# 2027 Code & International Standard Update Process: Stakeholder Consultation Phase - International Standard for Therapeutic Use Exemptions (ISTUE)

Showing: All (187 Comments)

## Article 4 (17)

## **Council of Europe**

Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

#### **General Comments**

Art. 4.0 Criteria for obtaining a TUE (new comment)

An additional comment is not necessary since it is already clear from the existing provisions that athletes may start treatment using a prohibited substance or method prior to the grant of a TUE, but that a retroactive TUE would be required and must still meet the 4.2 conditions. The emphasis should be placed on having a medical file ready should a retroactive TUE be required which is already addressed in the comment to Article 4.1 (c, d and e).

## EOKAN/HADA

Spyridoula Christopoulou, Scientific Support & Quality Office Assistant (Greece) NADO - NADO

## **General Comments**

maybe it should be specified that this phrase applies to national level athletes if they start using a banned substance or method prior to the granting of a tue, as for athletes at a lower level of the national level it applies that they can apply retroactively

## NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

#### **General Comments**

'This article contains - according to the WADC wording - the new term '...who Use or Possess...', and we ask for clarification. In principle, a TUE is granted for the therapeutic use and not for the possession of a prohibited substance or method.

In our opinion, a TUE is the wrong instrument to legitimate the possession of a prohibited substance or method, especially the possession alone, without a use which would be possible because of the word 'or' in the term. If a TUE is necessary for the possession of a prohibited substance or method, this will have serious impact on the period of validity of TUEs.

For example: An athlete gets a prescription for glucocorticoid tablets for the treatment of an acute allergic reaction and purchased the tablets in a pharmacy. After the treatment there are a few tablets left in the package. The athlete keeps them for months in- and out-of-competition for the case that he suffers from a further allergic reaction. Regarding the new wording in this article the athlete would have to have a TUE for every incompetition day or period he still possesses this tablets.

We think this is not the intention of the new wording 'Use or Possess'. How should a period of validity of a TUE be managed in this case? Furthermore, Articles 2.6.1 and 2.6.2 WADC and comments to these articles clarify that the possession can also be justified by e.g. evidence that the Prohibited substance or Method was possessed or carried for acute or emergency treatments. See also our comment to Article 4.1. b)

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO SUBMITTED

#### **General Comments**

SSI notes that this comment might be misleading for international- and national-level athletes who are obliged to apply for advance TUEs. Such athletes could misunderstand this comment and start treatment (in no Article 4.1 a or 4.1 e situations) assuming they can apply for a retroactive TUE.

#### For Article 3

In the Comment to the definition for International-Level Athlete, consider changing the wording from "must" to "shall," particularly, for publishing the criteria in a clear and concise form. Additionally, the definitions created by IFs should not reference other policies within the definition and should not direct undue applications to NADOs. Consider also creating a section in ADAMS to centralize the definitions of International Athletes.

Code Article XX: Sanctions for athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE: The CCES supports the three-month fixed sanction as it is in favour of the athletes, who arguably committed an administrative lapse of filing paperwork (assuming their TUE would be approved). This mechanism also reduces the administrative burden on ADOs in determining fault for each situation.

Alternatively, the CCES would also support, in such situations, the finding of a violation, with no associated period of ineligibility. If it is accepted that the athlete was properly using the prohibited substance for medical reasons, and a full TUE is subsequently granted going forward (meaning the athlete's error was purely administrative in not filing for a TUE in advance), the fact that a violation has been determined seems a sufficient punishment (given the heightened consequences that would come from any additional violation) and should disincentivize athletes from deliberately delaying the filing of an application.

## Japan Anti-Doping Agency

Chika HIRAI, Director of International Relations (Japan) NADO - NADO

**General Comments** 

Article 4.0 We support this revision.

**UK Anti-Doping** 

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

Comment to Article 4.0 - We appreciate that the intention behind this new comment is to recognise that national and international level athletes who start to use a prohibited substance or method prior to the grant of a TUE are contravening the overarching 'obtain a TUE first' principle of the ISTUE (unless one of the exceptions in Article 4.1 has been satisfied). However, the proposed new wording refers to all athletes which undermines the existing comment to Article 4.0 and Articles 4.1 (c) and (d) (in which a TUE is not required prior to use or possession for athletes who are not at a national or international level, nor are within a NADO's prioritisation list for obtaining a TUE in advance of use).

