

**UCI REGULATIONS
FOR
THERAPEUTIC USE EXEMPTIONS
("UCI TUER")**

Version entering into force on 1 January 2021

UCI Anti-Doping Regulations

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

1.0 Introduction and Scope

The *UCI* Regulations for Therapeutic Use Exemptions (***UCI TUER***) are mandatory regulations supplementing the *UCI* Anti-Doping Regulations (***UCI ADR***).

The purpose of the *UCI TUER* 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 the *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 one *Anti-Doping Organization* recognized 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 the *UCI TUER* that are defined terms from the *UCI ADR* are italicized. Terms that are defined in the *UCI TUER* or another Regulations are underlined.

2.0 *UCI ADR* Provisions

The following articles in the 2021 *UCI ADR* are directly relevant to the *UCI TUER*:

- Article 4.4 *Therapeutic Use Exemptions ("TUEs")*.
- Article 13.4 Appeals Relating to *TUEs*.

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3.0 Definitions and Interpretation

3.1 Defined terms from the 2021 UCI ADR that are used in the UCI TUER

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, establishes in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* or evidence of the *Use* of a *Prohibited Method*.

Anti-Doping Organization: WADA or 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*, 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).

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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 Event Period*. However, for the purpose of the *Prohibited List*, *In-Competition* is the period commencing at 11:59 p.m. on the day 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*.

[Comment to In-Competition: Having a universally accepted definition for In-Competition provides greater harmonization among Riders across all sports, eliminates or reduces confusion among Riders about the relevant timeframe for In-Competition Testing, avoids inadvertent Adverse Analytical Findings in between Competitions during an Event and assists in preventing any potential performance enhancement benefits from Substances prohibited Out-of-Competition being carried over to the Competition period.]

International Event: 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*.

For the purpose of Article 5.3 UCI ADR exclusively, *International Events* are *Events* for which the UCI has *Testing* responsibility and are referred to as “*UCI International Events*”. *UCI International Events* are defined annually by the UCI. The list of such *UCI International Events* is communicated to the relevant *Anti-Doping Organizations* before the start of the season and whenever required.

International-Level Rider: *Riders* who compete in sport at the international level, as defined in the Introduction of the UCI ADR.

International Standard: A standard adopted by WADA in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any *Technical Documents* issued pursuant to the *International Standard*.

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*, manage test results and conduct *Results Management* 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.

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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 to Possession: Under this definition, anabolic 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 Rider did not have exclusive control over the car, the Rider knew about the anabolic steroids and intended to have control over them. Similarly, in the example of anabolic 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 them. 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*.

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Rider: Any *Person* subject to the *UCI ADR* who competes in the sport of cycling 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 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 elected to exercise its authority to test and who competes below the international or national level, then the *Consequences* set forth in the *Code* 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 a *Rider*.

[Comment to Rider: Individuals who participate in sport may fall in one of five categories: 1) International-Level Rider, 2) National-Level Rider, 3) individuals who are not International or National-Level Riders but over whom the International Federation or National Anti-Doping Organization has chosen to exercise authority, 4) Recreational Rider, and 5) individuals over whom no International Federation or National Anti-Doping Organization has, or has chosen to, exercise authority. 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.]

Recreational Rider: A natural *Person* who is so defined by the relevant *National Anti-Doping Organization*; provided, however, the term shall not include any *Person* who is or was contracted to a *UCI* registered Team at the time of the anti-doping rule violation or within the five (5) years prior to committing any anti-doping rule violation, has been an *International-Level Rider* (as defined by each International Federation consistent with the *International Standard for Testing and Investigations*) or *National-Level Rider* (as defined by each *National Anti-Doping Organization* consistent with the *International Standard for Testing and Investigations*), has represented any country in an *International Event* in an open category or has been included within any *Registered Testing Pool* or other whereabouts information pool maintained by any International Federation or *National Anti-Doping Organization*.

[Comment to Recreational Rider: The term “open category” is meant to exclude competition that is limited to junior or age group categories.]

Registered Testing Pool: The pool of highest-priority *Rider* 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 5.5 and the *International Standard for Testing and Investigations*.

