

2015 *UCI* Anti-Doping Regulations

***UCI* REGULATIONS
FOR THERAPEUTIC
USE EXEMPTIONS**

JANUARY 2015

UCI Regulations for Therapeutic Use Exemptions

The *UCI Regulations for Therapeutic Use Exemptions* ("*UCI TUER*") are mandatory regulations supplementing the *UCI Anti-Doping Regulations* ("*UCI ADR*"), in particular articles 4.4 of the *UCI ADR*.

The *UCI TUER* comes into effect on 1 January 2015.

The official text of the *UCI TUER* shall be maintained by *UCI* 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.

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PART ONE: INTRODUCTION, UCI ANTI-DOPING REGULATIONS PROVISIONS AND DEFINITIONS

1.0 Introduction and Scope

The *UCI TUE* are mandatory regulations supplementing the *UCI Anti-Doping Regulations (UCI ADR)*, in particular Article 4.4 of the *UCI ADR*.

The purpose of the *UCI TUE* is to establish (a) the conditions that must be satisfied in order for a *Therapeutic Use Exemption (TUE)* to be granted, permitting the presence of a *Prohibited Substance* in a *Rider's Sample* or the *Rider'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 *UCI* in making and communicating *TUE* decisions; (c) the process for a *Rider* to apply for a *TUE*; (d) the process for a *Rider* to get a *TUE* granted by the *UCI*; (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 *UCI TUE* that are defined terms from the *UCI ADR* are written in italics. Terms that are defined in this *UCI TUE* are underlined.

2.0 UCI ADR Provisions

The following articles in the 2015 *UCI ADR* are directly relevant to the *UCI TUE*:

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 UCI TUE Regulations.

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

4.4.2.1 Notwithstanding the above, any Rider who wishes to participate in an International Event must, prior to such participation, obtain recognition of a TUE already granted by his or her National Anti-Doping Organization from the UCI in accordance with Article 4.4.3.1 and the UCI TUE Regulations.

4.4.2.2 If the need for the TUE arises during the International Event Period, the Rider may apply directly to the UCI as set forth in the UCI TUE Regulations.

[If the UCI chooses to conduct Testing on a Rider who is not an International-Level Rider outside the situations contemplated in Article 4.4.2.1 or 4.4.2.2, it shall recognize a TUE granted to the Rider by his or her National Anti-Doping Organization]

4.4.3 A Rider who is an International-Level Rider must apply to the UCI for a TUE.

4.4.3.1 Where the Rider already has a TUE granted by his/her National Anti-Doping Organization for the substance or method in question, if that TUE meets the criteria set out in Section 4.0 of the UCI TUE Regulations, then the UCI shall recognize it. If the UCI considers

that the TUE does not meet those criteria and so refuses to recognize it, it shall notify the Rider and his or her National Anti-Doping Organization promptly, with reasons.

The Rider 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.

The UCI may, in accordance with the UCI TUE Regulations, publish notice on the UCI Website that it will automatically recognize TUE decisions (or categories of such decisions) made by National Anti-Doping Organizations. If a Rider's TUE falls into a category of automatically recognized TUEs, then he/she does not need to apply to the UCI for recognition of that TUE.

4.4.3.2 Where the Rider does not already have a TUE granted by his or her National Anti-Doping Organization for the substance or method in question, the Rider must apply directly to the UCI for a TUE in accordance with the UCI TUE Regulations. If the UCI denies the Rider's application, it must notify the Rider promptly, with reasons. If the UCI grants the Rider's application, it must notify not only the Rider but also his or her National Anti-Doping Organization.

If the National Anti-Doping Organization considers that the TUE does not meet the criteria set out in Section 4.0 UCI TUE Regulations, 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 UCI 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 UCI becomes valid for national-level Competition as well when the 21-day review deadline expires.

4.4.3.3 The UCI shall appoint a TUE Committee (the "TUEC") to consider applications for the grant or recognition of TUEs in accordance with the UCI TUE Regulations. Its decision shall be the final decision of the UCI, and shall be reported to WADA and other relevant Anti-Doping Organizations, including the Rider's National Anti-Doping Organization, through ADAMS.

