

WORLD ANTI-DOPING CODE
INTERNATIONAL
STANDARD



THERAPEUTIC USE EXEMPTIONS

JANUARY 2016



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International Standard for Therapeutic Use Exemptions

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

The International Standard for Therapeutic Use Exemptions was first adopted in 2004 and came into effect 1 January 2005. Further revisions were made in 2009, 2010, 2011 and 2015. The enclosed ISTUE incorporates revisions approved by the WADA Executive Committee on 18 November 2015. It will come into effect on 1 January 2016.

The official text of the International Standard for Therapeutic Use Exemptions 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.

Published by:

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PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS

1.0 Introduction and Scope

The International Standard for Therapeutic Use Exemptions is a mandatory *International Standard* developed as part of the World Anti-Doping Program.

The purpose of the International Standard for Therapeutic Use Exemptions is to establish (a) the conditions that must be satisfied in order for a Therapeutic Use Exemption (or *TUE*) to be granted, permitting the presence of a *Prohibited Substance* in an *Athlete's Sample* or the *Athlete's Use* or *Attempted Use*, *Possession* and/or *Administration* or *Attempted Administration* of a *Prohibited Substance* or *Prohibited Method* for therapeutic reasons; (b) the responsibilities imposed on *Anti-Doping Organizations* in making and communicating *TUE* decisions; (c) the process for an *Athlete* to apply for a *TUE*; (d) the process for an *Athlete* to get a *TUE* granted by one *Anti-Doping Organization* recognized by another *Anti-Doping Organization*; (e) the process for *WADA* to review *TUE* decisions; and (f) the strict confidentiality provisions that apply to the *TUE* process.

Terms used in this *International Standard* that are defined terms from the *Code* are written in italics. Terms that are defined in this *International Standard* are underlined.

2.0 Code Provisions

The following articles in the 2015 *Code* are directly relevant to the International Standard for Therapeutic Use Exemptions:

Code Article 4.4 Therapeutic Use Exemptions ("TUEs").

4.4.1 The presence of a *Prohibited Substance* or its *Metabolites* or *Markers*, and/or the *Use* or *Attempted Use*, *Possession* or *Administration* or *Attempted Administration* of a *Prohibited Substance* or *Prohibited Method* shall not be considered an anti-doping rule violation if it is consistent with the provisions of a *TUE* granted in accordance with the International Standard for Therapeutic Use Exemptions.

4.4.2 An *Athlete* who is not an *International-Level Athlete* should apply to his or her *National Anti-Doping Organization* for a *TUE*. If the *National Anti-Doping Organization* denies the application, the *Athlete* may appeal exclusively to the national-level appeal body described in Articles 13.2.2 and 13.2.3.

4.4.3 An *Athlete* who is an *International-Level Athlete* should apply to his or her International Federation.

4.4.3.1 Where the *Athlete* already has a *TUE* granted by his or her *National Anti-Doping Organization* for the substance or method in question, if that *TUE* meets the criteria set out in the International Standard for Therapeutic Use Exemptions, then the International Federation must recognize it. If the International Federation considers that the *TUE* does not meet those criteria and so refuses to recognize it, it must notify the *Athlete* and his or her *National Anti-Doping Organization* promptly, with reasons. The *Athlete* or the *National Anti-Doping Organization* shall have 21 days from such notification to refer the matter to *WADA* for review. If the matter is referred to *WADA* for review, the *TUE* granted by the *National Anti-Doping Organization* remains valid for national-level *Competition* and *Out-of-Competition Testing* (but is not valid for international-level *Competition*) pending *WADA's* decision. If the matter is not referred to *WADA* for review, the *TUE* becomes invalid for any purpose when the 21-day review deadline expires.

4.4.3.2 If the *Athlete* does not already have a *TUE* granted by his or her *National Anti-Doping Organization* for the substance or method in question, the *Athlete* must apply directly to his or her International Federation for a *TUE* as soon as the need arises. If the International Federation (or the *National Anti-Doping Organization*, where it has agreed to consider the application on behalf of the International Federation) denies the *Athlete's* application, it must notify the *Athlete* promptly, with reasons. If the International Federation grants the *Athlete's* application, it must notify not only the *Athlete* but also his or her *National Anti-Doping Organization*, and if the *National Anti-Doping Organization* considers that the *TUE* does not meet the criteria set out in the International Standard for Therapeutic Use Exemptions, it has 21 days from such notification to refer the matter to *WADA* for review. If the *National Anti-Doping Organization* refers the matter to *WADA* for review, the *TUE* granted by the International Federation remains valid for international-level *Competition* and *Out-of-Competition Testing* (but is not valid for national-level *Competition*) pending *WADA's* decision. If the *National Anti-Doping Organization* does not refer the matter to *WADA* for review, the *TUE* granted by the International Federation becomes valid for national-level *Competition* as well when the 21-day review deadline expires.

[Comment to Article 4.4.3: If the International Federation refuses to recognize a TUE granted by a National Anti-Doping Organization only because medical records

or other information are missing that are needed to demonstrate satisfaction with the criteria in the International Standard for Therapeutic Use Exemptions, the matter should not be referred to WADA. Instead, the file should be completed and re-submitted to the International Federation.

If an International Federation chooses to test an Athlete who is not an International-Level Athlete, it must recognize a TUE granted to that Athlete by his or her National Anti-Doping Organization.]

4.4.4 A *Major Event Organization* may require *Athletes* to apply to it for a *TUE* if they wish to *Use a Prohibited Substance* or a *Prohibited Method* in connection with the *Event*. In that case:

4.4.4.1 The *Major Event Organization* must ensure a process is available for an *Athlete* to apply for a *TUE* if he or she does not already have one. If the *TUE* is granted, it is effective for its *Event* only.