#### Suggested changes to the wording of the Article

Comment to Article 4.0 - Recommendation to delete the new wording within this comment in its entirety or re-draft the wording so that it specifically refers to national and international level athletes (and athletes included within a NADO's TUE prioritisation list).

## Agence Nationale Antidopage

Agence Nationale Antidopage Tunisie, Direction Générale (Tunisie) NADO - NADO

#### **General Comments**

Devant l'approche moins restrictive prévue par ces changements pour les critères d'octroi des autorisations d'usage à des fins thérapeutiques (rétroactives ou non), doit être mis en exergue le besoin d'assurer l'équilibre entre cette optique en faveur de la santé des sportifs et l'évitement du recours excessif aux AUT rétroactives pour supporter au mieux les sportifs propres.



#### General remarks about the standard as a whole:

1) In general we think the whole tone of the ISTUE is very restrictive. It leaves hardly any room for interpretation or some kind of flexibility

2) Define or clarify the term "physician". (article 3.3)

We would like to address the problem that the ISTUE uses the term "physician" while the "TUE Application Form" mentions "Medical Practitioner's Declaration" under 6.

This leads to confusion, for instance among psychologists and nurse practitioners. Clarification is recommended.

#### Additional proposals

1) Continuous professional development for TUEC's.

We feel that the TUEC community would also benefit from more frequent interaction to continue to improve the knowledge of the membership. This could be achieved through the introduction of webinars every six to twelve months that contains: i. anonymous examples of best practice in dealing with certain cases; ii. commentary regarding difficult TUE cases (that is, what was difficult about the case, what options could the TUEC have taken, which option was the best one to take); and iii. examples of poor decision-making (that is, why the decision was not the right one, and the lessons learnt). Probably the TUEC should also be included as one of the Target Groups in the ISE.

2) Recognition of the roles of TUE managers

TUE managers or "TUE Administrators" play an important role in the whole TUE process: they are the boots on the ground. They are the direct link between the athletes and the TUEC, and they are the ones to explain the rules and solve potentially problems. There is even a "Professional Standard and Role Descriptor" for it, but it is not mentioned in the ISTUE. It would be beneficial that the position would be in some shape or form, recognized in the ISTUE.

#### **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

SUBMITTED

#### **General Comments**

Recommended change: Under the definition of "Therapeutic", USADA agrees that the addition of "diagnosed" is a helpful addition. However, USADA is concerned about the lack of rigor in with some diagnoses made with athletes therefore suggests that more qualification is needed around a "diagnosed medical condition". One solution to this would be to qualify this by stating "and agreed by the TUEC after evaluation of the TUE application" to ensure that high medical standards are upheld. We instruct athletes that the TUEC must be able to come to the same medical diagnoses based on the complete TUE application without ever seeing the athlete.

#### Suggested changes to the wording of the Article

Recommended change: Article 4.0: While the intent of this comment is understood, it may have a negative effect toward athletes in that it may deter them from seeking emergency treatment at the expense of their health. Add clarification language: However, in situations of a medical emergency or need for urgent treatment, an athlete should not jeopardize or risk their health and should be aware that they will, in such circumstances, be able to apply retroactively for a TUE. Such a TUE request is still subject to the criteria listed in ISTUE Article 4.2 (unless ISTUE Article 4.3 applies).

## **Anti-Doping Norway**

Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO

#### SUBMITTED

**General Comments** 

An additional comment is not necessary since it is already clear from the existing provisions that athletes may start treatment using a prohibited substance or method prior to the grant of a TUE, but that a retroactive TUE would be required and must still meet the 4.2 conditions. The emphasis should be placed on having a medical file ready should a retroactive TUE be required which is already addressed in the comment to Article 4.1

## Agence française de lutte contre le dopage

Adeline Molina, General Secretary Deputy (France) NADO - NADO

## **General Comments**

Plusieurs modifications contribuent à assouplir le régime des AUT en permettant de mieux prendre en considération la situation concrète d'un sportif et la réalité médicale. De même, plusieurs contraintes, comme l'obligation de dépôt trente jours au moins avant la compétition, sont supprimées ou des dérogations, comme l'octroi d'une AUT à effet rétroactif pour des sportifs de niveau national, sont étendues. Ces modifications sont souhaitables et permettent d'éviter les complications procédurales pour les sportifs dont la situation médicale justifie réellement l'octroi d'une AUT.

