

2027 CODE & IS UPDATE PROCESS

Final Draft: Summary of Major Changes

International Standard for Therapeutic Use Exemptions

Executive Summary

Following the review and consideration of stakeholder comments provided during the <u>Third Consultation Phase</u>, including Athlete feedback provided as part of the <u>Athlete-Centered Consultation</u>, and through further consultations with the anti-doping community, the International Standard for Therapeutic Use Exemptions (**ISTUE**) Drafting Team has proposed further key changes in a final draft of the 2027 ISTUE as part of the ongoing 2027 Code & IS Update Process.

The purpose of this document is to summarize the major changes proposed in the final draft of the 2027 ISTUE, which predominantly build on those proposed in the <u>second draft of the 2027 ISTUE</u> and as summarized in the corresponding <u>second draft Summary of Major Changes</u>.

As part of the Third Consultation Phase, nearly 150 comments were submitted, reflecting the continued engagement of stakeholders in the refinement of the ISTUE. The general sentiment indicated strong support for the amendments introduced during the Second Drafting Phase, particularly the reordering of Article 4 and the reintroduction of the "no reasonable permitted therapeutic alternative" criterion in Article 4.2. Several stakeholders also expressed support for a more Athlete-centered approach to retroactive TUEs and called for further clarity regarding the TUE recognition process. While certain suggestions could not be incorporated directly into the ISTUE due to its regulatory scope, they will be addressed through corresponding updates to the ISTUE Guidelines, the ADAMS NextGen TUE module, and related educational and communication materials to be provided as part of the Code Implementation Support Program (CISP). The final drafting phase focused primarily on refining the text in response to stakeholder feedback and included direct discussions with stakeholders to explain and clarify the proposed revisions.

The following section offers a concise article-by-article summary of the changes in this final draft of the 2027 ISTUE.

Article 3: Interpretation

Changes from the Second Draft

Defined terms have been moved to Appendix I to harmonize the document's format and structure with the Code and other International Standards. Additional clarification has also been provided to clearly distinguish between mandatory requirements and recommendations in the document.



Article 4.0: Criteria for Obtaining a TUE

Changes from the Second Draft

Article 4.1

In light of stakeholder feedback, the ISTUE Drafting Team has removed the proposed comment to Article 4.1, as its inclusion was deemed unnecessary and potentially misleading. Concerns were raised that it could undermine the general obligation to obtain a TUE in advance, misrepresent the limited scope of retroactive TUEs, and prompt inappropriate requests for prospective TUEs from non-priority or non-elite athletes. Article 4.1, as currently drafted, sufficiently reflects the overarching principle.

The ISTUE Drafting Team has added a new comment to Article 4.1 to reference Code Article 10.2.4, which outlines a revised sanctioning framework introduced in the second draft of the 2027 Code. This addition is intended to guide stakeholders to the applicable provision in cases where an Athlete has failed to satisfy any of the criteria for the retroactive approval of a TUE.

Article 4.2(b)

The reference to "physician experience" from the comment to Article 4.2(b) has been removed. It was noted that such a criterion may be difficult to evaluate objectively and is sufficiently encompassed by the existing factors, which include evidence-based guidelines, side-effect profiles, accessibility, and relevant regional medical practice.

Article 4.5

Article 4.5 has been restructured to enhance clarity regarding the roles and responsibilities in the TUE decision-making process. The criterion in Article 4.3(a) shall be evaluated by the relevant Anti-Doping Organization in consultation with one or more members of a Therapeutic Use Exemption Committee (TUEC), ensuring expert clinical input where complex medical determinations are required. The criteria in Articles 4.3(b) to (e) shall be evaluated by the relevant Anti-Doping Organization, which may, at its discretion, consult an appropriate medical or scientific expert, such as a TUEC member or qualified staff, to maintain scientific rigor and procedural efficiency.

Article 5.0: TUE Responsibilities of Anti-Doping Organizations

Changes from the Second Draft

Article 5.5

The ISTUE Drafting Team has amended Article 5.5 to introduce flexibility for timely applications seeking the renewal of an existing TUE. In such cases, where the TUEC renders a decision before the current TUE expires, the effective date of the new TUE may be set prospectively to commence immediately after the expiration of the existing TUE. A new comment has been added to illustrate this scenario and to promote an Athlete-centered approach.