4.4.4.2 Where the *Athlete* already has a *TUE* granted by his or her *National Anti-Doping Organization* or International Federation, if that *TUE* meets the criteria set out in the International Standard for Therapeutic Use Exemptions, the *Major Event Organization* must recognize it. If the *Major Event Organization* decides the *TUE* does not meet those criteria and so refuses to recognize it, it must notify the *Athlete* promptly, explaining its reasons.

4.4.4.3 A decision by a *Major Event Organization* not to recognize or not to grant a *TUE* may be appealed by the *Athlete* exclusively to an independent body established or appointed by the *Major Event Organization* for that purpose. If the *Athlete* does not appeal (or the appeal is unsuccessful), he or she may not *Use* the substance or method in question in connection with the *Event*, but any *TUE* granted by his or her *National Anti-Doping Organization* or International Federation for that substance or method remains valid outside of that *Event*.

[Comment to Article 4.4.4.3: For example, the CAS Ad Hoc Division or a similar body may act as the independent appeal body for particular Events, or WADA may agree to perform that function. If neither CAS nor WADA are performing that function, WADA retains the right (but not the obligation) to review the TUE decisions made in connection with the Event at any time, in accordance with Article 4.4.6.]

4.4.5 If an *Anti-Doping Organization* chooses to collect a *Sample* from a *Person* who is not an *International-Level* or *National-Level Athlete*, and that *Person* is *Using a Prohibited Substance* or *Prohibited Method* for therapeutic reasons, the *Anti-Doping Organization* may permit him or her to apply for a retroactive *TUE*.

4.4.6 WADA must review an International Federation's decision not to recognize a TUE granted by the *National Anti-Doping Organization* that is referred to it by the *Athlete* or the *Athlete's National Anti-Doping Organization*. In addition, WADA must review an International Federation's decision to grant a TUE that is referred to it by the *Athlete's National Anti-Doping Organization*. WADA may review any other TUE decisions at any time, whether upon request by those affected or on its own initiative. If the TUE decision being reviewed meets the criteria set out in the International Standard for Therapeutic Use Exemptions, WADA will not interfere with it. If the TUE decision does not meet those criteria, WADA will reverse it.

[Comment to Article 4.4.6: WADA shall be entitled to charge a fee to cover the costs of (a) any review it is required to conduct in accordance with Article 4.4.6; and (b) any review it chooses to conduct, where the decision being reviewed is reversed.]

4.4.7 Any TUE decision by an International Federation (or by a *National Anti-Doping Organization* where it has agreed to consider the application on behalf of an International Federation) that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon review, may be appealed by the *Athlete* and/or the *Athlete's National Anti-Doping Organization*, exclusively to CAS.

[Comment to Article 4.4.7: In such cases, the decision being appealed is the International Federation's TUE decision, not WADA's decision not to review the TUE decision or (having reviewed it) not to reverse the TUE decision. However, the time to appeal the TUE decision does not begin to run until the date that WADA communicates its decision. In any event, whether the decision has been reviewed by WADA or not, WADA shall be given notice of the appeal so that it may participate if it sees fit.]

4.4.8 A decision by WADA to reverse a TUE decision may be appealed by the *Athlete*, the *National Anti-Doping Organization* and/or the International Federation affected, exclusively to CAS.

4.4.9 A failure to take action within a reasonable time on a properly submitted application for grant/recognition of a TUE or for review of a TUE decision shall be considered a denial of the application.

Code Article 13.4 Appeals relating to TUEs

TUE decisions may be appealed exclusively as provided in Article 4.4.

3.0 Definitions and Interpretation

3.1 Defined terms from the 2015 *Code* that are used in the International Standard for Therapeutic Use Exemptions:

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.

Administration: Providing, supplying, supervising, facilitating, or otherwise participating in the *Use* or *Attempted Use* by another *Person* of a *Prohibited Substance* or *Prohibited Method*. However, this definition shall not include the actions of bona fide medical personnel involving a *Prohibited Substance* or *Prohibited Method* used for genuine and legal therapeutic purposes or other acceptable justification and shall not include actions involving *Prohibited Substances* which are not prohibited in *Out-of-Competition Testing* unless the circumstances as a whole demonstrate that such *Prohibited Substances* are not intended for genuine and legal therapeutic purposes or are intended to enhance sport performance.

Adverse Analytical Finding: A report from a *WADA*-accredited laboratory or other *WADA*-approved laboratory 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 competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization*). An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "Athlete." In

relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 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-Level 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. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond International- or National-Level Athletes to competitors at lower levels of Competition or to individuals who engage in fitness activities but do not compete at all. Thus, a National Anti-Doping Organization could, for example, elect to test recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering, results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2). The decision on whether Consequences apply to recreational-level Athletes who engage in fitness activities but never compete is left to the National Anti-Doping Organization. In the same manner, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not analyze Samples for the full menu of Prohibited Substances. 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 sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport 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.

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: Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "*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*.

[Comment: An International Federation or ruling body for an Event may establish an "In-Competition" period that is different than the Event Period.]

International-Level Athlete: *Athletes* who compete in sport at the international level, as defined by each International Federation, consistent with the International Standard for Testing and Investigations.

[Comment: Consistent with the International Standard for Testing and Investigations, the International Federation is free to determine the criteria it will use to classify Athletes as International-Level Athletes, e.g., by ranking, by participation in particular International Events, by type of license, etc. However, it must publish those criteria in clear and concise form, so that Athletes are able to ascertain quickly and easily when they will become classified as International-Level Athletes. For example, if the criteria include participation in certain International Events, then the International Federation must publish a list of those International Events.]

Major Event Organizations: The continental associations of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.

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 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.

National-Level Athlete: *Athletes* who compete in sport at the national level, as defined by each *National Anti-Doping Organization*, consistent with the International Standard for Testing and Investigations.

