staff that may have a right to this information under the provisions of the Code.

I understand that my information will only be used for evaluating my TUE request and in the context of possible anti-doping violation investigations and procedures. I understand that if I ever wish to (1) obtain more information about the use of my information; (2) exercise my right of access and correction or (3) revoke the right of these organizations to obtain my health information, I must notify my medical practitioner and my ADO in writing of that fact. I understand and agree that it may be necessary for TUE-related information submitted prior to revoking my consent to be retained for the sole purpose of establishing a possible anti-doping rule violation, where this is required by the Code.

I understand that if I believe that my personal information is not used in conformity with this consent and the International Standard for the Protection of Privacy and Personal Information I can file a complaint to WADA or CAS.

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:

Note 1	Diagnosis <i>Evidence confirming the diagnosis shall 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.