

# 2027 CODE & IS UPDATE PROCESS

# **International Standard for Therapeutic Use Exemptions**

# **Concepts for Consideration and Feedback**

#### **Executive Summary**

The International Standard for Therapeutic Use Exemptions (ISTUE) was created to provide detailed, fair, and understandable regulations for athletes, Anti-Doping Organizations (ADOs), physicians and athlete support personnel (ASP) to follow when situations arise where, due to illness or medical condition, an athlete may require the use of substances or methods that are specifically included in the World Anti-Doping Agency's (WADA) Prohibited List.

It is always in the interest of the sport and anti-doping community to update or upgrade WADA's regulatory documents. The aim is to produce a comprehensive International Standard that upholds the strict ISTUE criteria and protection of clean sport while ensuring that it remains practical and manageable for stakeholders, particularly athletes and ADOs.

The concepts set out below have been identified as key topics for specific consideration and feedback from stakeholders. However, stakeholders should not feel confined to the concepts listed; indeed, comments and suggestions on any topic are welcome.

## Concept #1 - Clarify when a prospective TUE begins

The ISTUE Article 4.0 states that "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."

In the general population, when a patient is prescribed medication from their physician, it would be very unusual not to start their treatment right away. The Code and ISTUE state that athletes must obtain a TUE before starting treatment unless they meet the requirements for a retroactive TUE. If an athlete is using the medication while the Therapeutic Use Exemption Committee (TUEC) is still deliberating, they do so at the risk of an anti-doping rule violation.

Once the TUE is approved, the effective date, based on the wording of the ISTUE, should be the date of the TUEC decision, such that it would not cover any prior use and/or adverse analytical finding. For practical reasons, however, certain ADOs assign the effective date as the date the application was received or when the medication was prescribed (without assessing the criteria for a retroactive TUE).

The ISTUE Drafting Team is looking for feedback and may consider adding or amending an article (or comment) to the ISTUE to clarify when a prospective TUE should begin in these circumstances and, more



generally, whether any mechanism could be introduced to address the practical concerns while mitigating the risk of this issue.

#### Concept #2 – National-level Prioritization

Within the ISTUE, should National Anti-Doping Organizations (NADOs) be allowed to prioritize certain substance categories, not just sports and disciplines (see ISTUE Article 4.1(c) and the comment to ISTUE Article 5.1)?

The ISTUE Drafting Team is considering whether to amend ISTUE Article 4.1(c) to also allow NADOs to prioritize certain substances (in addition to certain sports or disciplines), by only requiring advance TUE applications for certain categories of prohibited substances.

For example, all national level athletes using S1 or S2 substances would have to apply for a TUE in advance, even if their sport is not included in the NADO's "sport prioritization" group. While other national-level athletes using S7 substances, even if included in the NADO's "sport prioritization" group, would not need to apply in advance and can always apply retroactively.

#### Concept #3 – Major Event Organizations (MEOs) Prioritization

The ISTUE Drafting Team is considering whether to expand ISTUE Article 4.1(c) on retroactive TUEs to include MEOs.

There are several MEOs who deal with relatively low-level athletes. This addition would be practical and greatly reduce the burden of work for these organizations.

## Concept #4 – TUEC Membership and Operation

TUECs are an integral part of the TUE process. However, concerns have been raised that the ISTUE does not adequately provide guidance on TUEC establishment and procedures/operations. In an effort to provide requirements and/or guidance to ADOs and create a harmonized approach, the ISTUE Drafting Team is seeking stakeholder feedback and input on the practical considerations relating to this topic.

## Concept #5 - Short term TUEs

The ISTUE Drafting Team is aware that ADOs sometimes approve TUEs for a short term while the TUEC awaits further medical information from medical specialists. This is because TUECs recognize the fact that the athlete very likely suffers from a legitimate medical condition that would result in a longer-term TUE being granted.

This is not expressly provided for in the ISTUE and the Drafting Team is seeking feedback and input on the practical considerations.