Possession: The actual, physical *Possession*, or the constructive *Possession* (which shall be found only if the *Person* has exclusive control or intends to exercise 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: 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 must 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 must establish that the Athlete knew the steroids were in the cabinet and that the Athlete intended to exercise control over the steroids. The act of purchasing a Prohibited Substance alone constitutes Possession, even where, for example, the product does not arrive, is received by someone else, or is sent to a third party address.]

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, or class of substances, so described on the *Prohibited List*.

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, as provided in Article 23.

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

TUE: Therapeutic Use Exemption, as described in Article 4.4.

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 Further defined term from the International Standard for the Protection of Privacy and Personal Information that is used in the International Standard for Therapeutic Use Exemptions:

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*.

[3.2 Comment: It is understood that Personal Information includes, but is not limited to, information relating to an Athlete's name, date of birth, 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. Such information remains Personal Information and is regulated by this Standard for the entire duration of its Processing, irrespective of whether the relevant individual remains involved in organized sport.]

3.3 Further defined terms specific to the International Standard for Therapeutic Use Exemptions:

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

Therapeutic Use Exemption Committee (or "TUEC"): The panel established by an *Anti-Doping Organization* to consider applications for *TUEs*.

WADA TUEC: The panel established by *WADA* to review the *TUE* decisions of other *Anti-Doping Organizations*.

3.4 Interpretation:

3.4.1 Unless otherwise specified, references to articles are references to articles of the International Standard for Therapeutic Use Exemptions.

3.4.2 The comments annotating various provisions of the International Standard for Therapeutic Use Exemptions shall be used to interpret that *International Standard*.

3.4.3 The official text of the International Standard for Therapeutic Use Exemptions 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.

PART TWO: STANDARDS AND PROCESS FOR GRANTING *TUES*

4.0 Obtaining a *TUE*

4.1 An *Athlete* may be granted a *TUE* if (and only if) he/she can show, by a balance of probability, that each of the following conditions is met:

- a. The *Prohibited Substance* or *Prohibited Method* in question is needed to treat an acute or chronic medical condition, such that the *Athlete* would experience a significant impairment to health if the *Prohibited Substance* or *Prohibited Method* were to be withheld.
- b. The Therapeutic Use of the *Prohibited Substance* or *Prohibited Method* is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the *Athlete's* normal state of health following the treatment of the acute or chronic medical condition.
- c. There is no reasonable Therapeutic alternative to the *Use* of the *Prohibited Substance* or *Prohibited Method*.
- d. The necessity for the *Use* of the *Prohibited Substance* or *Prohibited Method* is not 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 such *Use*.

[Comment to 4.1: When a TUEC is deciding whether or not to recognize a TUE granted by another Anti-Doping Organization (see Article 7, below), and when WADA is reviewing a decision to grant (or not to grant) a TUE (see Article 8, below), the issue will be the same as it is for a TUEC that is considering an application for a TUE under article 6, below, i.e., has the Athlete demonstrated by a balance of probability that each of the conditions set out in article 4.1 is met?]

The WADA documents titled "Medical Information to Support the Decisions of TUECs", posted on WADA's website, should be used to assist in the application of these criteria in relation to particular medical conditions.]

4.2 Unless one of the exceptions set out in Article 4.3 applies, an *Athlete* who needs to *Use* a *Prohibited Substance* or *Prohibited Method* for Therapeutic reasons must obtain a *TUE* prior to *Using* or *Possessing* the substance or method in question.

4.3 An *Athlete* may only be granted retroactive approval for his/her Therapeutic Use of a *Prohibited Substance* or *Prohibited Method* (i.e., a retroactive *TUE*) if:

- a. Emergency treatment or treatment of an acute medical condition was necessary; or
- b. Due to other exceptional circumstances, there was insufficient time or opportunity for the *Athlete* to submit, or for the TUEC to consider, an application for the *TUE* prior to *Sample* collection; or
- c. The applicable rules required the *Athlete* (see comment to Article 5.1) or permitted the *Athlete* (see *Code* Article 4.4.5) to apply for a retroactive *TUE*; or

[Comment to 4.3(c): Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.1, in case an application for a retroactive TUE is necessary following Sample collection.]

- d. It is agreed, by *WADA* and by the *Anti-Doping Organization* to whom the application for a retroactive *TUE* is or would be made, that fairness requires the grant of a retroactive *TUE*.

[Comment to 4.3(d): If WADA and/or the Anti-Doping Organization do not agree to the application of Article 4.3(d), that may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.]

5.0 TUE Responsibilities of Anti-Doping Organizations

5.1 *Code* Article 4.4 specifies (a) which *Anti-Doping Organizations* have authority to make *TUE* decisions; (b) how those *TUE* decisions should be recognized and respected by other *Anti-Doping Organizations*; and (c) when *TUE* decisions may be reviewed and/or appealed.

[Comment to 5.1: See Annex 1 for a flow-chart summarizing the key provisions of Code Article 4.4.

Code Article 4.4.2 specifies the authority of a National Anti-Doping Organization to make TUE decisions in respect of Athletes who are not International-Level Athletes. In case of dispute as to which National Anti-Doping Organization should deal with the TUE application of an Athlete who is not an International-Level Athlete, WADA will decide. WADA's decision will be final and not subject to appeal.

Where national policy requirements and imperatives lead a National Anti-Doping Organization to prioritize certain sports over others in its test distribution planning (as contemplated by Article 4.4.1 of the International Standard for Testing and Investigations), the National Anti-Doping Organization may decline to consider advance applications for TUEs from Athletes in some or all of the non-priority

sports, but in that case it must permit any such Athlete from whom a Sample is subsequently collected to apply for a retroactive TUE. The National Anti-Doping Organization should publicize any such policy on its website for the benefit of affected Athletes.]

5.2 Each *National Anti-Doping Organization*, International Federation and *Major Event Organization* must establish a TUEC to consider whether applications for grant or recognition of TUEs meet the conditions set out in Article 4.1.