## FINCIS

Anna Simula, Pharmacist (Finland) NADO - NADO

#### **General Comments**

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

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 Reprimand for the first time.

For any subsequent violation in this regard, the period of eligibility could be 2 months.

#### Reasons for suggested changes

This would be more in line with the spirit of the anti-doping code, because in these cases the athlete has used, for medical reason, a medication for which the criteria for obtaining a TUE in Article 4.2 of the ISTUE are met (but the criteria for a retroactive TUE are not met). The only fault is that the athlete failed to apply for a TUE in advance. Because of this, the sanction should be lighter than the sanction for Substance of Abuse.

#### **Anti-Doping Sweden**

Jessica Wissman, Head of legal department (Sverige) NADO - NADO

#### **General Comments**

The review process of retroactive TUE's based on ISTUE article 4.3 should be specified with regards to time limit for WADA to give its reasoned decision (approval/denial) after ADO's conditional approval. Furthermore, ADSE finds that ADO's are differently inclined to apply this article and that more examples of how and when article 4.3 can be applied would be helpful in the ISTUE guidelines.

## Sport Integrity Commission Te Kahu Raunui Jono McGlashan, GM Athlete Services (New Zealand) NADO - NADO

SUBMITTED

#### **General Comments**

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

- We support the proposed changes although see merit in both options proposed.
- A fault analysis allows for consideration around the athlete's degree of fault- it allows for many factors to be assessed such as lack of support team around the athlete (a variation dependent on sport), lack of education, experience in top-level sport, medical condition which impacts their ability to undertake admin, previous history of not meeting Anti-Doping responsibilities. This seems fairer than a fixed sanction which does not consider these factors assuming all administrative errors are equal. Given the intention appears to be 'fairer' on athletes, it makes sense for the factors surrounding the lack of application be considered.
- However, we recognise the simplicity of a fixed sanction to avoid the use of resources such as a hearing panel as highlighted here; this is especially relevant for smaller ADOs. We would suggest that if the athlete has already been granted a fixed sanction for not completing the TUE process in the past as per their responsibilities, the second sanction should be extended to a longer fixed length. This would avoid disincentivising athletes who need to apply for a TUE in advance as it is important that they continue to take their responsibilities seriously within all aspects of the WADA Code and International Standards. The intention would be that the athlete only makes this mistake once.

 We support both suggestions as they allow for leniency and are athlete-centric. However, both suggested terms of ineligibility, 3 months fixed or 3-6 months depending on the degree of fault may be overly lenient. We would suggest lengthening their sanctions to a start point of 6 months.

"This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

#### **General Comments**

#### Agree but with new comments

In particular use prior to becoming subject to anti-doping rules does not need a TUE.

For above situation there is usually at least some time lag between becoming subject to anti-doping rules and applying for TUE for a long standing medication. Could there be comments to allow for some flexibility?

Chair

Athlete Council, WADA (Canada) Other SUBMITTED

#### General Comments

#### **Overall Comment for the ISTUE**

The introduction of the Stakeholder Consultation Phase: Summary of Changes to the ISTUE states, "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."

While the process is undoubtedly detailed, we find it hardly understandable and therefore questionably fair for athletes. The complexity of the flowchart on page 24 of the ISTUE is a vivid portrayal of the challenge athletes face as they navigate this process. We think athletes would benefit from a reimagined, streamlined system, where TUEs granted by one signatory would automatically be recognized by all others.

Even the name, "TUE"— an acronym for an advanced technical English phrase— is unhelpful at best and detrimental at worst to athlete understanding. A change in name to "medical exception," "doctor's permission," or similar, might help.

We will offer feedback on a number of specific articles of the ISTUE, but we also wonder if, after eight past revisions, it might be worthwhile to start with a fresh document. We appreciate the drafting team's creativity as they parse these difficult questions and propose innovative solutions. One example of such creative thinking is the query on page five of the Summary of Major Changes, "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)? While this particular proposal makes us nervous that athletes would face uncertainty, we acknowledge that a major change may be the best way forward.

