2027 CODE & IS UPDATE PROCESS

Second Draft: Summary of Major Changes

International Standard for Therapeutic Use Exemptions

Executive Summary

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

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

It is to be noted that any new changes in the second draft of the 2027 ISTUE, which do not otherwise stem from or build on those changes indicated in the first draft, will be accordingly marked as "New Addition". Particularly, in this respect, the ISTUE Drafting Team wishes to draw the attention of stakeholders to the following new changes which have been included in this second draft:

- The consideration for permitted alternatives, which had been removed in the first draft, has been reintroduced into Article 4.2 based on stakeholder feedback received during the Stakeholder Consultation Phase.
- The TUE recognition process has been revised based on strong stakeholder feedback to create a more streamlined and athlete-centered system. NADO-granted TUEs will be automatically recognized at the international level, unless an International Federation (IF) requests an exception from WADA, ensuring consistency and fairness. This approach also enhances data collection and will allow WADA and ADOs to better guide athletes.

Furthermore, the ISTUE Drafting Team wishes to mention certain other key developments which arose from its review of stakeholder comments and discussions with the anti-doping community during the Second Drafting Phase:

- Article 4 has been restructured for a more logical and coherent flow, integrating previous amendments and newly proposed changes. This revision incorporates stakeholder feedback emphasizing the need for greater clarity and readability.
- Article 5 and 6 have been reordered to make TUE processes more logical and accessible for athletes, ADOs, physicians, and all stakeholders.

The following section will offer a concise Article-by-Article summary of the changes in this second draft of the 2027 ISTUE.

Article 4.0: Criteria for Obtaining a TUE

Changes from the First Draft

Article 4.1

Previously included in the introduction to this Article, the updated Article 4.1 clarifies that athletes must apply for a TUE before using or possessing a prohibited substance, unless they are eligible for a retroactive TUE under Article 4.3 or another justification under Code Article 2.6. These refinements improve clarity, consistency, and procedural alignment within the anti-doping framework.

Article 4.2(b)

Following strong stakeholder sentiment, Article 4.2(b) reintroduces the concept that a prohibited substance or method must not only be indicated for treatment but there should also be no reasonable permitted therapeutic alternative. Despite the fact that most Anti-Doping Organizations (ADOs) agreed that medical practice does not usually consider permitted alternatives, the retention of the concept could assist Therapeutic Use Exemption Committees (TUECs) in some situations. The revised comment clarifies that alternative treatments should be assessed based on physician experience, evidence-based guidelines, and accessibility, and it will still not be necessary for athletes to try and fail alternatives before using a prohibited substance. These changes establish clearer and more rigorous TUE criteria, balancing medical necessity with anti-doping principles.

Article 4.3

Previously Article 4.1, Article 4.3 enhances clarity and consistency in the retroactive TUE process while keeping the eligibility criteria unchanged. Its new placement ensures that the Article 4.2 criteria are in a more prominent position, emphasizing that they are the key requirements of the Standard.

Article 4.4

Previously Article 4.3, Article 4.4 maintains the framework for granting retroactive TUEs in exceptional circumstances while improving clarity and streamlining procedures. WADA's oversight remains unchanged, requiring prior approval for International- and National-Level Athletes but allowing flexibility for non-elite athletes. The reporting and evaluation requirements have been removed from Article 4 and added later in the Standard aligning with the overall restructuring of the Standard.

Article 4.5

NEW ADDITION

Article 4.5 defines who is responsible for assessing TUE criteria, provides clear accountability, and ensures that TUE decisions are made by the most qualified appropriate personnel or medical experts, improving fairness and consistency in the process.



Article 5.0: TUE Responsibilities of Anti-Doping Organizations

Changes from the First Draft

Article 5.1

Article 5.1 removes direct quotes from the Code, incorporates elements from the former Article 5.4, and shifts the focus from defining ADOs' authority over TUE decisions to mandating that each ADO establish a clear and standardized process for TUE applications in compliance with the ISTUE. The updated comment references Annex 1 which contains flowcharts summarizing key TUE procedures, including decision-making authority, TUE recognition, and rights of review or appeal. This change ensures that the first Article in this section delivers a clear and concise directive to ADOs, reinforcing one of their key responsibilities.

Article 5.2

NEW ADDITION

Article 5.2 consolidates elements from previous Articles and centralizes all TUE publishing requirements for ADOs in one place. Aligned with the new, more logical structure, this Article has been placed second in this section.

Article 5.2 requires each ADO to publish key TUE information on its website in a way that is easily accessible to athletes and stakeholders, including:

- TUE application process details;
- TUE application forms;
- Definitions of National-Level and International-Level Athletes;
- NADOs' sports prioritizing information that may affect athlete's TUE obligations; and
- IFs and Major Event Organizations (MEOs) recognition information.