[*Comment to 5.2: While a Major Event Organization may choose to recognize pre-existing TUEs automatically, there must be a mechanism for Athletes participating in the Event to obtain a new TUE if the need arises. It is up to each Major Event Organization whether it sets up its own TUEC for this purpose, or rather whether it outsources the task by agreement to a third party (such as Sport Accord). The aim in each case should be to ensure that Athletes competing in such Events have the ability to obtain TUEs quickly and efficiently before they compete.*]

- a. 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 cases involving *Athletes* with impairments, at least one TUEC member should possess general experience in the care and treatment of *Athletes* with impairments, or possess specific experience in relation to the *Athlete's* particular impairment(s).
- b. In order to ensure a level of independence of decisions, at least a majority of the members of a TUEC should have no political responsibility in the *Anti-Doping Organization* that appoints them. All members of the TUEC must sign a conflict of interest and confidentiality declaration. (A template declaration is available on *WADA's* website).

5.3 Each *National Anti-Doping Organization*, International Federation and *Major Event Organization* must establish a clear process for applying to its TUEC for a TUE that complies with the requirements of this *International Standard*. It must also publish details of that process by (at a minimum) posting the information in a conspicuous place on its website and sending the information to *WADA*. *WADA* may re-publish the same information on its own website.

5.4 Each *National Anti-Doping Organization*, International Federation and *Major Event Organization* must promptly report (in English or French) all decisions of its TUEC granting or denying TUEs, and all decisions to recognize or refusing to recognize other *Anti-Doping Organizations' TUE* decisions, through *ADAMS* or any other system approved by *WADA*. In respect of TUEs granted, the information reported shall include (in English or French):

- a. not only the approved substance or method, but also the dosage(s), frequency and route of *Administration* permitted, the duration of the *TUE*, and any conditions imposed in connection with the *TUE*; and
- b. the *TUE* application form and the relevant clinical information (translated into English or French) establishing that the Article 4.1 conditions have been satisfied in respect of such *TUE* (for access only by *WADA*, the *Athlete's National Anti-Doping Organization* and International Federation, and the *Major Event Organization* organizing an *Event* in which the *Athlete* wishes to compete).

[*Comment to 5.4: The process of recognition of TUEs is greatly facilitated by use of ADAMS.*]

5.5 When a *National Anti-Doping Organization* grants a *TUE* to an *Athlete*, it must warn him/her in writing (a) that that *TUE* is valid at national level only, and (b) that if the *Athlete* becomes an *International-Level Athlete* or competes in an *International Event*, that *TUE* will not be valid for those purposes unless it is recognized by the relevant International Federation or *Major Event Organization* in accordance with Article 7.1. Thereafter, the *National Anti-Doping Organization* should help the *Athlete* to determine when he/she needs to submit the *TUE* to an International Federation or *Major Event Organization* for recognition, and should guide and support the *Athlete* through the recognition process.

5.6 Each International Federation and *Major Event Organization* must publish a notice (at a minimum, by posting it in a conspicuous place on its website and sending it to *WADA*) that sets out clearly (1) which *Athletes* coming under its jurisdiction are required to apply to it for a *TUE*, and when; (2) which *TUE* decisions of other *Anti-Doping Organizations* it will automatically recognize in lieu of such application, in accordance with Article 7.1(a); and (3) which *TUE* decisions of other *Anti-Doping Organizations* will have to be submitted to it for recognition, in accordance with Article 7.1(b). *WADA* may re-publish the notice on its own website.

5.7 Any *TUE* that an *Athlete* has obtained from a *National Anti-Doping Organization* shall not be valid if the *Athlete* becomes an *International-Level Athlete* or competes in an *International Event* unless and until the relevant *International Federation* recognizes that *TUE* in accordance with Article 7.0. Any *TUE* that an *Athlete* has obtained from an International Federation shall not be valid if the *Athlete* competes in an *International Event* organized by a *Major Event Organization*, unless and until the relevant *Major Event Organization* recognizes that *TUE* in accordance with Article 7.0. As a result, if the International Federation or *Major Event Organization* (as applicable) declines to recognize that *TUE*, then (subject to the *Athlete's* rights of review and appeal) that *TUE* may not be relied upon to excuse the presence, *Use*, *Possession* or *Administration* of the *Prohibited Substance* or *Prohibited Method* mentioned in the *TUE* vis-à-vis that International Federation or *Major Event Organization*.

6.0 TUE Application Process

6.1 An *Athlete* who needs a *TUE* should apply as soon as possible. For substances prohibited *In-Competition* only, the *Athlete* should apply for a *TUE* at least 30 days before his/her next *Competition*, unless it is an emergency or exceptional situation. The *Athlete* should apply to his/her *National Anti-Doping Organization*, International Federation and/or a *Major Event Organization* (as applicable), using the *TUE* application form provided. *Anti-Doping Organizations* shall make the application form they want *Athletes* to use available for download from their websites. That form must be based on the template set out in Annex 2. The template may be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items may be removed.

6.2 The *Athlete* should submit the *TUE* application form to the relevant *Anti-Doping Organization* via *ADAMS* or as otherwise specified by the *Anti-Doping Organization*. The form must be accompanied by:

- a. a statement by an appropriately qualified physician, attesting to the need for the *Athlete* to *Use the Prohibited Substance* or *Prohibited Method* in question for Therapeutic reasons; and
- b. a comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible) and the results of all examinations, laboratory investigations and imaging studies relevant to the application.

[Comment to 6.2(b): The information submitted in relation to the diagnosis, treatment and duration of validity should be guided by the WADA documents titled "Medical Information to Support the Decisions of TUECs".]

6.3 The *Athlete* should keep a complete copy of the *TUE* application form and of all materials and information submitted in support of that application.

6.4 A *TUE* application will only be considered by the TUEC following the receipt of a properly completed application form, accompanied by all relevant documents. Incomplete applications will be returned to the *Athlete* for completion and re-submission.

