



**WORLD CONFERENCE
ON DOPING IN SPORT**
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SESSION 12

The International Standard for Therapeutic Use Exemptions (ISTUE)

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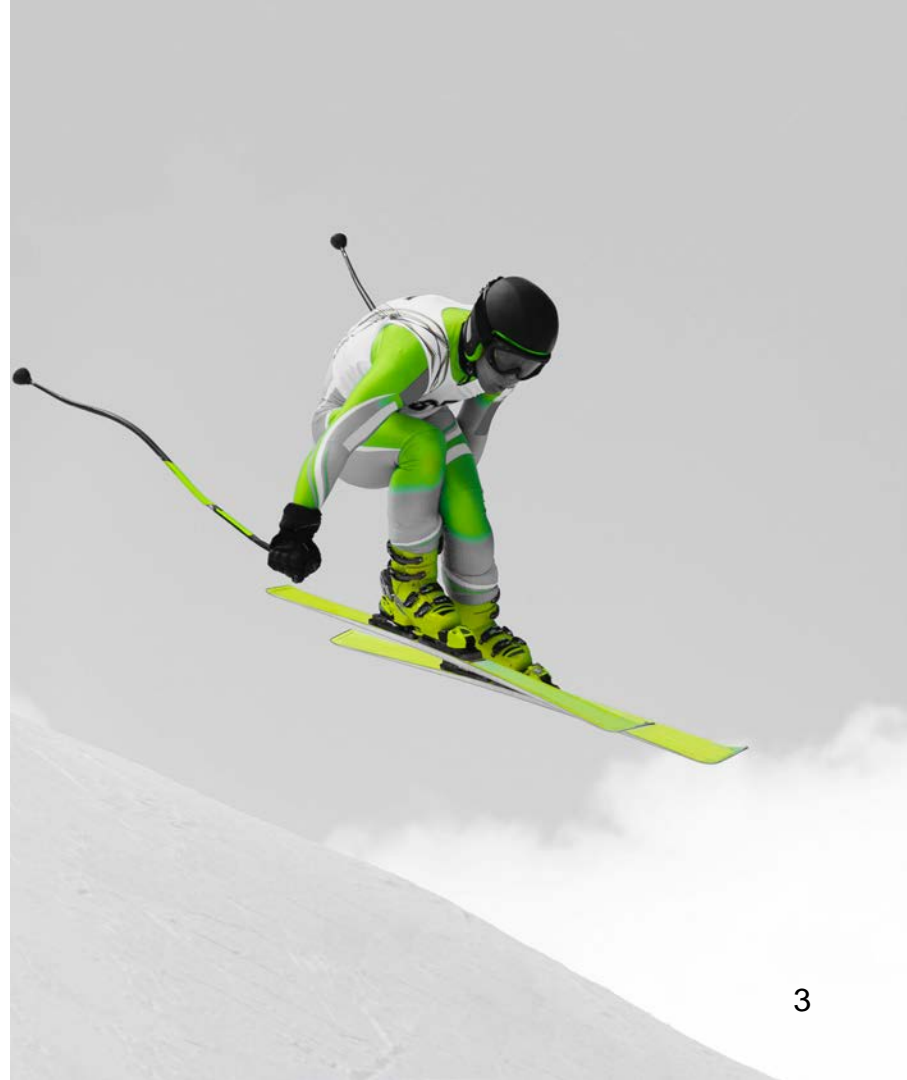
Overview of key proposed changes



- Article 4 (obtaining a TUE) restructured and clarified
- Expanded discretion to grant retroactive TUEs
- How to determine an athlete's National Anti-Doping Organization (NADO) for TUE purposes?
- Clarify that NADO TUEs are valid at national level on a global basis

Overview of key proposed changes (Cont'd)

- Change to position where an IF refuses to recognize a NADO TUE
 - The TUE could still remain valid at national level
- TUE reporting requirements in ADAMS tightened up



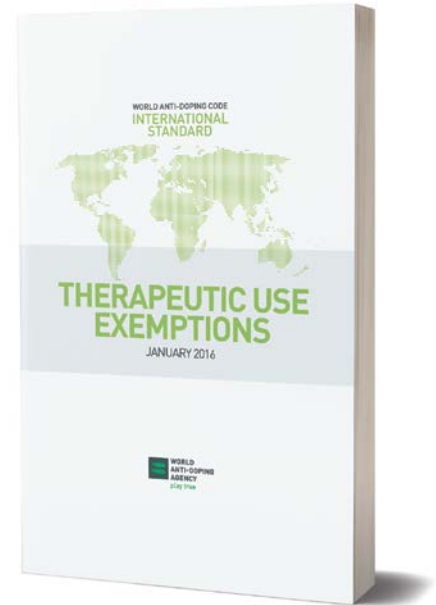


**Key proposed changes:
TUE definition**

Definition of a TUE

- **TUE definition:**

A Therapeutic Use Exemption allows an Athlete 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