Article 5.6

The ISTUE Drafting Team has amended Article 5.6 to clarify that the maximum duration of any TUE shall not exceed ten (10) years, thereby ensuring consistency and limiting indefinite authorizations.



Article 5.8

NEW ADDITION

The ISTUE Drafting Team has introduced a new Article to ensure the appropriate notification of parties not covered under Article 5.7, in instances where an International Federation grants a TUE or refuses to recognize a TUE. This provision aligns with the requirements set out in Code Articles 4.4.3.1 and 4.4.3.2 and aims to promote greater clarity and consistency in communication obligations across Anti-Doping Organizations.

Article 5.12

NEW ADDITION

The ISTUE Drafting Team has introduced a new Article to address the absence of explicit guidance in the ISTUE concerning the appeal of TUE decisions. This Article reflects Code Articles 4.4.2, 4.4.4.3, 4.4.7, 4.4.8 and 13.4 and where appropriate corresponds with the flowcharts in Annex A of the ISTUE. This Article provides greater procedural clarity regarding the available appellate recourse for Athletes in such circumstances.

Article 6.0: TUE Application Process

Changes from the Second Draft

Article 6.10

The ISTUE Drafting Team has removed the term "materially" from Article 6.10, as it was considered ambiguous, difficult to assess objectively, and ultimately unnecessary given the clarity already provided in the Article. In addition, the comment to Article 6.10 has been expanded to reflect the clinical reality that an Athlete may be prescribed a fluctuating dosing regimen. The revised comment clarifies that such fluctuations should be addressed in the approved TUE decision by specifying a dosage range or upper limit. WADA will accordingly update the relevant ISTUE Medical Information for TUEs documents.

Article 6.12

The ISTUE Drafting Team has removed the reference to WADA's authority to review TUEs from this Article, as such authority is already addressed under the Code 4.4.6 and Article 8 of the ISTUE. The revised provision is now solely focused on the responsibilities of the Anti-Doping Organization and has been made more concise. In addition, the ISTUE Drafting Team has included language clarifying that where the TUE criteria are no longer met due to a change in circumstances, the Anti-Doping Organization may withdraw the TUE. For example, when the Athlete no longer requires the prohibited substance or method. The ISTUE Drafting Team will provide other examples in the updated Guidelines for the ISTUE.

Article 6.16

This Article has been relocated to Section 7, relating to recognition of TUEs, as the ISTUE Drafting Team considered it more appropriately placed there to enhance the overall structure and coherence of the document.

NEW ADDITION

To improve clarity and structural coherence, the ISTUE Drafting Team has divided the former Article 6.17 into two distinct provisions. Article 6.16 now addresses exclusively TUEs granted by a National Anti-Doping Organization where the Athlete subsequently becomes subject to the requirements of an International Federation



or Major Event Organization. This restructuring ensures a clearer distinction between recognition pathways and enhances the document's readability. Under the revised provision, such TUEs are not valid unless recognized by the relevant body. If recognition is denied, and subject to the Athlete's rights of review and appeal, the TUE cannot be relied upon to justify the Use, Possession, or Administration of the Prohibited Substance or Method.

Article 6.17

NEW ADDITION

To enhance clarity and improve the structure of the document, the ISTUE Drafting Team has split the former Article 6.17 into two distinct provisions. The new Article 6.17 now deals exclusively with TUEs granted by an International Federation that require recognition by a Major Event Organization. This separation ensures that the respective recognition pathways are clearly delineated, making the document easier to interpret. Under the revised provision, such TUEs are not valid for Major Event purposes unless recognized in accordance with Article 7. If recognition is denied, and subject to the Athlete's rights of review and appeal, the TUE cannot be relied upon to justify the Use, Possession, or Administration of the Prohibited Substance or Method for those Major Event purposes.

Article 7.0: TUE Recognition Process

Changes from the Second Draft

Article 7.1

Previously Article 6.16, this Article has been relocated to Section 7 on retroactive TUEs, as the Drafting Team considered it more appropriately placed there to enhance the overall structure and coherence of the document. For the avoidance of doubt, the Article states that 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. For example, if an Athlete is granted a TUE by their 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 the other National Anti-Doping Organization.