[Comments to Article 4.4.3:

A Rider should not assume that his/her application for grant or recognition of a TUE (or for renewal of a TUE) will be granted. Any Use or Possession or Administration of a Prohibited Substance or Prohibited Method before an application has been granted is entirely at the Rider's own risk.

If the UCI 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 UCI TUE Regulations, the matter should not be referred to WADA for review. Instead, the file should be completed and re-submitted to the UCI.]

4.4.4 A Major Event Organization may require Riders to apply to it for a TUE if they wish to Use a Prohibited Substance or a Prohibited Method in connection with the Event. Riders shall refer to the applicable rules of the Major Event Organization for the requirements and procedure to follow in this situation.

4.4.5 If the UCI chooses to conduct Testing on a Person who is neither an International-Level nor a National-Level Rider, and that Person is Using a Prohibited Substance or Prohibited Method for therapeutic reasons, the UCI may permit him or her to apply for a retroactive TUE.

4.4.6 WADA must review a decision by the UCI not to recognize a TUE granted by the National Anti-Doping Organization that is referred to it by the Rider or the Rider's National Anti-Doping Organization. WADA must also review a decision by the UCI to grant a TUE that is referred to it by the Rider'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 Section 4.0 of the UCI TUE Regulations, 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 the UCI that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon review, may be appealed by the Rider and/or the Rider's National Anti-Doping Organization, exclusively to CAS.

[Comment to Article 4.4.7: In such cases, the decision being appealed is the UCI'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 Rider, the National Anti-Doping Organization and/or the UCI, 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.

4.4.10 A TUE granted pursuant to these Anti-Doping Rules: (a) shall expire automatically at the end of any term for which it was granted, without the need for any further notice or other formality; (b) may be withdrawn as set forth in the UCI TUE Regulations; or (c) may be reversed on review by WADA or on appeal.

13.4 Appeals Relating to TUEs

TUE decisions may be appealed exclusively as provided in Article 4.4 and within the time limits set forth in Article 13.2.5.

3.0 Definitions and Interpretation

3.1 Defined terms from the Appendix 1 of the UCI ADR 2015 that are used in the UCI TUE:

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*.

Attempt: Purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an anti-doping rule violation. Provided, however, there shall be no anti-doping rule violation based solely on an *Attempt* to commit a violation if the Person renounces the *Attempt* prior to it being discovered by a third party not involved in the *Attempt*.

CAS: *The Court of Arbitration for Sport*.

Code: The World Anti-Doping Code.

Competition: A single race organized separately (for example: each of the time trial and road race at the road World Championships; a stage in a stage race; a Cross-country Eliminator heat) or a series of races forming an organizational unit and producing a final winner and/or general classification (for example: a track sprint race tournament, a cyclo-ball tournament).

Event: A single *Competition* organized separately (for example: a one day road race) or a series of *Competitions* conducted together as a single organization (for example: road World Championships; a road stage race, a track World Cup *Event*); a reference to *Event* includes reference to *Competition*, unless the context indicates otherwise.

In-Competition: the period commencing twelve hours before a *Competition* in which the *Rider* is scheduled to participate through the end of such *Competition* and the Sample collection process related to such *Competition*.

International Event: For the sport of cycling, *UCI International Events* are defined annually by the *UCI* in a list on the *UCI Website*.

[*Comment: in general, the International Events within the meaning of the Code include: An Event or Competition 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. Under these Anti-Doping Rules, the relevant definition is specific to the sport of cycling*]

International-Level Rider: *Riders* who compete in sport at the international level, as defined in the Introduction of these Anti-Doping Rules.

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 Event: A sport *Event* or *Competition* involving International- or *National-Level Riders* that is not an *International Event*.

National-Level Rider: *Riders 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.*

Out-of-Competition: Any period 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 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 a Rider 's car would constitute a violation unless the Rider establishes that someone else used the car; in that event, the Anti-Doping Organization must establish that, even though the did not have exclusive control over the car, the Rider 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 a Rider and spouse, the Anti-Doping Organization must establish that the Rider knew the steroids were in the cabinet and that the Rider 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*.

Registered testing pool: The pool of highest-priority *Riders* established separately at the international level by International Federations and at the national level by *National Anti-Doping Organizations*, who are subject to focused *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or *National Anti-Doping Organization's* test distribution plan and therefore are required to provide whereabouts information as provided in Article 5.6.

