



INTERNATIONAL CONVENTION AGAINST DOPING IN SPORT

Annex II – International Standard for Therapeutic Use Exemptions

Paris, 1 January 2016

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.