#### Other

Somewhere, perhaps in the Code Article 4.4 (TUEs), or Article 20 (Roles and Responsibilities of Signatories) or in the ISTUE, there should be a requirement that signatories issuing TUEs report publicly (e.g. in a NADO annual report, an IF website, etc.) basic statistics about TUEs granted.

## Article 4.1 (13)

#### World Rugby

David Ho, Senior Manager Anti-Doping Operations (Ireland) Sport - IF – Summer Olympic SUBMITTED

#### **General Comments**

World Rugby supports the proposed wording for 4.1b) and its intent to make obtaining a retroactive TUE less restrictive.

World Rugby however query why the categorisation of priorities references only NADOs in 4.1c? If an IF can prioritise certain levels of International Level athlete over others (IST Article 4.4.1) then they may also have some lower-priority athletes subject to retrospective applications who would fall between the NADO and IF (being international athletes deemed low level by the IF). This also relates to the wording of Article 5.5.

World Rugby consider that the aim in principle should not be to impose sanctions on athletes who fulfill the fundamental ISTUE Article 4.2 criteria, however we support the rationale behind the proposal, which when paired with the changes to 4.1b) will nevertheless ensure that there are consequences for athletes who clearly ignore or at best overlook their obligations. No sanction, we agree would simply disincentivise athletes from applying in advance, which could change the culture around diligence in keeping good medical records, which in turn may disadvantage less well-resourced/educated athletes, particularly those with less direct access to experienced medical support staff.

If sanctions were to be introduced, we would be supportive of a fixed 3 month sanction, rather than introducing a complicated fault based system which may be open to inconsistency.

The suggestion of removing the requirement to apply in advance altogether and rely solely on whether a TUE application meets the 4.2 criteria in our opinion is unworkable, in the sense that for the benefit of the anti-doping system and athletes there must be a mechanism of checks and balances and an imperative to maintain diligent medical records which the existing system attempts to do.

## NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

#### **General Comments**

Art. 4.1 b) 'This article contains the new term '...prior to Using or Possessing', and we ask for clarification.

In principle, a TUE is granted for the therapeutic use and not for the possession of a prohibited substance or method. In our opinion, a TUE is the wrong instrument to legitimate the possession of a prohibited substance or method, especially the possession alone, without a use which would be possible because of the word 'or' in the term. If a TUE is necessary for the possession of a prohibited substance or method, this will have serious impact on the period of validity of TUEs.

For example: An athlete gets a prescription for glucocorticoid tablets for the treatment of an acute allergic reaction and purchased the tablets in a pharmacy. After the treatment there are a few tablets left in the package. The athlete keeps them for months in- and out-of-competition for the case that he suffers from a further allergic reaction. Regarding the new wording in this article the athlete would have to have a TUE for every incompetition day or period he still possesses this tablets.

We think this is not the intention of the new wording 'Using or Possessing'. How should a period of validity of a TUE be managed in this case? Furthermore, Articles 2.6.1 and 2.6.2 WADC and comments to these articles clarify that the possession can also be justified by e.g. evidence that the Prohibited substance or Method was possessed or carried for acute or emergency treatments. See also our comment to Article 4.0.

## RUSADA

Viktoriya Barinova, Deputy director (Russia) NADO - NADO

#### **General Comments**

We propose further elaboration of the concept and principles of requests for Retroactive TUE or consider eliminating this concept.

#### Reasons for suggested changes

If a TUEC decides that an Athlete does need treatment and the request meets the criteria for a TUE, it does not matter when the treatment was initiated. To penalize an athlete because he or she genuinely needed treatment for a medical condition but simply did not make a timely request or obtain an authorization is in no way consistent with basic principles of humanity.

It is also not clear how this Article should relate to Article 6.12.

Retroactive requests are very closely related to antidoping rule violations and different Anti-Doping Organizations make different decisions. For example, an athlete used a diuretic once in hospital and a few months later submitted a retroactive TUE request to the IF. The IF did not consider it because the use was long-standing and the sample was clean for the substance. We would then request a retroactive TUE.

