

PART TWO: STANDARDS AND PROCESS FOR GRANTING TUES

4.0 Obtaining a TUE

- 4.1 An *Athlete* 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, an *Athlete* 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 *Athlete* 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 *Athlete's National Anti-Doping Organization* did not permit or require the *Athlete* to apply for a prospective TUE (see comment to Article 5.1);
- d) If an *Anti-Doping Organization* chooses to collect a *Sample* from an *Athlete* who is not an *International-Level Athlete* or *National-Level Athlete*, and that *Athlete* is *Using* a *Prohibited Substance* or *Prohibited Method* for Therapeutic reasons, the *Anti-Doping Organization* must permit the *Athlete* to apply for a retroactive TUE; or
- e) The *Athlete Used Out-of-Competition*, for Therapeutic reasons, a *Prohibited Substance* that is only prohibited *In-Competition*.

[Comment to Article 4.1(c), (d) and (e): Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.2, 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, 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. In such situations, the Anti-Doping Organization must permit the Athlete to apply for a retroactive TUE (where the Athlete has not applied in advance). This also seeks to prevent Anti-Doping Organizations from having to assess advance TUE applications that may not be necessary.]

- 4.2 An *Athlete* 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.]

- 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.]

- 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 an International Federation 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 Athlete 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 *International Standard for Therapeutic Use Exemptions*, 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 *International-Level Athletes* and *National-Level Athletes*, an *Anti-Doping Organization* 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 *Anti-Doping Organization's* decision).

For *Athletes* who are not *International-Level Athletes* or *National-Level Athletes*, the relevant *Anti-Doping Organization* 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 *Anti-*