Rider: Any Person subject to these Anti-Doping Rules who competes in the sport of cycling, whether at the international level as defined by the UCI in the Introduction to these Anti-Doping Rules (*International-Level Rider*), at the national level (*National-Level Rider*) as defined by each *National Anti-Doping Organization*), or otherwise.

An *Anti-Doping Organization* has discretion to apply anti-doping rules to a *Rider* who is neither an *International-Level Rider* nor a *National-Level Rider*, and thus to bring them within the definition of "*Rider*." In relation to *Riders* who are neither *International-Level* nor *National-Level Riders*, 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 *Rider* 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 antidoping information and education, any Person who participates in sport under the authority of any Signatory, government, or other sports organization accepting the *Code* is a *Rider*.

[Comment to *Rider*: This definition makes it clear that all *International* and *National-Level Riders* 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 *Riders* 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 13.4.2). The decision on whether Consequences apply to recreational-level *Riders* 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.]

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.

Therapeutic Use Exemption Committee (or "TUEC"): The panel established by the UCI to consider applications for *TUEs*.

UCI: Union Cycliste Internationale, the International Federation governing the sport of cycling.

UCI Website: a website on which these Anti-Doping Rules and other documents referred to in these Anti-Doping Rules are made available in their current version.

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 Rider'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 a Rider 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.

WADA TUEC: The panel established by WADA to review the TUE decisions of the UCI .

3.4 Interpretation:

3.4.1 Unless otherwise specified, references to articles are references to articles of the UCI TUEC.

3.4.2 The comments annotating various provisions of the UCI TUEC shall be used to interpret that UCI TUEC .

3.4.3 The official text of the UCI TUEC shall be maintained by the UCI 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

[See also, in particular, 4.4.1/4.4.5/4.4.10 of the UCI ADR]

4.1 A *Rider* may be granted a TUE if (and only if) he/she can show 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 *Rider* 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 *Rider'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: The WADA documents titled "Medical Information to Support the Decisions of TUECs", posted on WADA's website, can 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, a *Rider* 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 A *Rider* 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 *Rider* to submit, or for the TUEC to consider, an application for the TUE prior to Sample collection; or
- c. The applicable rules required the *Rider* or permitted the *Rider* (see UCI ADR Article 4.4.5) to apply for a retroactive TUE; or

[Comment to 4.3(c): Such Riders 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 the UCI that fairness requires the grant of a retroactive TUE.

[Comment to 4.3(d): If the UCI does 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 the UCI

[See also, in particular, Article 4.4.2/4.4.3 of the UCI ADR]

5.1 UCI ADR Article 4.4 specifies (a) the authority of the UCI to make TUE decisions in respect of Riders who are *International-Level Riders* or for participation in an *International Event*; (b) how TUE decisions granted by *National Anti-Doping Organizations* should be recognized and respected by the UCI; and (c) when TUE decisions issued by the UCI may be reviewed and/or appealed.

5.2 The list of Riders who are *International-Level Riders* included in UCI's *Registered Testing Pool* and therefore required to obtain a TUE from the UCI is published on the UCI Website.

UCI ADR Article 4.4.2 specifies the authority of a *National Anti-Doping Organization* to make TUE decisions in respect of Riders who are not *International-Level Riders* and the manner in which the UCI will recognize these TUEs.

5.3 UCI shall appoint a TUEC to consider whether applications for grant or recognition of TUEs meet the conditions set out in Article 4.1.

- a. The TUEC shall be composed of at least three members, two of whom act as chairman and deputy chairman. The deputy chairman shall replace the chairman if the latter is unavailable or facing a conflict of interest.
- b. A majority of the members of the TUEC shall be physicians with experience in the care and treatment of Riders and a sound knowledge of clinical, sports and exercise medicine. The TUEC may seek whatever medical or scientific expertise it deems appropriate in reviewing the circumstances of any application for a TUE. In cases involving Riders with impairments, advice shall be sought from an expert possessing specific experience with the care and treatment of Riders with impairments, if no member of the TUEC possesses such experience.
- c. A majority of the members of the TUEC shall be free of conflicts of interest or political responsibility in the UCI or a National Federation. All the members (including the chairman) must sign a conflict of interest and confidentiality declaration. Each member of the TUEC must voluntarily disclose any circumstances likely to constitute a conflict of interest. A member of the TUEC shall not take part in the examination of a TUE application involving a Rider of his nationality or affiliated to the national federation of the country of his nationality. A member of the TUEC shall not take part either in the examination of a file that could potentially present a particular interest for him or for his national federation, whether directly or indirectly. In case of disagreement on the existence of a conflict of interest, the TUEC decides after a hearing of the member in question and without his taking part in the decision.