6.5 The TUEC may request from the *Athlete* or his/her physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the *Athlete's* application; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate.

6.6 Any costs incurred by the *Athlete* in making the *TUE* application and in supplementing it as required by the TUEC are the responsibility of the *Athlete*.

6.7 The TUEC shall decide whether or not to grant the application as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than 21 days of receipt of a complete application. Where a *TUE* application is made a reasonable time prior to an *Event*, the TUEC must use its best endeavors to issue its decision before the start of the *Event*.

6.8 The TUEC's decision must be communicated in writing to the *Athlete* and must be made available to *WADA* and to other *Anti-Doping Organizations* via *ADAMS* or any other system approved by *WADA*, in accordance with Article 5.4.

- a. A decision to grant a *TUE* must specify the dosage(s), frequency, route and duration of *Administration* of the *Prohibited Substance* or *Prohibited Method* in question that the TUEC is permitting, reflecting the clinical circumstances, as well as any conditions imposed in connection with the *TUE*.
- b. A decision to deny a *TUE* application must include an explanation of the reason(s) for the denial.

6.9 Each *TUE* will have a specified duration, as decided by the TUEC, at the end of which the *TUE* will expire automatically. If the *Athlete* needs to continue to *Use* the *Prohibited Substance* or *Prohibited Method* after the expiry date, he/she must submit an application for a new *TUE* well in advance of that expiry date, so that there is sufficient time for a decision to be made on the application before the expiry date.

[Comment to 6.9: The duration of validity should be guided by the WADA documents titled "Medical Information to Support the Decisions of TUECs".]

6.10 A *TUE* will be withdrawn prior to expiry if the *Athlete* does not promptly comply with any requirements or conditions imposed by the *Anti-Doping Organization* granting the *TUE*. Alternatively a *TUE* may be reversed upon review by *WADA* or on appeal.

6.11 Where an *Adverse Analytical Finding* is issued shortly after a *TUE* for the *Prohibited Substance* in question has expired or has been withdrawn or reversed, the *Anti-Doping Organization* conducting the initial review of the *Adverse Analytical Finding* (Code Article 7.2) shall consider whether the finding is consistent with *Use* of the *Prohibited Substance* prior to the expiry, withdrawal or reversal of the *TUE*. If so, such *Use* (and any resulting presence of the *Prohibited Substance* in the *Athlete's Sample*) is not an anti-doping rule violation.

6.12 In the event that, after his/her *TUE* is granted, the *Athlete* requires a materially different dosage, frequency, route or duration of *Administration* of the *Prohibited Substance* or *Prohibited Method* to that specified in the *TUE*, he/she must apply for a new *TUE*. If the presence, *Use*, *Possession* or *Administration* of the *Prohibited Substance* or *Prohibited Method* is not consistent with the terms of

the *TUE* granted, the fact that the *Athlete* has the *TUE* will not prevent the finding of an anti-doping rule violation.

7.0 *TUE* Recognition Process

7.1 *Code* Article 4.4 requires *Anti-Doping Organizations* to recognize *TUEs* granted by other *Anti-Doping Organizations* that satisfy the Article 4.1 conditions. Therefore, if an *Athlete* who becomes subject to the *TUE* requirements of an International Federation or *Major Event Organization* already has a *TUE*, he/she should not submit an application for a new *TUE* to the International Federation or *Major Event Organization*. Instead:

- a. The International Federation or *Major Event Organization* may publish notice that it will automatically recognize *TUE* decisions made pursuant to *Code* Article 4.4 (or certain categories of such decisions, e.g., those made by specified *Anti-Doping Organizations*, or those relating to particular *Prohibited Substances*), provided that such *TUE* decisions have been reported in accordance with Article 5.4 and therefore are available for review by *WADA*. If the *Athlete's TUE* falls into a category of *TUEs* that are automatically recognized in this way at the time the *TUE* is granted, he/she does not need to take any further action.

[Comment to 7.1(a): To ease the burden on Athletes, automatic recognition of TUE decisions once they have been reported in accordance with Article 5.4 is strongly encouraged. If an International Federation or Major Event Organizer is not willing to grant automatic recognition of all such decisions, it should grant automatic recognition of as many such decisions as possible, e.g., by publishing a list of Anti-Doping Organizations whose TUE decisions it will recognize automatically, and/or a list of those Prohibited Substances for which it will automatically recognize TUEs. Publication should be in the same manner as is set out in Article 5.3, i.e., the notice should be posted on the International Federation's website and sent to WADA and to National Anti-Doping Organizations.]

- b. In the absence of such automatic recognition, the *Athlete* shall submit a request for recognition of the *TUE* to the International Federation or *Major Event Organization* in question, either via *ADAMS* or as otherwise specified by that International Federation or *Major Event Organization*. The request should be accompanied by a copy of the *TUE* and the original *TUE* application form and supporting materials referenced at Articles 6.1 and 6.2 (unless the *Anti-Doping Organization* that granted the *TUE* has already made the *TUE* and supporting materials available via *ADAMS* or other system approved by *WADA*, in accordance with Article 5.4).

7.2 Incomplete requests for recognition of a *TUE* will be returned to the *Athlete* for completion and re-submission. In addition, the TUEC may request from the *Athlete* or his/her physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the *Athlete's* request for recognition of the *TUE*; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate.

7.3 Any costs incurred by the *Athlete* in making the request for recognition of the *TUE* and in supplementing it as required by the TUEC are the responsibility of the *Athlete*.

7.4 The TUEC shall decide whether or not to recognize the *TUE* as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than 21 days of receipt of a complete request for recognition. Where the request is made a reasonable time prior to an *Event*, the TUEC must use its best endeavors to issue its decision before the start of the *Event*.

7.5 The TUEC's decision will be notified in writing to the *Athlete* and will be made available to *WADA* and to other *Anti-Doping Organizations* via *ADAMS* or any other system approved by *WADA*. A decision not to recognize a *TUE* must include an explanation of the reason(s) for the non-recognition.