### Concept #6 – Recognition Process

The TUE recognition process has on occasion created conflicts between NADOs and International Federations (IFs) in regard to the follow up on certain conditions attached to the TUE.

At present, an IF either must recognize the NADO TUE in full or reject the NADO TUE. To provide fairness to the athletes while maintaining the strengths of the ISTUE, the ISTUE Drafting Team suggests that IFs be allowed to add certain conditions, if necessary, when recognizing TUEs (in the exact same way as if the original TUE application had been made straight to the IF).

The responsibility for monitoring these conditions would be assigned to the IF, although it could be accomplished through the assistance of NADOs.

The ISTUE Drafting Team also seeks feedback from MEOs on whether they should also be allowed to add certain conditions, if necessary.

This change would also need to be reflected in Code Article 4.4.

## Concept #7 – TUE Ownership following Recognition

Once a TUE is recognized (whether automatically or not), all the conditions associated with the TUE should thereafter be monitored by the IF, which has jurisdiction (for example, testosterone monitoring). As mentioned in Concept #6, this could be accomplished with agreement and assistance of a NADO.

To provide clarity and ensure a harmonized approach, the ISTUE Drafting Team is considering including an article explaining that once a TUE is recognized, the IF becomes the 'custodian'.

## Concept #8 - Recognition for a Single Event

Often lower-level athletes may compete in a one-time international-level event. This requires the recognition of their TUE according to most IF rules. Currently a TUE must be recognized for its full duration. This provides an inaccurate view of TUEs associated with international-level athletes. The IF would also become the TUE custodian for the duration of the TUE.

The ISTUE Drafting Team is looking for feedback or proposals on this issue.

## Concept #9 - Consequences

WADA has a responsibility to monitor the global TUE process, not just individual TUEs. There are situations where some ADOs may repeatedly produce poor TUE decisions and/or are not responsive to WADA queries and suggestions.

The ISTUE Drafting Team is seeking feedback on appropriate consequences that would not be part of the compliance process. For example, WADA could extend ISTUE Article 8.8 to discretionary reviews.



### Concept #10 - Lower-level Athletes

Should athletes who are not international or national-level athletes be afforded extra flexibility when the ISTUE regulations are applied?

The ISTUE is fit for purpose for elite athletes, but the question has been raised as to whether it is too onerous for lower-level athletes who, in particular, do not receive the same amount of (if any) formal anti-doping education. Further, avoiding full TUE applications from the broad base of non-elite lower-level athletes who are otherwise subject to Code-compliant anti-doping rules would help to protect limited ADO (and TUEC) resources.

In an effort to provide fairness to lower-level athletes while still promoting the values instilled in the ISTUE, the ISTUE Drafting Team is seeking feedback on the possibility of allowing ADOs the ability to apply different rules to a designated class of lower-level athletes.

#### Concept #11 – Appeal Panels

It is logical that TUE appeal bodies include physicians. The current appeal bodies description is an International Standard for Results Management provision and does not require the presence of a physician on the appeal panel in a TUE case. Indeed, the procedural rules and list of arbitrators of the Court of Arbitration for Sport do not currently seem compatible with the presence of a physician on the panel.

In an effort to harmonize the system for TUE appeal bodies (for national and international-level athletes) and to provide athletes with fair decisions on TUEs (i.e., medical matters), the Drafting Team is considering including further specific requirements in the Code/ISTUE on this matter to ensure that physicians are part of a TUE appeal panel. The ISTUE Drafting Team is seeking feedback from stakeholders on whether such a proposal would be supported.

# Concept #12 – Sanctions for athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE

When there is a clear medical condition and appropriate treatment (i.e., the ISTUE Article 4.2 conditions are fully satisfied), yet the athlete does not meet the requirements for a retroactive TUE for their positive test, concerns have been raised that the sanctions may be excessive and disproportionate.

This topic is also being addressed by the Code Drafting Team (see Concept #4 of the Code Concept Paper). WADA is seeking feedback on this issue from stakeholders.