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Results Management: The process encompassing the timeframe between notification as per Article 5 of the *International Standard for Results Management*, or in certain cases (e.g., *Atypical Finding, Rider Biological Passport, Whereabouts Failure*), such pre-notification steps expressly provided for in Article 5 of the *International Standard for Results Management*, through the charge until the final resolution of the matter, including the end of the hearing process at first instance or on appeal (if an appeal was lodged).

Sample or Specimen: Any biological material collected for the purposes of *Doping Control*.

[Comment to Sample or Specimen: It has sometimes been claimed that the collection of blood Samples violates the tenets of certain religious or cultural groups. It has been determined that there is no basis for any such claim.]

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

Testing Pool: The tier below the *Registered Testing Pool* which includes *Riders* from whom some whereabouts information is required in order to locate and *Test* the *Rider Out-of-Competition*.

Therapeutic Use Exemption (TUE): A *Therapeutic Use Exemption* allows a *Rider* with a medical condition to use a *Prohibited Substance* or *Prohibited Method*, but only if the conditions set out in Article 4.4 and the *International Standard for Therapeutic Use Exemptions* are met.

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 Defined terms from the *International Standard* for the Protection of Privacy and Personal Information

Personal Information: Information, including without limitation Sensitive Personal Information, relating to an identified or identifiable *Participant* or other *Person* whose information is Processed solely in the context of an *Anti-Doping Organization's Anti-Doping Activities*.

[Comment to Personal Information: It is understood that Personal Information includes, but is not limited to, information relating to a Rider's name, date of birth, contact details and sporting affiliations, whereabouts, designated TUEs (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,

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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 International Standard for the entire duration of its Processing, irrespective of whether the relevant individual remains involved in organized sport.]

Processing (and its cognates, **Process** and **Processed**): Collecting, accessing, retaining, storing, disclosing, transferring, transmitting, amending, deleting or otherwise making use of Personal Information.

3.3 Defined terms specific to the *UCI TUE*R

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 *TUE*s.

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

3.4 Interpretation

3.4.1 The official text of the *UCI TUE*R shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

3.4.2 Like the *UCI ADR*, the *UCI TUE*R have been drafted giving consideration to the principles of proportionality, human rights, and other applicable legal principles. It shall be interpreted and applied in that light.

3.4.3 The comments annotating various provisions of the *UCI TUE*R shall be used to guide its interpretation.

3.4.4 Unless otherwise specified, references to Sections and Articles are references to Sections and Articles of the *UCI TUE*R.

3.4.5 Where the term "days" is used in these Regulations, it shall mean calendar days unless otherwise specified.

3.4.6 The Annexes to the *UCI TUE*R have the same mandatory status as the rest of these Regulations.

PART TWO: STANDARDS AND PROCESS FOR GRANTING TUES

4.0 Obtaining a TUE

- 4.1 A Rider who needs to Use a Prohibited Substance or Prohibited Method for Therapeutic reasons must apply for and obtain a TUE under Article 4.2 prior to Using or Possessing the substance or method in question.

However, a Rider may apply retroactively for a TUE (but must still meet the conditions in Article 4.2) if one of any of the following exceptions applies:

- a) Emergency or urgent treatment of a medical condition was necessary;
- b) There was insufficient time, opportunity or other exceptional circumstances that prevented the Rider from submitting (or the TUEC to consider) an application for the TUE prior to Sample collection;
- c) Due to national level prioritization of certain sports, the Rider's National Anti-Doping Organization did not permit or require the Rider to apply for a prospective TUE (see comment to Article 5.1);
- d) If the UCI chooses to collect a Sample from an Rider who is not an International-Level Rider or National-Level Rider, and that Rider is Using a Prohibited Substance or Prohibited Method for Therapeutic reasons, the UCI must permit the Rider to apply for a retroactive TUE; or
- e) The Rider Used Out-of-Competition, for Therapeutic reasons, a Prohibited Substance that is only prohibited In-Competition.

[Comment to Articles 4.1(c), (d) and (e): 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 4.2, in case an application for a retroactive TUE is necessary following Sample collection.]

[Comment to Article 4.1(e): This seeks to address situations where, for Therapeutic reasons, a Rider Uses a substance Out-of-Competition that is only prohibited In-Competition, but there is a risk that the substance will remain in his/her system In-Competition. In such situations, the UCI must permit the Rider to apply for a retroactive TUE (where the Rider has not applied in advance). This also seeks to prevent the UCI from having to assess advance TUE applications that may not be necessary.]