**Key proposed changes:
Obtaining a TUE (Articles 4.1- 4.3)**

Obtaining a TUE – Article 4.1



- **Art. 4.1** An athlete must obtain a TUE under Article 4.2 prior to using or possessing the substance/method unless one of the following applies:
 - a) Emergency or urgent treatment of a medical condition was necessary
 - b) Insufficient time, opportunity or other exceptional circumstances that prevented submission/consideration of a TUE application prior to sample collection
 - c) Rules did not allow/require the athlete to apply prospectively for a TUE
 - d) Non-international (ILA) or non-national level (NLA) athletes who are tested
 - e) Athlete used out-of-competition a substance that is only prohibited in-competition



Obtaining a TUE – Article 4.2 a)



- **Art. 4.2** An athlete may be granted a TUE 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, ~~such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.~~

[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.]

Obtaining a TUE – Article 4.2 b)



- 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 Athlete's normal state of health following the treatment of the medical condition.

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

Obtaining a TUE – Article 4.2 c)



- c) ~~There is no reasonable Therapeutic alternative to the Use of~~ 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.]

Obtaining a TUE – Article 4.2 d)

- 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.



Obtaining a TUE – Article 4.2 comments



- **Comment to Art. 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.

Obtaining a TUE – Article 4.3



- **Art. 4.3** In exceptional circumstances (...) an Athlete may apply for and be granted retroactive approval for his/her Therapeutic Use of a Prohibited Substance or Prohibited Method if, considering the purpose of the Code, it would be **manifestly unfair not to grant a retroactive TUE**.
- For ILA/NLA, an Anti-Doping Organization (ADO) may grant an Athlete'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 ADO's decision).
- For non-ILA/NLA, the relevant ADO may grant an Athlete's application for a retroactive TUE pursuant to this Article **without first consulting WADA**; however, WADA **may at any time review an ADO's decision** to grant a retroactive TUE pursuant to this Article, and may in its absolute discretion agree with **or reverse** the decision.

Obtaining a TUE – Article 4.3 (Cont'd)



- Any decision made by WADA and/or an ADO under this Article may not be challenged either as a defense to proceedings for an Anti-Doping Rule Violation (ADRV), 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 5.5.

[Comment to 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 Athlete did not apply in advance; the Athlete's experience; whether the Athlete declared the Use of the substance or method on the Doping Control Form; and the recent expiration of the Athlete's TUE. In making its decision, WADA may, at its discretion, consult with a member(s) of a WADA TUE Committee (TUEC).]



**Key proposed changes:
TUE responsibilities of NADOs**

TUE responsibilities of NADOs

[Comment to Art. 5.1: (...) Code Article 4.4.2 specifies the authority of a National Anti-Doping Organization to make TUE decisions in respect of Athletes who are not International-Level Athletes. In case of dispute as to which National Anti-Doping Organization should deal with the TUE application of an Athlete who is not an International-Level Athlete, WADA will decide. WADA's decision will be final and not subject to appeal.]



TUE responsibilities of NADOs (Cont'd)



- **NADO TUEs are valid at national level on a global basis:**


Art. 5.2: For the avoidance of doubt, when a National Anti-Doping Organization grants a TUE to an Athlete, that TUE is valid at national level on a global basis and does not need to be formally recognized by other National Anti-Doping Organizations under Article 7.0 (for example, if an Athlete is granted a TUE by his/her National Anti-Doping Organization and then trains or competes in the country of another National Anti-Doping Organization, that TUE will be valid if the Athlete is then tested by such other National Anti-Doping Organization)

TUE responsibilities of NADOs (Cont'd)



- **Code Article 4.4.3.1:**

[If the IF refuses to recognize the TUE] (...) If the matter is not referred to WADA for review **within the 21-day deadline, the Athlete's National Anti-Doping Organization must determine whether the original TUE granted by that National Anti-Doping Organization **should nevertheless remain valid for national-level Competition and Out-of-Competition Testing**** (provided that the Athlete ceases to be an International-Level Athlete and does not participate in international-level Competition). Pending the National Anti-Doping Organization's decision, the TUE remains valid for national-level Competition and Out-of-Competition Testing (but is not valid for international-level Competition).