8.0 Review of *TUE* Decisions by *WADA*

8.1 *Code* Article 4.4.6 provides that *WADA*, in certain cases, must review *TUE* decisions of International Federations, and that it may review any other *TUE* decisions, in each case to determine compliance with the Article 4.1 conditions. *WADA* shall establish a WADA TUEC that meets the requirements of Article 5.2 to carry out such reviews.

8.2 Each request for review must be submitted to *WADA* in writing, and must be accompanied by payment of the application fee established by *WADA*, as well as copies of all of the information specified in Article 6.2 (or, in the case of review of a *TUE* denial, all of the information that the *Athlete* submitted in connection with the original *TUE* application). The request must be copied to the party whose decision would be the subject of the review, and to the *Athlete* (if he/she is not requesting the review).

8.3 Where the request is for review of a *TUE* decision that *WADA* is not obliged to review, *WADA* shall advise the *Athlete* as soon as practicable following receipt of the request whether or not it will refer the *TUE* decision to the WADA TUEC for review. If *WADA* decides not to refer the *TUE* decision, it will return the application fee to the *Athlete*. Any decision by *WADA* not to refer the *TUE* decision to the WADA TUEC is final and may not be appealed. However, the *TUE* decision may still be appealable, as set out in *Code* Article 4.4.7.

8.4 Where the request is for review of a *TUE* decision of an International Federation that *WADA* is obliged to review, *WADA* may nevertheless refer the decision back to the International Federation (a) for clarification (for example, if the reasons are not clearly set out in the decision); and/or (b) for re-consideration by the International Federation (for example, if the *TUE* was only denied because medical tests or other information required to demonstrate satisfaction of the Article 4.1 conditions were missing).

8.5 Where a request for review is referred to the WADA TUEC, the WADA TUEC may seek additional information from the *Anti-Doping Organization* and/or the *Athlete*, including further studies as described in Article 6.5, and/or it may obtain the assistance of other medical or scientific experts as it deems appropriate.

8.6 The WADA TUEC shall reverse any grant of a *TUE* that does not comply with the Article 4.1 conditions. Where the *TUE* reversed was a prospective *TUE* (rather than a retroactive *TUE*), such reversal shall take effect upon the date specified by *WADA* (which shall not be earlier than the date of *WADA*'s notification to the *Athlete*). The reversal shall not apply retroactively and the *Athlete*'s results prior to such notification shall not be *Disqualified*. Where the *TUE* reversed was a retroactive *TUE*, however, the reversal shall also be retroactive.

8.7 The WADA TUEC shall reverse any denial of a *TUE* where the *TUE* application met the Article 4.1 conditions, i.e., it shall grant the *TUE*.

8.8 Where the WADA TUEC reviews a decision of an International Federation that has been referred to it pursuant to *Code* Article 4.4.3 (i.e., a mandatory review), it may require whichever *Anti-Doping Organization* "loses" the review (i.e., the *Anti-Doping Organization* whose view it does not uphold) (a) to reimburse the application fee to the party that referred the decision to *WADA* (if applicable); and/or (b) to pay the costs incurred by *WADA* in respect of that review, to the extent they are not covered by the application fee.

8.9 Where the WADA TUEC reverses a *TUE* decision that *WADA* has decided in its discretion to review, *WADA* may require the *Anti-Doping Organization* that made the decision to pay the costs incurred by *WADA* in respect of that review.

8.10 *WADA* shall communicate the reasoned decision of the WADA TUEC promptly to the *Athlete* and to his/her *National Anti-Doping Organization* and International Federation (and, if applicable, the *Major Event Organization*).

9.0 Confidentiality of Information

9.1 The collection, storage, processing, disclosure and retention of Personal Information during the *TUE* process by *Anti-Doping Organizations* and *WADA* shall

comply with the International Standard for the Protection of Privacy and Personal Information.

9.2 An *Athlete* applying for the grant of a *TUE* or for recognition of a *TUE* shall provide written consent:

- a. for the transmission of all information pertaining to the application to members of all TUECs with authority under this *International Standard* to review the file and, as required, other independent medical or scientific experts, and to all necessary staff (including *WADA* staff) involved in the management, review or appeal of *TUE* applications;
- b. for the *Athlete's* physician(s) to release to the TUEC upon request any health information that the TUEC deems necessary in order to consider and determine the *Athlete's* application; and
- c. for the decision on the application to be made available to all *Anti-Doping Organizations* with *Testing* authority and/or results management authority over the *Athlete*.

*[Comment to 9.2: Prior to collecting Personal Information or obtaining consent from an *Athlete*, the *Anti-Doping Organization* shall communicate to the *Athlete* the information set out in Article 7.1 of the *International Standard for the Protection of Privacy and Personal Information*.]*

9.3 The *TUE* application shall be dealt with in accordance with the principles of strict medical confidentiality. The members of the TUEC, independent experts and the relevant staff of the *Anti-Doping Organization* shall conduct all of their activities relating to the process in strict confidence and shall sign appropriate confidentiality agreements. In particular they shall keep the following information confidential:

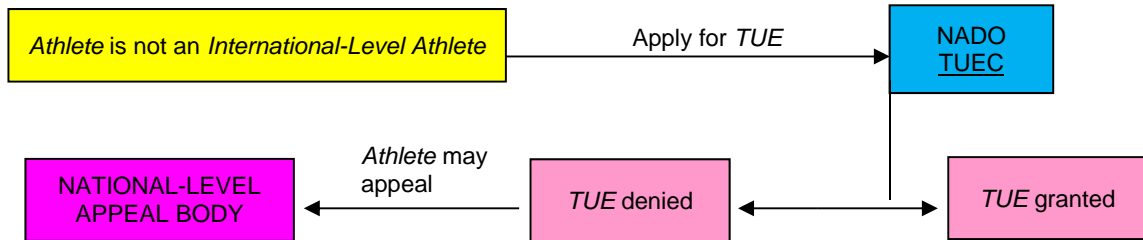
- a. All medical information and data provided by the *Athlete* and physician(s) involved in the *Athlete's* care.
- b. All details of the application, including the name of the physician(s) involved in the process.