In a number of situations, an Athlete may not be able to trace back to the point at which they become a National-Level Athlete, i.e., they may not be able to submit a retroactive TUE for a number of substances (including life-saving substances). The current Code and TUEs do or may result in situations where it is more advantageous for an Athlete not to have to contact an Anti-Doping Organization in order to properly submit a TUE because of the risk of being disqualified for using a TUE while he or she was already a national-level Athlete. In this case, the risk of receiving a disqualification is greater than the risk of being tested and caught using prohibited substance. In order to encourage compliance, either the list of cases where an athlete can make a retro TUE request without the risk of being disqualified for the use of prohibited substance should be expanded, or the concepts of retro TUE or TUE should be effectively merged: that is, in any situation where a request meets the requirements for the issuance of a TUE (without meeting the criteria for making a retro TUE), an authorization should be granted without any sanction.

#### SUBMITTED

4.1b: SSI proposes a specification of "exceptional circumstances", "insufficient time" and "opportunity" in a comment to Article 4.1 b in order to prevent an excessive interpretation of this article. In addition, there need to be strong guidance when to apply 4.1 b, or eventually 4.3, and when a sanction for athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE (Code Article 4.4) will be applied. Otherwise the suggested changes for 4.1b, 4.2 b (removal of permitted alternatives) while keeping 4.3 open for cases where not all elements of 4.2 and/or 4.1 are met, and a new sanctioning option will lead to disharmonized case management.

#### Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

**General Comments** 

The whole article on retroactive TUEs has gotten way too difficult to be practical.

Japan Anti-Doping Agency Chika HIRAI, Director of International Relations (Japan) NADO - NADO

#### **General Comments**

#### Regarding to the Article 4.1 and 4.2

It's difficult to choose one because we've received "support" or "concerns" about all three proposals ("No sanction, "3-6 months sanction", and "3 months sanction") from our stakeholders in Japan.

#### Article 4.1 b)

We welcome the proposed revision to ISTUE 4.1(b) to reduce the occurrence of athletes with legitimate medical conditions who fail to get their TUE application evaluated.

CHINADA MUQING LIU, Coordinator of Legal Affair Department (CHINA) NADO - NADO

**General Comments** 

## **Retroactive TUEs**

We do not support the recommendation in the Summary of Major Changes to the 2027 Code that "for nationallevel TUE appeals the appellate body include at least one physician with experience in the care and treatment of Athletes and a sound knowledge of clinical, sports and exercise". We believe that the appellate body should be independent of the NADO and that we cannot interfere in its composition. In addition, the members of the appellate body typically have legal backgrounds. As far as we know, many Signatories' appellate bodies do not meet this requirement. More importantly, we believe that relevant personnel should participate in cases as expert witnesses rather than as arbitrators.

SUBMITTED

Suggested changes to the wording of the Article

## **Retroactive TUEs**

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Reasons for suggested changes

## **Retroactive TUEs**

We believe that the appellate body should be independent of the NADO and that we cannot interfere in its composition. In addition, the members of the appellate body typically have legal backgrounds. As far as we know, many Signatories' appellate bodies do not meet this requirement. More importantly, we believe that relevant personnel should participate in cases as expert witnesses rather than as arbitrators.

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

4.1 (b) - We welcome the attempt to be less restrictive regarding the circumstances that may entitle an athlete to seek a retroactive TUE under Article 4.1 (b). However, some examples of the type of circumstances that are now considered to be exceptional would be useful so that there is some consistency in how ADOs interpret the expansion of this article.

Recommendation to add some further examples of exceptional circumstances to the ISTUE guidelines document.

## **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

General comment: Article 4.1b: While the amendments are welcome, USADA recommends clear guidance around scenarios this clause is intended to address is needed. And perhaps more importantly, those scenarios under which this clause should not be applied as it has the potential to be applied incorrectly as a universal get-out-of-jail free card due to the wide interpretation of "exceptional circumstances."

Suggested changes to the wording of the Article

Article 4.1 second paragraph: Add the word "all" to "(but must still meet all the conditions in Article 4.2).

