

2027 CODE & IS UPDATE PROCESS

Stakeholder Consultation Phase: Summary of Major Changes

International Standard for Therapeutic Use Exemptions

Executive Summary

The International Standard for Therapeutic Use Exemptions (ISTUE) was first adopted in 2004 and came into effect on 1 January 2005. It was subsequently amended eight times and updated versions were introduced in 2010, 2011, 2015, 2016, 2019, 2021, and 2023, following consultations with Signatories, public authorities, and other relevant stakeholders.

The ISTUE was created to provide a detailed, fair, and understandable process for athletes, Anti-Doping Organizations (ADOs), physicians and athlete support personnel to follow when situations arise where, due to illness or medical condition, an athlete may require the use of substances or methods that are included in the World Anti-Doping Agency (WADA) Prohibited List. The Therapeutic Use Exemption (TUE) process provides athletes with an opportunity to apply for a TUE when medical treatment is required involving the use of a prohibited substance or prohibited method. This process protects all clean athletes and promotes competition on a level playing field.

The main proposed changes to the ISTUE are consistent with the concepts that received strong stakeholder endorsement during the [Stakeholder Engagement Phase](#). The proposed changes also incorporate additional proposals that emerged during the consultation process with stakeholders and the anti-doping community including:

- The expansion of the retroactive criteria (ISTUE Article 4.1 b));
- The restructuring of the key criteria to grant a TUE under ISTUE Article 4.2 (including the removal of the requirement to trial permitted alternatives);
- The harmonization of TUE Committee (TUEC) operational procedures; and
- Further clarifications on prospective and retroactive TUEs.

When reviewing the proposed changes to the 2027 ISTUE, stakeholders are invited to consider the following:

- Stakeholders will be given the opportunity to offer additional feedback through WADACONnect on those articles where fewer or no substantive changes have been made by the ISTUE Drafting Team.
- The language of the proposed changes in this International Standard should be considered as a starting point for further consultations.
- The numbering of certain articles in this International Standard has changed due to the introduction of new articles.

The following section offers a concise summary of the key changes proposed by the ISTUE Drafting Team.

Article 4.0: Criteria for obtaining a TUE

Article 4.0

The ISTUE Drafting Team has added a new comment to Article 4.0 to recognize that athletes may start treatment using a prohibited substance or method prior to the grant of a TUE. However, they do so at their own risk as they would require a retroactive TUE to cover the use.

Article 4.1 b)

In an effort to be more athlete centered and reduce the occurrence of athletes with legitimate medical conditions failing to get their TUE application evaluated, the ISTUE Drafting Team has amended this article to be less restrictive.

Article 4.2

Article 4.2 has undergone a restructuring and has been simplified to create a more logical flow due to prior and new proposed changes to this section.

- Article 4.2 a): This amended article now solely focuses on the requirement that the athlete has a diagnosed medical condition supported by relevant clinical evidence. The “needed to treat” element is now part of the new 2027 ISTUE Article 4.2 b).
- Article 4.2 b): This article corresponds to 2023 ISTUE Article 4.2 c). However, the requirement to trial permitted alternatives has been removed. The ISTUE Drafting Team has implemented this change to better reflect medical practice and be more athlete centered and given that this was identified by stakeholders as a problematic area. The change further protects the health of athletes using prohibited substances or methods to treat legitimate medical conditions, for example combination hypertensives containing diuretics to treat hypertension. The comment to 4.2 b) expands further on considerations for appropriate treatment.
- Article 4.2 c): This article corresponds to 2023 ISTUE Article 4.2 b).

Article 4.3

The ISTUE Drafting Team has clarified in the comment to Article 4.3 that ADOs and WADA must consult with an appropriate medical expert when evaluating TUE applications. This addition will help to ensure that there is a globally harmonized evaluation process.

Article 5: TUE Responsibilities of Anti-Doping Organizations

Article 5.1

The ISTUE Drafting Team has moved a part of the comment to Article 5.1 to 2027 ISTUE Article 5.4 (see below).

Article 5.3

Article 5.3 clarifies that Article 4.1 and Article 4.3 applications can be evaluated by the ADO in consultation with an appropriate medical expert, who may be a member of its TUEC or also a member of staff. The comment to this article has been deleted as it is already clearly set out in Code Article 4.4.

Article 5.3 b)

Article 5.3 b) is a new addition that serves to globally harmonize how TUECs reach a decision on TUE applications.

Article 5.3 d)

Article 5.3 d) is a new addition that reflects the current functioning of some ADOs and aims to guide others in the ways of best practice.

Article 5.4

Following feedback from stakeholders during the Stakeholder Consultation Phase, and in an effort to be more athlete centered, the ISTUE Drafting Team has expanded this article to require an ADO to clearly state on their website which athletes are required to apply to it for a TUE and when.

Article 5.5

This article was previously the comment to 2023 ISTUE Article 5.1 and has been re-titled and expanded to highlight the key objective of ensuring that when NADOs prioritize certain sports or disciplines, and do not require certain athletes to apply for a TUE in advance, they do so in a transparent manner that is easily understandable for athletes and can be found on their website.

Article 5.6

The ISTUE Drafting Team has expanded Article 5.6 to make it a mandatory requirement for ADOs to upload the reasons for a TUE denial to ADAMS.

Article 6: TUE Application Process

(Former) Article 6.1

2023 ISTUE Article 6.1 has been deleted as it was deemed outdated and unnecessary and was already dealt with in ISTUE Article 4.

Article 6.9

Article 6.9 corresponds to 2023 ISTUE Article 6.10 and has been expanded to mandate that if an ADO denies an athlete's TUE application, it must provide the athlete with reasons for the denial and information on their appeal/review rights. This updated article ensures that athletes are well informed and aware of the necessary next steps following a TUE denial.