This Article emphasizes the importance for ADOs to clearly explain the TUE process, promoting consistency across ADOs while ensuring that athletes are able to understand their responsibilities in regard to TUEs.

Article 5.3

Aligned with the overarching structural improvements, this Article consolidates elements from other Articles and has been restructured for better flow. The revised Article 5.3 clarifies that TUECs are primarily responsible for assessing Article 4.2 criteria, but may seek medical or scientific expert assistance, ensuring flexibility in complex cases. These updates enhance clarity, and fairness in the TUE application process while ensuring that medical input is accessed where appropriate.

Article 5.4

Previously Article 6.8, this Article was relocated to Article 5 as part of the efforts of the ISTUE Drafting Team to improve the structure of the Standard. It mandates that ADOs or TUECs decide on TUE applications or recognition requests within 21 days.

Article 5.5

Previously Article 6.12, this Article was relocated to Article 5 to improve the structure of the Standard. The comment clarifies that this change should not place an extra burden on ADOs, as it will be automatically facilitated in ADAMS.

Article 5.6

The text of Article 5.6, previously Article 6.13, has been relocated as part of the efforts of the ISTUE Drafting Team to improve the structure of the Standard. Additionally, this Article has been expanded to clarify that the duration of a TUE should generally align with the treatment duration to ensure a more medically appropriate timeframe. Exceptions to this principle would be long-term chronic conditions, which are further described in the WADA TUE Physician Guidelines.

Article 5.7

Previously Article 6.9, this Article has been relocated to Article 5 as part of the efforts of the ISTUE Drafting Team to improve the structure of the Standard. The Article has been refined to clarify the ADO's responsibilities in notifying the athlete. Since all decisions will be recorded in ADAMS, both WADA and the applicable ADO will also receive notifications.

Article 5.8

Previously Article 5.6, this Article has been renumbered. This Article now outlines an ADO's TUE reporting responsibilities. The comment regarding the TUE application form requirements has been correctly relocated to Article 5.2, ensuring a more logical and structured placement within the Standard.

Article 5.9

Previously Article 6.10, this Article has been relocated to Article 5 as part of the efforts of the ISTUE Drafting Team to improve the structure of the Standard. The Article has been slightly reworded to provide extra clarity to better understand an ADO's TUE monitoring responsibilities.

Article 5.10

Previously Article 5.9, this Article has been renumbered.

Article 6.0: TUE Application Process

Changes from the First Draft

Article 6.1

Article 6.1 has been restructured and its content redistributed within the Standard. The newly revised Article now serves as a clear introduction to Article 6, outlining that athletes must apply to the appropriate ADO for a TUE.

Article 6.2

Previously Article 6.1, this Article has been refined for additional clarity. For those athletes unsure of their NADO jurisdiction, the comment still provides a step-by-step hierarchy for determining where to apply.

Article 6.3

NEW ADDITION

Article 6.3, which is derived from Code Article 4.4.3, improves the flow of the Standard, and describes that International-Level Athletes must apply for a TUE through their IF. In addition, it mentions the recognition process in the event that the athlete already has a NADO granted TUE.

Article 6.4

NEW ADDITION

Article 6.4, which is derived from Code Article 4.4.4, describes an athlete's TUE obligations when attending a MEO event. This new Article enhances the overall flow of the Article, improving clarity and structural coherence.

Article 6.5

Previously Article 6.3, this Article has been renumbered and updated. It clarifies that a physician signature is still required on the TUE application form, however an electronic physician signature is acceptable.

Article 6.6

Previously Article 6.5, this Article has been expanded to clarify that if an athlete fails to respond within a reasonable timeframe after being requested to provide additional information, the ADO may cancel the TUE application.

Article 6.7

Previously Article 6.6, this Article has been renumbered and refined. The Article detailing the ADO/TUEC's ability to seek further medical or scientific expert opinions has been relocated to more appropriate Articles within the Standard for better clarity and structure.

Article 6.8

Previously Article 6.4, this Article has been renumbered.

Article 6.9

Previously Article 6.7, this Article has been renumbered.

Article 6.10

Previously Article 6.11, this Article has been renumbered.

Article 6.11

Previously Article 6.13, this Article has been renumbered and refined. The Article outlining TUEC responsibilities has been relocated to Article 5.6 for better alignment within the Standard.

Article 6.12

Previously Article 6.14, this Article has been renumbered.

Article 6.13

Previously Article 6.2, this Article has been renumbered and further clarified to explain that an athlete may hold multiple TUEs for different treatments or medical conditions.

Article 6.14

Previously Article 6.15, this Article has been renumbered.



Article 6.15

Previously Article 5.2, this Article was relocated to Article 6 as part of the efforts of the ISTUE Drafting Team to improve the structure of the Standard.