Recommended change: Article 4.1a: add "diagnosed" to "emergency or urgent treatment of a diagnosed medical condition was necessary;"

## Sport Integrity Commission Te Kahu Raunui Jono McGlashan, GM Athlete Services (New Zealand)

NADO - NADO

SUBMITTED

#### **General Comments**

- WADA proposes to expand this criterion to 'there was insufficient time, opportunity or exceptional circumstances that results in the Athlete not being able to obtain a TUE prior to Using or Possession the substance or method in question'. The reasoning to widen the criterion is to be more athlete-centric. However, we have reservations to this approach:
  - o This clause already was too open to subjective interpretation and this does not resolve the issue
  - It does not flag that if the athlete continues to compete while their TUE is still being considered, that they risk an ADRV should it be rejected (they apply this in comment only to all clauses in the ISTUE)
- Therefore, we think that the wording requires greater clarification so that clause can be applied consistently.

"This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

Australian Sports Drug Medical Advisory Committee Kim Revnolds, Senior ASDMAC Officer (Australia) NADO - NADO General Comments Agree with 4.1.b Could examples be given in ISTUE guidelines? Sport Ireland Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO **General Comments** Update to 4.1b suggested We suggest a comment be added to 4.1b, whereby the athlete/doctor should be encouraged/required to keep a detailed record of the circumstances that stopped them from being able to get a TUE prior to using/possessing the substance? Suggested changes to the wording of the Article Comment 4.1b The athlete and their physician should keep a record of the circumstances that resulted in the athlete not being able to obtain a TUE prior to using or possessing the substance or method in question. Reasons for suggested changes If that information is pivotal to an athlete being permitted to apply retroactively then it is important information and the details should be recorded accurately. It may be many weeks before the information is required and important details can be forgotten in the meantime. **Anti-Doping Norway** Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO General Comments We welcome the amendment to 4.1 b), which reflects that the access to apply for a TUE should be seen in relation to insufficient time (etc.) prior to the ahtlete's use or possession and not to the sample collection.

## Article 4.2 (19)

**Tug of War International Federation** Peter Dyer, Senior Vice President (England) Sport - IF – IOC-Recognized SUBMITTED

#### **General Comments**

The amount of medical evidence required should be on a 'risk-based' approach on a case-by-case basis. Professional and amateur sports should be assessed as a different risk where large financial gains can be made through winning, for instance. Also, the burden of providing such medical evidence as an amateur athlete is huge, while a professional athlete probably has a whole medical team behind them. In addition, the impact of an individual in a team sport should be considered within the risk assessment

The ISTUE, the Physicians Guidelines, and the Checklist use inappropriate terminology and contradict each other. For instance, the checklist for Asthma uses 'must' in the first four points, and then the rest says 'should' (the English definition is 'not mandatory') then it uses the term "not mandatory'. Why use two different words for the same meaning? However, even worse, is the use of the word 'Must' in the Physicians Guidelines, which contradicts the checklist. In addition, I am informed by the WADA medical department that the TUE Physician Guidelines and Checklist are not mandatory documents, so why are words such as mandatory, must etc used? Overall these documents make a very poor use

of the English language and I suggest a very thorough review is undertaken to remedy this problem and that it is made clear in the Physicians Guidelines that they are NOT mandatory and a 'risk based' approach should be used in assessing TUEs.

## World Rugby

David Ho, Senior Manager Anti-Doping Operations (Ireland) Sport - IF – Summer Olympic

## **General Comments**

World Rugby support any simplification of the TUE process but would like to retain an element of due diligence and suggest the Comment to 4.2(b) be reworded to "The physician must explain the appropriateness of the treatment including factors such as why permitted alternatives are not deemed suitable, the physician's own experience, side-effect profiles or other medical justifications, which can include, where applicable, geographically..."

## Suggested changes to the wording of the Article

Comment to 4.2(b) reworded to "The physician must explain the appropriateness of the treatment including factors such as why permitted alternatives are not deemed suitable, the physician's own experience, side-effect profiles or other medical justifications, which can include, where applicable, geographically..."