Article 7.4

The ISTUE Drafting Team has clarified that retroactive recognition of a TUE is only applicable where automatic recognition is not applied by the Anti-Doping Organization. Where WADA grants an exception under Article 7.2(b), the relevant International Federation or Major Event Organization may retroactively recognize the TUE, provided the Athlete establishes, on the balance of probabilities, that all criteria under Article 4.2 are satisfied.

Article 8.0: Review of TUE Decisions by WADA

Changes from the Second Draft

Article 8.2

The ISTUE Drafting Team has clarified that the assessment of Article 4.3(a) must involve consultation with a member(s) of the WADA TUEC. In regard to Articles 4.3(b) to (e) WADA may, at its discretion, consult an appropriate medical or scientific expert, such as a TUEC member or qualified staff, to maintain scientific rigor and procedural efficiency



Article 9.0: Confidentiality of Information

Changes from the Second Draft

Article 9.5

The ISTUE Drafting Team has expanded the scope of the Article to more accurately reflect operational realities and to reinforce transparency within the TUE framework. TUE data constitutes a critical resource for Anti-Doping Organizations, including WADA, enabling the development of evidence-based policies, the refinement and targeting of education programs, and the effective allocation of resources.

Systematic monitoring of TUE data is equally essential to safeguard the integrity of the TUE system. It facilitates the early detection of atypical patterns, disproportionate use of certain substances, or other indicators of potential misuse, thereby allowing timely and appropriate intervention. Such oversight ensures that the TUE process is applied consistently and fairly, that Athletes with legitimate medical needs receive appropriate treatment, and that the principle of a level playing field is maintained.

This expanded Article therefore underscores the necessity of collecting and utilizing TUE data, in accordance with the International Standard for Data Protection, as a cornerstone of operational efficiency, regulatory oversight, and the long-term protection of clean sport.

Code Definition of an Athlete

Changes from the Second Draft of the Code

The ISTUE Drafting Team wishes to highlight an additional comment introduced to the definition of "Athlete" in the Code, which provides important clarification of the existing regulatory framework. This clarification confirms that an Anti-Doping Organization may not establish or apply different rules to such Athletes, including in relation to Therapeutic Use Exemptions, except where expressly permitted under the definition. The intent is to ensure uniformity in the application of the Code across all Anti-Doping Organizations, thereby ensuring the consistent treatment of Athletes and preventing regulatory discrepancies.

Athlete-Centered Consultation

The ISTUE Drafting Team wishes to thank all the respondents for their valuable input during the Athlete-Centered Consultation. The feedback received during this consultation has directly influenced enhancements to the 2027 ISTUE, ensuring the TUE process is more transparent, user-friendly, and accessible for all Athletes.

Criteria to obtain a TUE and process to apply for a TUE (Total number of responses: 504)

Overall, 80% of respondents found the restructured TUE process clearer and easier to understand. Some feedback highlighted areas of continued complexity and the ISTUE Drafting Team have taken suggestions into account during the final drafting phase.

While some of these suggestions cannot be incorporated directly into the 2027 ISTUE itself, they will be integrated into the accompanying Guidelines for the ISTUE and reflected in various educational resources which shall notably be provided as part of CISP. These include visual flowcharts, condition-specific examples, awareness materials for Athletes and medical professionals, and communication tools to support Athletes with different needs.



This approach will ensure that the process remains compliant with the Standard while providing Athletes (particularly younger Athletes, Athletes with impairments, and those less familiar with the process) with clear, practical, and user-friendly guidance.

TUE recognition process (Total number of responses: 434)

The majority of respondents reported no issues with the recognition process and feedback confirmed that automatic recognition is generally viewed as helpful, as it simplifies procedures and reduces the administrative burden on Athletes.

Suggestions for further improvement included: (i) clearer, more youth-friendly explanations; step-by-step guides, (ii) practical examples, and short videos; (iii) defined timelines and faster decision-making, especially for incompetition cases; (iv) a centralized digital system to track TUE status in real time, with automatic updates and clear reasons for refusals; (v) stronger communication between NADOs and IFs to avoid delays or duplicate applications; and (vi) enhanced athlete and coach education on banned substances and conditions requiring a TUE.

While some of these suggestions cannot be incorporated directly into the 2027 ISTUE itself, due to its scope and regulatory nature, they will be integrated into the Guidelines for the ISTUE, the ADAMS NextGen TUE module and reflected in a range of educational and communication resources.