Article 6.10

Following feedback received from stakeholders during the Stakeholder Engagement Phase, the ISTUE Drafting Team has included this new article which outlines the ADO responsible for monitoring conditions attached to a TUE. The reasoning behind the approach outlined in this article stems from the fact that the granting ADO will usually be the most familiar with the athlete and their TUE and thus make the process easier for the athlete (i.e., share the same language, etc.). This new article allows for flexibility for alternative arrangements to be made if both parties agree. However, in the absence of mutual agreement, the default is for the ADO that granted the TUE to retain responsibility.

Article 6.11

The article corresponds to 2021 ISTUE Article 6.14 but has been re-titled to highlight its key purpose.

Article 6.12

The ISTUE Drafting Team has incorporated this new article into the Standard based on feedback received during the Stakeholder Engagement Phase, specifically in response to Concept #1. This article now clarifies what the effective date of a prospective TUE will be. In addition, this article clarifies that retroactive TUEs cannot extend into the future, i.e., any TUE granted retroactively does not apply to future dates. The comment to this article further clarifies that ADOs are not obliged to evaluate these applications separately; rather, it acknowledges the differences between the two granted TUEs. Furthermore, as it concerns this new article, it should be noted that WADA will ensure that this procedure does not impose an additional burden on ADOs when recording TUEs in ADAMS.

Article 7: TUE Recognition Process

No substantive changes have been made to this article following the feedback received during the Stakeholder Engagement Phase.

This noted, the ISTUE does not clearly address the question of whether the recognition of a TUE granted by another ADO needs to be done in advance, i.e., it cannot be recognized retroactively. However, there is currently no ISTUE provision that clearly permits retroactive recognition. The ISTUE Drafting Team is also aware that the rules of several ADOs require that any request for the recognition of a TUE be made in advance.

The only retroactive criteria under 2023 ISTUE Article 4.1 that might apply to recognition is 2023 ISTUE Article 4.1 b), i.e., there was insufficient time, opportunity or exceptional circumstances that resulted in the athlete not being able to obtain a TUE prior to using or possessing the substance or method in question. This would apply, for example, in circumstances where an athlete is selected for an international event at very short notice and therefore does not have time to have their TUE recognized in advance of the event.

Accordingly, the ISTUE Drafting Team wishes to receive stakeholder feedback on whether these aspects should be addressed in the 2027 ISTUE.

When providing feedback in this respect, stakeholders are encouraged to consider the following questions:

- Should athletes be able to apply for recognition at any time?
 - Or should athletes always be required to satisfy the conditions of 2023 ISTUE Article 4.1(b) if applying retroactively?
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Article 8: Review of TUE decisions by WADA

Article 8.1

The ISTUE Drafting Team has clarified that when reviewing a TUE decision based on Article 4.1, WADA may consult with medical expert(s).

Article 8.8 & 8.9

The ISTUE Drafting Team has clarified both articles to describe the costs that WADA may require an ADO to incur when it reviews a TUE decision.

Code Article 13.4: Appeals Relating to TUEs

In an effort to harmonize the system for TUE appeal bodies (for both national and international-level athletes) as well as to provide athletes with fair decisions on TUEs (i.e., medical matters), a comment has been added to the Code Article 13.4 recommending that physician(s) are included in any national-level appellate body which is considering a TUE appeal from an athlete.

Code Article XX: Sanctions for athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE.

Based on the stakeholder feedback received, the Code Drafting Team is continuing to consider appropriate sanctioning flexibility in anti-doping rule violation cases where the criteria for obtaining a TUE in Article 4.2 of the International Standard for Therapeutic Use Exemptions are met (but the athlete has not met the criteria for a retroactive TUE).

While there was strong stakeholder support for a more lenient and flexible sanctioning regime in such cases, the Code Drafting Team is seeking further feedback on what such a regime might look like. In particular:

- Applying a standard ‘fault’ analysis to impose a period of ineligibility between a reprimand to two years does not appear to work well in such cases. In particular, the fault of the athlete can often be assessed as high in that context/using such definition, as the athlete has not met the criteria for a retroactive TUE and often has simply failed to apply for a TUE in advance.
- One potential option would be to have a specific, standalone sanctioning regime for such therapeutic use cases (similar to the regime for substances of abuse). For example, a provision such as the following:
- “Notwithstanding any other provision in Article 10.2, if the Athlete can establish that the presence, Use or Attempted Use or Possession met the criteria in Article 4.2 of the International Standard for Therapeutic Use Exemptions, then the period of Ineligibility shall be between three (3) and six (6) months depending on the Athlete’s degree of Fault. The period of Ineligibility established in this Article [x] is not subject to any reduction based on any provision in Article 10.6.”
- Another option would be to simply have a fixed 3-month sanction in such cases (which also has the benefit of simplicity and not requiring an ADO/hearing panel to have to spend time trying to assess fault.
- If no sanction at all were to be imposed, there is a concern that this would be granting a retroactive TUE in all but name (albeit through a different process to the TUE process). This may risk disincentivizing athletes to apply for a TUE in advance, and other potential consequences would also need to be carefully considered e.g. would this approach risk putting ADOs/hearing panels under undue pressure when trying to retroactively determine if the Article 4.2 criteria are met? There is also concern that this would be setting up a highly complex and time-intensive retroactive TUE process and accompanying Code sanctioning process only to ultimately get to the exact same outcome. If this is the desired policy approach from stakeholders, query if it would be more straightforward to just remove the need to apply for a TUE in advance and state that if an athlete meets the criteria in Article 4.2 they will get a TUE (whether prospective or retroactive)?