(text modified on 30.06.2016)

5.4 Where no national *TUEC* is operational and depending on the circumstances, the *UCI* may accept to consider applications from *Riders* for *TUEs* in situation that would fall under the authority from a *National Anti-Doping Organization*.

6.0 TUE Application Process

[See also, in particular, Article 4.4.2.2/4.4.3.2/4.4.3.3 of the *UCI ADR*]

6.1 A *Rider* who needs a *TUE* should apply as soon as the need arises. For substances prohibited *In-Competition* only, the *Rider* should apply for a *TUE* as soon as the need arises but in any event at least 30 days before his/her next *Competition*, unless it is an emergency or exceptional situation. The *Rider* should apply to the *UCI*, using the *TUE* application form available on *ADAMS*.

6.2 The *Rider* should submit the *TUE* application form to the *UCI* via *ADAMS*. The form must be completed legibly, in English or French, and accompanied by:

- a. a statement by an appropriately qualified physician, attesting to the need for the *Rider* to Use the *Prohibited Substance* or *Prohibited Method* in question for Therapeutic reasons. The dosage(s), frequency, route and duration of *Administration* of the *Prohibited Substance* or *Prohibited Method* in question must be specified; 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". Both documents can be found on WADA's website under World Anti-Doping Code, International Standards, International standard for Therapeutic Use Exemptions or obtained from the UCI. Riders should take care to consult and use the most recent version of these documents.]

6.3 The *Rider* 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 and legibly completed application form in English or French, accompanied by all relevant documents. Incomplete or illegible applications will be returned to the *Rider* for completion and re-submission. Any information attached to the *TUE* application form shall be in English or French. If such information has been originally established in another language, the *Rider* shall attach the original document and a translation in English or French.

[Comment: Providing false or misleadingly incomplete information may constitute an anti-doping rule violation under article 2.5 of the UCI ADR (Tampering or Attempted Tampering with any part of Doping Control)].

6.5 A *Rider* may not apply to more than one *Anti-Doping Organization* for a *TUE*. The application must list any previous and/or current requests for permission to use an otherwise *Prohibited Substance* or *Prohibited Method*, the body to whom that request was made, and the decision of that body.

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

6.7 Any costs incurred by the *Rider* in making the *TUE* application and in supplementing it as required by the *TUEC* are the responsibility of the *Rider*. In particular, any additional relevant investigations, examinations or imaging studies requested by the *TUEC* will be undertaken at the expense of the *Rider*.

6.8 Upon the *UCI's* receipt of a *TUE* application via *ADAMS* system, the *TUEC* coordinator shall inform the chairman of the *TUEC*. The *TUEC* chairman will then appoint – or delegate to the coordinator of the *TUEC* the task to appoint – three members of the *TUEC* (which may include the chairman and/or the coordinator themselves) to consider such application and render a decision promptly. The appointed members of the *TUEC* receive the *TUE* documentation either via *ADAMS* or by email.

6.9 A decision to grant a *TUE* shall be taken unanimously by the three members of the *TUEC*. In the event of a lack of unanimity amongst the three members of the *TUEC*, the *TUE* will be denied. All decisions by the *TUEC* are rendered by exchange of emails.

6.10 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*.

6.11 The *TUEC's* decision must be communicated to the *Rider* via *ADAMS* and be made available to *WADA* and to other relevant *Anti-Doping Organizations* via *ADAMS*.

- 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.

6.12 Each *TUE* will have a specified duration, as decided by the *TUEC*, at the end of which the *TUE* will expire automatically. If the *Rider* 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.

6.13 The *TUEC* may submit the granting of a *TUE* to any conditions it may specify.

6.14 A *TUE* will be withdrawn prior to expiry if the *Rider* does not promptly comply with any requirements or conditions imposed by the *UCI*, or if it is subsequently determined that the criteria for grant of a *TUE* are in fact not met. Alternatively a *TUE* may be reversed upon review by *WADA* or on appeal in accordance with Section 8.