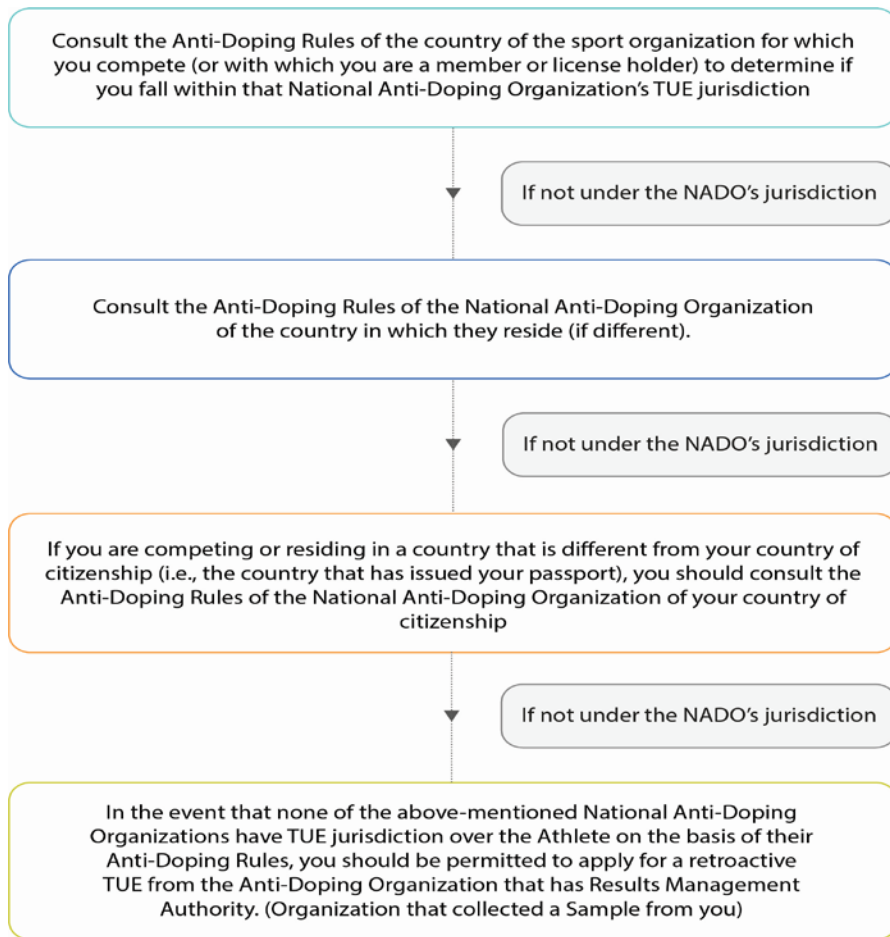


**Key proposed changes:
TUE application process**

TUE application process – Article 6.0



- **Comment to Art. 6.2:** In certain situations, an Athlete may not know which NADO they should apply to for a TUE. In such circumstances, the Athlete should consult the NADO of the **country of the sport organization for which they compete** (or with which they are a member or license holder), to determine if they fall within that NADO's TUE jurisdiction, according to their rules.
- If that NADO refuses to evaluate the TUE application because the Athlete does not fall within its TUE jurisdiction, the Athlete should consult the anti-doping rules of the NADO of the **country in which they reside** (if different).
- If the Athlete still does not fall within that NADO's TUE jurisdiction, the Athlete should then consult the anti-doping rules of the NADO of their **country of citizenship** (if different from where they compete or reside).
- Athletes may contact any of the above-referenced NADOs for assistance with determining whether the NADO has TUE jurisdiction. In the event that none of the above-mentioned NADOs have TUE jurisdiction, where there is an Adverse Analytical Finding the Athlete should ordinarily be permitted to apply for a retroactive TUE from the **ADO that has Results Management authority**. See also the summary flowcharts on “Where to Apply?” in the medical section of WADA's website.



TUE application process – Article 6.3



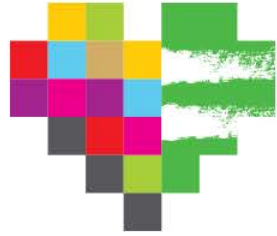
- **Art. 6.3** An Athlete may not apply to more than one Anti-Doping Organization for a TUE for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition. Nor may an Athlete have more than one TUE at a time for the Use of the same Prohibited Substance or Prohibited 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).

TUE application process – Article 6.14



- **Art. 6.14** If the Athlete requires a materially different dosage, frequency, route or duration of Administration of the Prohibited Substance or Prohibited Method to that specified in the TUE, he/she must contact the relevant ADO, who will then determine whether the Athlete needs to apply for a new TUE. (...)

*[Comment: 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 Athlete must contact the relevant ADO to determine whether a new TUE is required.]*



play true