

**SUMMARY OF CHANGES
INTERNATIONAL STANDARD ON THERAPEUTIC USE EXEMPTIONS
APRIL 2019**

Code changes

Code Article 4.4.3.1

At present, if an IF refuses to recognize a NADO TUE (and WADA does not overturn that decision), the NADO TUE becomes invalid at all levels. It is proposed to change this such that the matter is instead remitted back to the NADO for re-evaluation, with the possibility of re-granting the TUE at a national level only, assuming that the NADO considers that the ISTUE criteria are met.

Definitions

The TUE definition was clarified.

ISTUE changes

4.0 Obtaining a TUE

A restructuring of 4.1- 4.3 was undertaken. To avoid confusion often experienced in the previous version, it is now constructed to create a step-by-step pathway. If the athlete needs a TUE, they apply prospectively and proceed directly to 4.2 (critical criteria for obtaining a TUE). However, if this is not the case they need to fulfill one of the criteria in 4.1 (retroactive criteria) before they can proceed to 4.2.

4.3 is a new provision, to reflect current realities. It is a specific exemption where it would be manifestly unfair not to grant a retroactive TUE (even where all of the criteria in Article 4.2 may not be met). This exemption will continue to be reserved to truly exceptional circumstances, and will require the prior approval of WADA.

- **4.1** (prior 4.3): now deals with the criteria required to **apply** for a TUE retroactively. Once one of these conditions is fulfilled, and the athlete has submitted their application, the process moves to 4.2. If an athlete is applying prospectively, 4.1 is not relevant and the process automatically begins at 4.2.

- **4.1a** “treatment of an acute medical condition” was replaced with “urgent treatment”.
 - **4.1b** Reworded but essentially the same.
 - **4.1c** Reworded and expanded to better explain the clause.
 - **4.1d** Deals with non-ILA and non NLA right to apply for a retroactive TUE if tested.
 - **4.1e** New inclusion addressing situations where, for therapeutic reasons, an Athlete Uses a substance Out-of-Competition that is only prohibited In-Competition, but there is a risk that the substance will remain in their system In-Competition.
- **4.2** (prior 4.1): these are the critical criteria for obtaining a TUE. There was some further clarification of these criteria.
 - **4.2a** the concept of a diagnosis being an essential component of the application has been strengthened, and comments/examples have been added to provide additional clarification.
 - Removed the reference to acute or chronic condition.
 - Clarified that the use of a Prohibited Substance may be as part of a diagnostic investigation and not only a treatment.
 - **4.2b** “highly unlikely” replaced with “on the balance of probabilities”. Also an improved explanation of assessment of an athlete’s normal state of health is included.
 - **4.2c** the use of permitted alternative medications was clarified in the comment, in particular taking into account different practices in different geographical regions.
 - It was made clear that the grant of a TUE is based solely on consideration of the conditions set out in Article 4.2 and not whether the Prohibited Substance or Prohibited Method is the most appropriate or safe, or legal in all jurisdictions.
 - The relevant WADA TUEC documents are also now referenced.
 - **4.3** (4.3d on fairness is now a new stand-alone 4.3): as mentioned above, this would be for rare and exceptional situations. Now a retroactive TUE may be granted when it does not fulfill all of the 4.2 criteria. WADA will have oversight of these TUEs and ADOs will need to gain WADA’s approval before grant or denial. WADA’s decision is final.

5.0 TUE Responsibilities of ADOs

- **5.1:** clarification for NADOs about which athletes’ TUEs they need to assess prospectively.

- **5.2:** clarified that if an athlete already has a valid NADO TUE and is not an international athlete, the TUE remains valid globally and does not require to be formally recognized by another NADO.
- **5.3:** clarification that the fulfilment of the conditions set out in Articles 4.1 and 4.3 may be determined by the relevant Anti-Doping Organization in consultation with a member(s) of the TUEC. Further expansion on who a TUEC should comprise of.
- **5.5:** it was emphasized that ADOs must fully explain on what grounds a TUE was granted/denied and how they must report decisions in ADAMS within 21 days.
- **5.5c:** there was a clarification on what needs to be translated into English or French; diagnosis, dosage, as well as a clear summary of the medical condition and diagnostic tests.

6.0 TUE Application Process

- **6.0:** there was a need for more clarity on who an athlete's NADO is for the purposes of applying for a TUE: for athletes who are not International-Level Athletes, they should first contact the National Anti-Doping Organization of the country where the sport organization for which they compete (or with which they are a member or licence holder) is based or, if different, the country in which they reside. If that National Anti-Doping Organization considers that the Athlete does not fall within its TUE jurisdiction, the Athlete should contact the National Anti-Doping Organization of their country of citizenship (if different).
- **6.3:** a new article explaining clearly that an athlete may only apply to one ADO at a time for a TUE for the same medical condition. Nor may an athlete have more than one TUE for the same medical condition at the same time.
- **6.4:** extra guidance for the athlete on his TUE application and referencing the WADA TUEC guidelines.

Comment to 6.14: clarification on changing of dosages and when one should alert the ADO. The comment to 6.14 expands on these initial treatments dosage fluctuations and gives an example of insulin for diabetes.

7.0 TUE Recognition Process

- **7.6:** clarification that if an IF chooses to test an Athlete who is not an ILA, it must recognize a TUE granted by that Athlete's NADO unless the Athlete is required to apply for recognition of the TUE pursuant to Articles 5.8 and 7.0 i.e. because the Athlete is competing in an International Event (this provision has been moved across from the Code into the ISTUE).

8.0 Review of TUE Decisions by WADA

- **8.1:** inclusion of how WADA will assess the updated 4.1 and newly created 4.3 article.
- **Comment to 8.4:** a new inclusion to provide extra clarification to 8.4. If an International Federation 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 International Federation.

9.0 Confidentiality of Information

- Several edits were made to align this section with the new International Standard for the Protection of Privacy and Personal Information.
- **9.2:** Update on how ADOs shall communicate information regarding the application, health of the Athlete, decision on the application to Athletes as well as any other relevant information in accordance with article 7.1 of the ISPPPI.

Annex 1

- The flow charts have been re-ordered and updated to follow the order in the Code.