6.15 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 *UCI* 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 *Rider's Sample*) is not an anti-doping rule violation.

6.16 In the event that, after his/her *TUE* is granted, the *Rider* 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 *Rider* has the *TUE* will not prevent the finding of an anti-doping rule violation.

7.0 TUE Recognition Process

[See also, in particular, Article 4.4.2.1/4.4.3.1 of the UCI ADR]

7.1 UCI will recognize *TUEs* granted by *National Anti-Doping Organizations* that satisfy the Article 4.1 conditions. Therefore, if a *Rider* who becomes subject to the *TUE* requirements of the UCI 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. UCI may publish notice on the UCI Website that it will automatically recognize *TUE* decisions made pursuant to UCI ADR Article 4.4 (or certain categories of such decisions, e.g., those made by specified *Anti-Doping Organizations*), provided that such *TUE* decisions have been reported via ADAMS and are therefore available for review by WADA. If the *Rider'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.
- b. In the absence of such automatic recognition, the *Rider* shall submit a request for recognition of the *TUE* to the UCI, via ADAMS. 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 *National Anti-Doping Organization* that granted the *TUE* has already made the *TUE* and supporting materials available via ADAMS).

7.2 Incomplete requests for recognition of a *TUE* will be returned to the *Rider* for completion and re-submission. In addition, the *TUEC* may request from the *Rider* or his/her physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the *Rider'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 *Rider* in making the request for recognition of the *TUE* and in supplementing it as required by the *TUEC* are the responsibility of the *Rider*.

7.4 A decision to recognize a *TUE* delivered at national level shall be taken by the chairman or a member appointed by the chairman of the *TUEC*.

7.5 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*.

7.6 The *TUEC*'s decision will be notified in writing to the *Rider* 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*

[See also, in particular, Article 4.4.6-4.4.8 of the *UCI ADR*]

8.1 Article 4.4 of the *UCI ADR* provides that *WADA*, in certain cases, must review *TUE* decisions of the *UCI*, and that it may review any other *TUE* decisions, in each case to determine compliance with the Article 4.4 conditions. *WADA* shall establish a *WADA TUEC* that meets the requirements of Article 5.3 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 *Rider* 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 *Rider* (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 *Rider* 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 *Rider*. 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 Article 4.4.7 of the *UCI ADR*.

8.4 Where the request is for review of a *TUE* decision of the *UCI* that *WADA* is obliged to review, *WADA* may nevertheless refer the decision back to the *UCI* (a) for clarification (for example, if the reasons are not clearly set out in the decision); and/or (b) for re-consideration by the *UCI* (for example, if the *TUE* was only denied because medical tests or other information required to demonstrate satisfaction of the Section 4.0 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 *Rider involved*, including further studies as described in Article 6.6, 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 Section 4.0 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 *Rider*). The reversal shall not apply retroactively and the *Rider*'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 Section 4.0 conditions, i.e., it shall grant the *TUE*.

8.8 Where the WADA TUEC reviews a decision of the *UCI* that has been referred to it pursuant to Article 4.4.3 of the *UCI ADR* (i.e., a mandatory review), it may require the *UCI* should it “lose” the review (i.e., if *UCI*’s view is 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 *UCI* 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 the *UCI* (and, if applicable, the *Major Event Organization*).

8.11 Appeals against decisions made under this Section shall be appealable to *CAS* as set forth in Article 4.4.7 - 4.4.9 of the *UCI ADR*.

9.0 Confidentiality of Information

9.1 The collection, storage, processing, disclosure and retention of Personal Information during the *TUE* process by the *UCI* shall comply with the International Standard for the Protection of Privacy and Personal Information.

9.2 A *Rider* 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 the members of the *TUEC* with authority under these regulations 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 *TUE* applications;
- b. for the *Rider*’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 *Rider*’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 *Rider*.

*[Comment to 9.2: Prior to collecting Personal Information or obtaining consent from a *Rider*, the *UCI* shall communicate to the *Rider* 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 *UCI* 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 *Rider* and physician(s) involved in the *Rider*’s care.

- b. All details of the application, including the name of the physician(s) involved in the process.

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

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