- 4.2 A Rider may be granted a TUE if (and only if) he/she can show, on the balance of probabilities, that each of the following conditions is met:

- a) The Prohibited Substance or Prohibited Method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence.

[Comment to Article 4.2(a): The Use of the Prohibited Substance or Prohibited Method may be part of a necessary diagnostic investigation rather than a treatment per se.]

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- b) The Therapeutic Use of the *Prohibited Substance* or *Prohibited Method* will not, on the balance of probabilities, 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 medical condition.

[Comment to Article 4.2(b): A Rider's normal state of health will need to be determined on an individual basis. A normal state of health for a specific Rider is their state of health but for the medical condition for which the Rider is seeking a TUE.]

- c) The *Prohibited Substance* or *Prohibited Method* is an indicated treatment for the medical condition, and there is no reasonable permitted Therapeutic alternative.

[Comment to Article 4.2(c): The physician must explain why the treatment chosen was the most appropriate, e.g. based on experience, side-effect profiles or other medical justifications, including, where applicable, geographically specific medical practice, and the ability to access the medication. Further, it is not always necessary to try and fail alternatives before using 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 Article 4.2: The WADA documents titled "TUE Physician Guidelines", posted on WADA's website, should be used to assist in the application of these criteria in relation to particular medical conditions.

The granting of a TUE is based solely on consideration of the conditions set out in Article 4.2. It does not consider whether the Prohibited Substance or Prohibited Method is the most clinically appropriate or safe, or whether its Use is legal in all jurisdictions.

When the UCI or Major Event Organization TUEC is deciding whether or not to recognize a TUE granted by another Anti-Doping Organization (see Article 7), and when WADA is reviewing a decision to grant (or not to grant) a TUE (see Article 8), the issue will be the same as it is for a TUEC that is considering an application for a TUE under Article 6, i.e., has the Rider demonstrated on the balance of probabilities that each of the conditions set out in Article 4.2 is met?]

- 4.3** In exceptional circumstances and notwithstanding any other provision in this *UCI TUE*, a *Rider* may apply for and be granted retroactive approval for their Therapeutic Use of a *Prohibited Substance* or *Prohibited Method* if, considering the purpose of the *UCI ADR*, it would be manifestly unfair not to grant a retroactive *TUE*. For *International-Level Riders* and *National-Level Riders*, the *UCI* may grant a *Rider's* application for a retroactive *TUE* pursuant to this Article only with the prior approval of *WADA* (and *WADA* may in its absolute discretion agree with or reject the *UCI's* decision).

For *Riders* who are not *International-Level Riders* or *National-Level Riders*, the relevant *Anti-Doping Organization* may grant a *Rider's* application for a retroactive *TUE* pursuant to this Article without first consulting *WADA*; however, *WADA* may at any time review an *Anti-Doping Organization's* decision to grant a retroactive *TUE* pursuant to this Article, and may in its absolute discretion, agree with or reverse the decision.

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Any decision made by WADA, the UCI and/or an *Anti-Doping Organization* under this Article may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.

All decisions of an *Anti-Doping Organization* under this Article 4.3, whether granting or denying a TUE, must be reported through ADAMS in accordance with Article 5.3.

[Comment to Article 4.3: For the avoidance of doubt, retroactive approval may be granted under Article 4.3 even if the conditions in Article 4.2 are not met (although satisfaction of such conditions will be a relevant consideration). Other relevant factors might include the reasons why the Rider did not apply in advance; the Rider's experience; whether the Rider declared the Use of the substance or method on the Doping Control form; and the recent expiration of the Rider's TUE. In making its decision, WADA may, at its discretion, consult with a member(s) of a WADA TUEC.]