Article 6.16

Previously Article 5.9, this Article has been relocated to Article 6 as part of the efforts of the ISTUE Drafting Team to improve the structure of the Standard.

Article 6.17

Previously Article 5.6, this Article has been renumbered.

Article 6.18

NEW ADDITION

Article 6.18, which is derived from Code Article 4.4.3.2, outlines a NADO's ability to refer a TUE granted by an IF to WADA for review. The NADO has 21 days to request a WADA review of the TUE. If a review is requested, the TUE remains valid for international-level competition and Out-of-Competition Testing but not for national competition until WADA issues a decision. If no review is requested within the deadline, the TUE automatically becomes valid for national-level competition.

Article 7.0: TUE Recognition Process

Changes from the First Draft

Article 7.1 a)

The revised Article 7.1 a) shifts the default position to automatic TUE recognition unless WADA grants an exception to an IF or MEO. The new wording to this Article ensures all properly reported TUEs (under Article 5.8) are automatically accepted. Additionally, the new wording clarifies that once a TUE has been granted and automatically recognized, it cannot be reviewed further by the ADO. It is important to emphasize that IFs or MEOs still have the ability to evaluate and decide whether or not to recognize TUE decisions if they opt out of automatic recognition by requesting an exemption from WADA. However, the objective of these proposed amendments is to decrease administrative burdens for athletes and promote greater consistency and fairness in anti-doping procedures.

Article 7.1 b)

The revised Article 7.1 b) states that if an IF or MEO decides to opt out of the default automatic recognition, they must publicly disclose which TUE decisions will be automatically recognized, and those which will require athlete submission. Furthermore, once a TUE is automatically recognized, it cannot be further reviewed, ensuring finality. The objective of these proposed amendments is to reduce administrative burdens on athletes, enhance transparency, and promote greater consistency and fairness in anti-doping regulations. The accompanying comment is an updated and refined version of the previous comment on Article 7.1 a).

Article 7.2

The revised Article 7.2 describes how an IF or MEO can request additional medical information from the athlete or their physician. Additionally, the provision allowing TUECs to consult medical or scientific experts has been moved to Article 4.5. The objective of these proposed amendments is to streamline the process to reduce administrative burdens on athletes while ensuring additional scrutiny is applied only if necessary.

Article 7.3

NEW ADDITION

Although athletes should generally apply prospectively for recognition, Article 7.3 allows an IF or MEO to recognize a TUE retroactively. However, the comment to this Article describes that retroactive recognition of their TUE would be based on fulfilling the Article 4.2 criteria and is thus not guaranteed.

Article 7.4

Previously Article 7.3, this Article has been renumbered as Article 7.4. Former Articles 7.4 and 7.5 have been removed, with their content now incorporated into Article 5.4 and Article 5.7, respectively to create a more concise, structured Standard.

Article 7.5

NEW ADDITION

Article 7.5, which is derived from Code Article 4.4.3.1, outlines an athlete's responsibility when an IF refuses to recognize a TUE. In such cases, the athlete or their NADO has 21 days to refer the matter to WADA for review. During this review period, the TUE remains valid for national-level competition and Out-of-Competition Testing but not for international-level competition. If the case is not referred to WADA, the NADO must decide whether the TUE remains valid at the national level, provided the athlete ceases international competition.

The comment, previously the comment to Article 7.1b), clarifies that TUE recognition decisions must be based solely on medical criteria (Article 4.2) and that TUE duration alone is not a valid reason for denial. The objective of this restructuring is to enhance clarity and ensure that athletes and stakeholders receive consolidated guidance in one place.

Article 8.0: Review of TUE Decisions by WADA

Changes from the First Draft

Article 8.1

NEW ADDITION

Article 8.1, which is derived from Code Article 4.4.6, expands on previous references to the Code and now provides a clear description of WADA's authority and responsibilities in reviewing TUE decisions. It specifies the circumstances under which WADA must intervene in cases involving TUE approvals or rejections by NADOs and IFs. Additionally, this Article highlights WADA's dual role, outlining both its mandatory and discretionary powers to oversee, review, and potentially overturn TUE decisions, ensuring compliance with anti-doping regulations.



Article 8.2

Previously located in the second part of Article 8.1, the new placement of this Article enhances the overall flow of Article 8, improving clarity and structural coherence.

Article 8.3 - 8.10

These Articles have been renumbered to account for the new addition at the beginning of Article 8.

Article 9.0: Confidentiality of Information

Changes from the First Draft

Article 9.1

This Article, which outlines the requirements for the processing and handling of personal information during the TUE process by ADOs in accordance with the 2027 International Standard for Data Protection (ISDP), has been expanded to explicitly include compliance with specified data retention periods. Such retention times can be found in the Annex to the ISDP.