9.4 Should the *Athlete* wish to revoke the right of the TUEC to obtain any health information on his/her behalf, the *Athlete* shall notify his/her medical practitioner in writing of such revocation; provided that, as a result of that revocation, the *Athlete's* application for a *TUE* or for recognition of an existing *TUE* will be deemed withdrawn without approval/recognition having been granted.

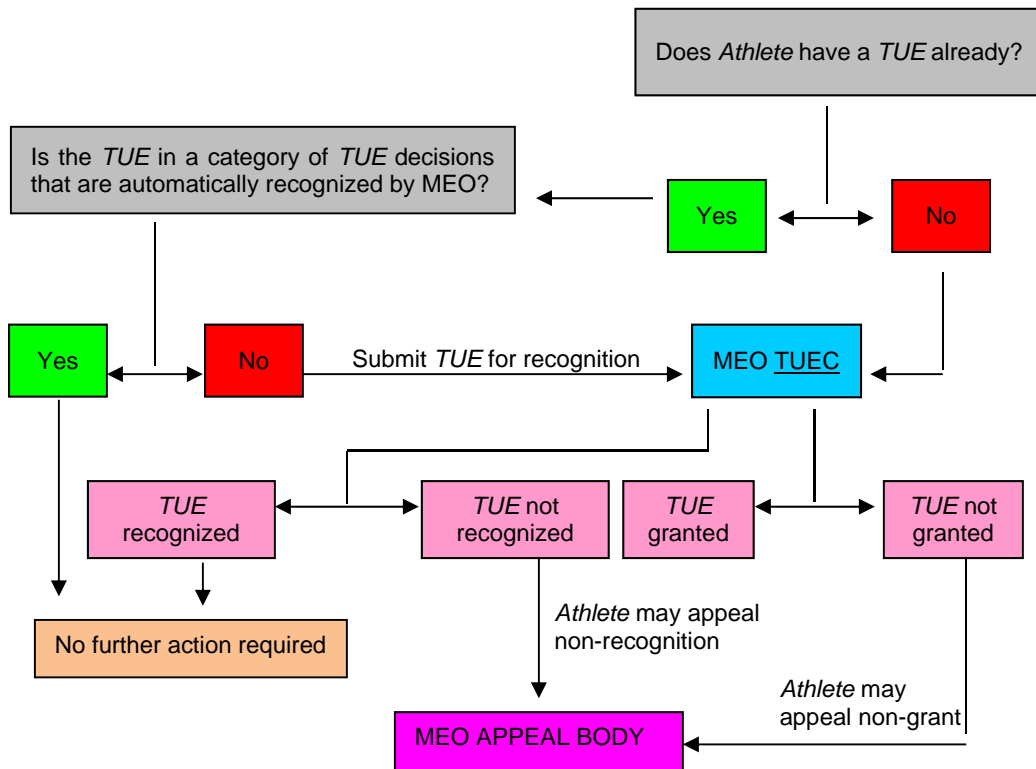
9.5 *Anti-Doping Organizations* shall only use information submitted by an *Athlete* in connection with a *TUE* application to evaluate the application and in the context of potential anti-doping rule violation investigations and proceedings.

ANNEX 1: CODE ARTICLE 4.4 FLOW-CHART

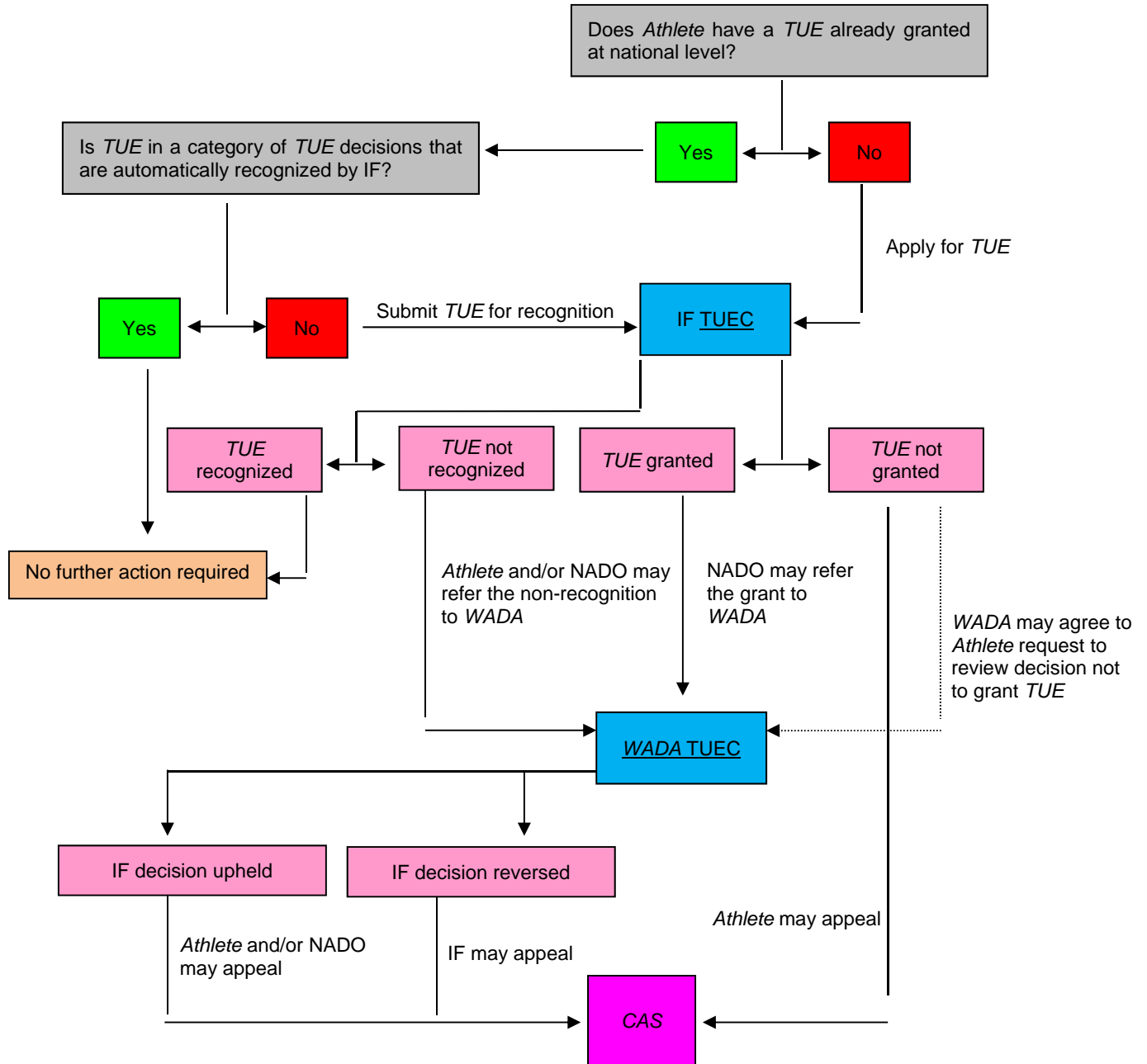
1. TUE procedure if Athlete is not an International-Level Athlete when need for TUE arises