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5.0 TUE Responsibilities of the UCI

- 5.1** Article 4.4 of the *UCI ADR* specifies (a) the *UCI's* authority to make *TUE* decisions with respect to *International Level Riders* or participation to *International Event* ; (b) how *TUE* decisions granted by *National Anti-Doping Organization* 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 *UCI* shall establish a TUEC to consider whether applications for grant or recognition of *TUEs* meet the conditions set out in Article 4.2.
- a) TUECs should include at least three (3) physicians with experience in the care and treatment of *Riders* and a sound knowledge of clinical, sports and exercise medicine. In cases where specific expertise is required (for example, for *Riders* with impairments where the substance or method pertains to the *Rider's* impairment), at least one (1) TUEC member or expert should possess such expertise. One (1) physician member should act as chair of the TUEC.
- b) In order to ensure impartiality of decisions, all members of the TUEC must sign a conflict of interest and confidentiality declaration.
- 5.3** The *UCI* 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* as soon as possible and in any event within twenty-one (21) days of receipt of the decision. A decision to deny a *TUE* shall include an explanation of the reason(s) for the denial. In respect of *TUEs* granted, the information reported shall include (in English or French):
- a) Whether the *Rider* was permitted to apply for a *TUE* retroactively under Article 4.1 and an explanation of the reason(s) why, or whether the *Rider* was permitted to apply for and was granted a *TUE* retroactively under Article 4.3 and an explanation of the reason(s) why;
- b) The approved substance or method, the dosage(s), frequency, route of *Administration* permitted, the duration of the *TUE* (and, if different, the duration of prescribed treatment), and any conditions imposed in connection with the *TUE*; and
- c) The *TUE* application form and the relevant clinical information establishing that the Article 4.2 conditions have been satisfied in respect of such *TUE* (for access only by *WADA*, the *Rider's National Anti-Doping Organization* and *UCI*, and the *Major Event Organization* organizing an *Event* in which the *Rider* wishes to compete).

[Comment to Article 5.3: The TUE application form may be translated into other languages by the UCI, but the original English or French text must remain on the form, and an English or French translation of the content must be provided.

The full medical file, including diagnostic tests, laboratory results and values must be provided, but need not be translated into English or French. However, a translated summary of all the key information (including key diagnostic tests) must be entered into ADAMS, with sufficient information to clearly establish the diagnosis. It is strongly

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suggested that the summary be prepared by a physician or other person with adequate medical knowledge, in order to properly understand and summarize the medical information. More detailed/full translations may be required by the UCI or WADA, upon request.]

- 5.4** The *UCI* shall publish and keep updated a notice on its website that sets out clearly (1) which *Riders* 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).
- 5.5** If a *National Anti-Doping Organization* grants a *TUE* to a *Rider* and the *Rider* subsequently becomes an *International-Level Rider* or competes in an *International Event*, the *TUE* will not be valid unless and until the *UCI* recognizes that *TUE* in accordance with Article 7.0. If the *UCI* grants a *TUE* to a *Rider* and the *Rider* then competes in an *International Event* organized by a *Major Event Organization*, the *TUE* will not be valid unless and until the relevant *Major Event Organization* recognizes that *TUE* in accordance with Article 7.0. As a result, if the *UCI* or *Major Event Organization* (as applicable) declines to recognize that *TUE*, then (subject to the *Rider'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 the *UCI* or *Major Event Organization*.

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6.0 TUE Application Process

- 6.1 A *Rider* who needs a *TUE* should apply as soon as possible. For substances prohibited *In-Competition* only, the *Rider* should apply for a *TUE* at least thirty (30) days before his/her next *Competition*, unless it is an emergency or exceptional situation.
- 6.2 The *Rider* shall apply to the *UCI* using the *TUE* application form.
- 6.3 A *Rider* may not apply to more than one (1) *Anti-Doping Organization* for a *TUE* for the *Use* of the same *Prohibited Substance* or *Prohibited Method* for the same medical condition. Nor may a *Rider* have more than one (1) *TUE* at a time for the *Use* of the same *Prohibited Substance* or *Prohibited Method* for the same medical condition (and any such new *TUE* will supersede the previous *TUE*, which should be cancelled by the relevant *Anti-Doping Organization*).
- 6.4 The *Rider* should submit the *TUE* application form to the *UCI* via *ADAMS* or otherwise specified by the *UCI*.

The form must be completed legibly, in English or French.

The form must be signed by the treating physician and accompanied by 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 Article 6.4: The information submitted in relation to the diagnosis and treatment should be guided by the relevant WADA documents posted on WADA's website.]

- 6.5 The *Rider* should keep a complete copy of the *TUE* application form and of all materials and information submitted in support of that application.
- 6.6 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 *Rider* for completion and re-submission.
- 6.7 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.
- 6.8 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*.
- 6.9 A decision to grant a *TUE* shall be taken unanimously by the three (3) members of the TUEC. In the event of a lack of unanimity amongst the three members of the TUEC, the *TUE* will be denied.
- 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 twenty-one (21)

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days of receipt of a complete application. Where a *TUE* application is made in 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 in writing to the *Rider* and must be made available to *WADA* and to other *Anti-Doping Organizations* via *ADAMS*, in accordance with Article 5.3.
- 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.

[Comment to Article 6.12: Where applicable, the duration of validity should be guided by the WADA documents titled "TUE Physician Guidelines".]

- 6.13** A *TUE* will be withdrawn prior to expiry if the *Rider* 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.
- 6.14** 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*, in accordance with Article 5.1.1.1 of the *UCI Results Management Regulations* 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.
- 6.15** In the event that, after their *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 contact the *UCI*, who will then determine whether the *Rider* needs to 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.

[Comment to Article 6.15: It is recognized that for certain medical conditions, dosages may fluctuate, particularly during the early stages of the establishment of a treatment regime or for a condition such as insulin-dependent diabetes. Such potential fluctuations should be accounted for in the TUE. However, in the event of a change that is not accounted for in the TUE, the Rider must contact the relevant Anti-Doping Organization to determine whether a new TUE is required.]

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7.0 TUE Recognition Process

- 7.1** The *UCI* will recognize *TUEs* granted by other *Anti-Doping Organizations* that satisfy the Article 4.2 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 *UCI*. Instead:
- a) The *UCI* may publish notice on the *UCI* website that it will automatically recognize certain categories of *TUE* decisions made pursuant to *UCI ADR* Article 4.4, provided that such *TUE* decisions have been reported in accordance with Article 5.3. 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* or otherwise specified by the *UCI*. The request should be accompanied by a copy of the *TUE* and the original *TUE* application form and supporting materials referenced at Article 6.4 (unless the *Anti-Doping Organization* that granted the *TUE* has already made the *TUE* and supporting materials available via *ADAMS*, in accordance with Article 5.3).
- 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** 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 twenty-one (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 *Rider* and will be made available to *WADA* and to the *Anti-Doping Organizations* via *ADAMS*. A decision not to recognize a *TUE* must include an explanation of the reason(s) for the non-recognition.
- 7.6** If the *UCI* chooses to test a *Rider* who is not an *International-Level Rider*, it must recognize a *TUE* granted by that *Rider's National Anti-Doping Organization* unless the *Rider* is required to apply for recognition of the *TUE* pursuant to Articles 5.5 and 7.0, i.e. because the *Rider* is competing in an *International Event*.

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8.0 Review of *TUE* Decisions by *WADA*

- 8.1** Article 4.4.8 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 4.1 and 4.2 conditions. In relation to the Article 4.2 conditions, *WADA* shall establish a *WADA TUEC* that meets the requirements of Article 5.2 to carry out such reviews. In relation to the Article 4.1 conditions, these can be reviewed by *WADA* (which may, at its discretion, consult with a member(s) of a *WADA TUEC*).
- 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 6.4 (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 *Anti-Doping Organization* 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 review the *TUE* decision. Any decision by *WADA* not to review the *TUE* decision is final and may not be appealed. However, the *TUE* decision may still be appealable, as set out in Article 4.4.8 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 Article 4.2 conditions were missing).
- [Comment to Article 8.4: If the UCI refuses to recognize a TUE granted by a National Anti-Doping Organization only because medical tests or other information required to demonstrate satisfaction of the Article 4.2 conditions are missing, the matter should not be referred to WADA. Instead, the file should be completed and re-submitted to the UCI.]*
- 8.5** Where a request for review of a decision of the *UCI* is referred to the *WADA TUEC*, the *WADA TUEC* may seek additional information from the *UCI* and/or the *Rider*, including further studies as described in Article 6.7, and/or it may obtain the assistance of other medical or scientific experts as it deems appropriate.
- 8.6** *WADA* shall reverse any grant of a *TUE* that does not comply with the Article 4.1 and 4.2 conditions (as applicable). 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** *WADA* shall reverse any denial of a *TUE* where the *TUE* application met the Article 4.1 and 4.2 conditions (as applicable), i.e. it shall grant the *TUE*.