2. Athlete enters Event for which Major Event Organization (or "MEO") has its own TUE requirements



3. *TUE* Procedure if *Athlete* is an *International-Level Athlete* (and so subject to the International Federation's *TUE* requirements) when need for *TUE* arises



ANNEX 2: TEMPLATE OF TUE APPLICATION FORM

Identification of Anti-Doping Organization (Logo or Name of the ADO)

Therapeutic Use Exemptions (TUE) APPLICATION FORM

Please complete all sections in capital letters or typing. Athlete to complete sections 1, 5, 6 and 7; physician to complete sections 2, 3 and 4. Illegible or incomplete applications will be returned and will need to be re-submitted in legible and complete form.

1. Athlete Information

Surname: _____	Given Names: _____	
Female <input type="checkbox"/>	Male <input type="checkbox"/>	Date of Birth (d/m/y): _____
Address: _____		
City: _____	Country: _____	Postcode: _____
Tel.: _____	E-mail: _____	
<i>(with International code)</i>		
Sport: _____	Discipline/Position: _____	
International or National Sport Organization: _____		
If you are an Athlete with an impairment, please indicate the impairment: _____		

2. Medical information *(continue on separate sheet if necessary)*

Diagnosis:

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

Comment:

Evidence confirming the diagnosis shall be attached and forwarded with this application. The medical information must 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. In the case of non-demonstrable conditions, independent supporting medical opinion will assist this application.

WADA maintains a series of guidelines to assist physicians in the preparation of complete and thorough TUE applications. These TUE Physician Guidelines can be accessed by entering the search term "Medical Information" on the WADA website: <https://www.wada-ama.org>. The guidelines address the diagnosis and treatment of a number of medical conditions commonly affecting athletes, and requiring treatment with prohibited substances.

3. Medication details

Prohibited Substance(s): <u>Generic name</u>	Dose	Route of Administration	Frequency	Duration of Treatment
1.				
2.				
3.				

4. Medical practitioner's declaration

I certify that the information at sections 2 and 3 above is accurate, and that the above-mentioned treatment is medically appropriate.

Name:

Medical specialty:

Address:

Tel.:

Fax:

E-mail:

Signature of Medical Practitioner: _____ Date: _____

5. Retroactive applications

<p>Is this a retroactive application?</p> <p>Yes: <input type="checkbox"/></p> <p>No: <input type="checkbox"/></p> <p>If yes, on what date was treatment started?</p> <hr/> <hr/>	<p>Please indicate reason:</p> <p>Emergency treatment or treatment of an acute medical condition was necessary <input type="checkbox"/></p> <p>Due to other exceptional circumstances, there was insufficient time or opportunity to submit an application prior to sample collection <input type="checkbox"/></p> <p>Advance application not required under applicable rules <input type="checkbox"/></p> <p>Other <input type="checkbox"/></p> <p>Please explain:</p> <hr/> <hr/> <hr/>
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6. Previous applications

<p>Have you submitted any previous TUE application(s)?</p>	<p>Yes <input type="checkbox"/></p>
<p>No <input type="checkbox"/></p>	
<p>For which substance or method?</p> <hr/>	
<p>To whom? _____ When? _____</p>	
<p>Decision: Approved <input type="checkbox"/> Not approved <input type="checkbox"/></p>	

7. Athlete's declaration

I, _____, certify that the information set out at sections 1, 5 and 6 is accurate. 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 World Anti-Doping Code ("*Code*") and/or the International Standard for Therapeutic Use Exemptions.

I consent to my physician(s) releasing to the above persons any health information that they deem necessary in order to consider and determine my application.

I understand that my information will only be used for evaluating my TUE request and in the context of potential anti-doping rule violation investigations and procedures. I understand that if I ever wish to (1) obtain more information about the use of my health 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 consent to the decision on this application being made available to all ADOs, or other organizations, with Testing authority and/or results management authority over me.

I understand and accept that the recipients of my information and of the decision on this application may be located outside the country where I reside. In some of these countries data protection and privacy laws may not be equivalent to those in my country of residence.

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 an impairment preventing him/her signing this form, a parent or guardian shall sign on behalf of the Athlete)

Please submit the completed form to by the following means (keeping a copy for your records):
.....