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- 8.8** If applicable, *WADA* shall communicate the reasoned decision of the WADA TUEC promptly to the *Rider* and to his/her *National Anti-Doping Organization* and the *UCI* (and, if applicable, the *Major Event Organization*).

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9.0 Confidentiality of Information

- 9.1** The Processing of Personal Information during the *TUE* process by the *UCI* shall comply with the *International Standard* for the Protection of Privacy and Personal Information. The *UCI* shall ensure that it has a valid legal authority or basis for such Processing, in accordance with the *International Standard* for the Protection of Privacy and Personal Information and applicable laws.
- 9.2** The *UCI* shall communicate in writing the following information to *Riders* as well as any other relevant information in accordance with Article 7.1 of the *International Standard* for the Protection of Privacy and Personal Information in connection with a *Rider's* application for the grant or recognition of a *TUE*:
- a) All information pertaining to the application will be transmitted to members of all TUECs with authority under the *UCI TUEC* 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) The *Rider* must authorize their physician(s) to release to any relevant TUEC upon request any health information that any such TUEC deems necessary in order to consider and determine the *Rider's* application; and
 - c) The decision on the application will be made available to all *Anti-Doping Organizations* with *Testing* authority and/or *Results Management* authority over the *Rider*.

[Comment to Article 9.2: Where Anti-Doping Organizations are relying upon the Rider's consent to Process Personal Information in connection with the TUE process, the Rider applying for the grant or recognition of a TUE shall provide written and explicit consent to the foregoing.]

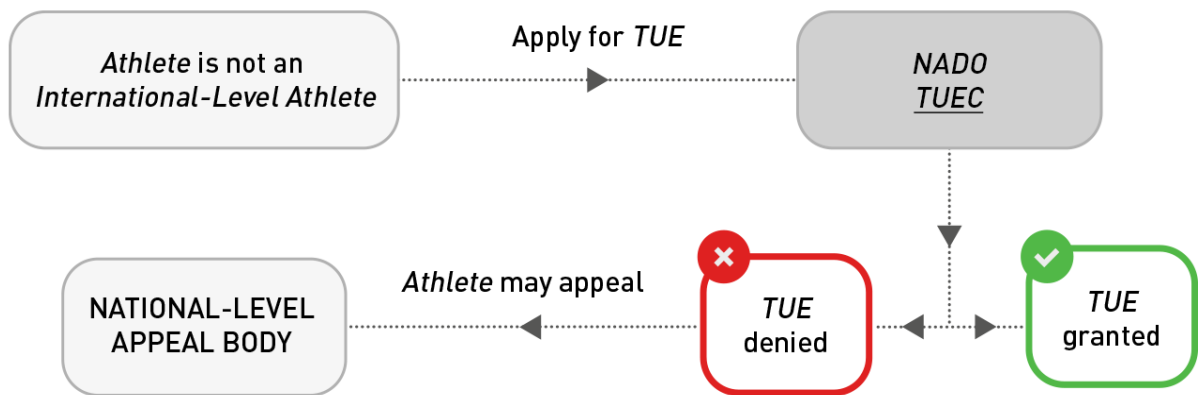
- 9.3** The *TUE* application shall be dealt with in accordance with the principles of strict medical confidentiality. The members of all relevant TUECs, any consulted independent experts and the relevant staff of the *UCI* shall conduct all of their activities relating to the process in strict confidence and shall sign appropriate confidentiality agreements. In particular, they shall keep the following information confidential:
- a) All medical information provided by the *Rider* and physician(s) involved in the *Rider's* care; and
 - 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 a TUEC to obtain any health information on their behalf, the *Rider* shall notify their physician 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.

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- 9.5** The *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.

ANNEX 1: UCI ADR ARTICLE 4.4 FLOWCHART

1. **TUE procedure if Rider is not an International-Level Rider and when the need for TUE does not arise in connection with the Rider's participation in an International Event**



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2. **TUE procedure if the Rider is an *International-Level Rider* (and so subject to the UCI's TUE requirements) when need for TUE arises, or if the Rider is not an *International-Level Rider* but the need for TUE arises in connection with the Rider's participation in an *International Event*.**