## USA Track & Field/American College Sports Medicine

Dr Mark Troxler DO MBA FACP FACSM, Chair, Anti-Doping Education Committee/Anti-Doping Interest Group (USA) Sport - Other SUBIMITTED

#### **General Comments**

Need more details on what is meant by "relevant clinical evidence"

Need more details on what is meant by "normal state of health"

We need to develop a TUE Physician Testing Pool that will consist of Physicians that have received WADA TUE education AND have successfully completed a TUE knowledge evaluation. Only physicians in the TUE Physician pool will be allowed to complete and submit a TUE on an athletes behalf.

#### Suggested changes to the wording of the Article

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#### Reasons for suggested changes

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## **Council of Europe**

SUBMITTED

Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

#### **General Comments**

Comment to Article 4.2.b

It should be clear that the "appropriate" treatment is also evidence-based and not just the diagnosis (Article 4.2(a) – "the diagnosis must be supported by relevant clinical evidence"). Proposed text:

An appropriate treatment should be supported by relevant clinical evidence and could be based on factors such as experience, side-effect profiles or other medical justifications, including, where applicable, geographically specific medical practice, and the ability to access the

medication.

#### Article 4.2.d

The Article 4.2.d should be removed, as it is very hard to prove and 2) it is difficult to understand why a possible reasonable treatment is withheld from an athlete.

## EOKAN/HADA

Spyridoula Christopoulou, Scientific Support & Quality Office Assistant (Greece) NADO - NADO

#### **General Comments**

• [Comment to ArticleArticles 4.2(a) and (b): The Use of the Prohibited Substance or Prohibited Method may be part of a necessary diagnostic investigation rather than a treatment per se.]: is there an example for this comment?

• [Comment to Article 4.2(b): An appropriate treatment could be based on factors such as experience, side-effect profiles or other medical justifications, including, where applicable, geographically specific medical practice, and the ability to access the medication.]: I would like to make more specific the part of geographical medical practice and in particular which substances are banned in medicines in which countries

#### NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

#### **General Comments**

#### Art. 4.2 b)

We suggest that the TUE application should contain an explanation when permitted alternatives have not been tried.

## **NADA Austria**

Dario Campara, Lawyer (Austria) NADO - NADO

#### **General Comments**

NADA Austria is against the deletion of 4.2.c. "The Prohibited Substance or Prohibited Method is an indicated treatment for the medical condition, and there is no reasonable permitted Therapeutic alternative.". This principle was widely accepted by athletes and physicians, is easy to understand and actively reduced the number of TUEs.

Comment to Article 4.2(b) states "An appropriate treatment could be based on factors such as experience, side-effect profiles or other medical justifications, including, where applicable, geographically specific medical practice, and the ability to access the medication." This essentially means that there is no requirement to use permitted alternatives first or at least explain why the use of the permitted alternative is not possible. This will lead to a further global disharmonization of TUE processes. Some countries might have a medical system where e.g. glucocorticoids or fenoterol are the first line medication. This would dramatically increase the number of TUEs.

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO SUBMITTED

#### **General Comments**

SSI supports the new wording of Article 4.2 a and b. However, SSI strongly recommends retaining the former Article 4.2 c (therapeutic alternatives).

1. Using permitted therapies in the first instance before using prohibited therapy seems to SSI a logical principle in the field of anti-doping. Based on our experience, this principle is also understood and supported by athletes, physicians and athlete support personnel.

2. ADOs may require additional resources if TUE applications for prohibited substances can be submitted without having tested permitted alternatives. Likely, there will be an increasing amount of TUE applications for beta-2 agonists, diuretics, iron infusions administered outside hospital settings, narcotics etc.

SUBMITTED

SUBMITTED

3. Depending on the region and country-specific guidelines, certain banned substances are more commonly used than in other regions. SSI acknowledges this while being concerned that omission of permitted alternatives could further contribute to global disharmonization. The primary use of permitted alternatives has counteracted this effect and the previous Article 4.2 c comment already allowed for flexibility in case of geographical differences.

4. Finally it is indicated in the summary document, that this change was introduced "given that this was identified by stakeholders as a problematic area". However, only two comments from 2023 consultation regarding ISTUE concept 10 highlight this issue and these two only concern lower level athletes due to the nature of concept 10. Therefore, it seems astonishing that this less restrictive practice should be applied to TUE applications from all athletes. SSI strongly welcomes consistent 4.2 criteria for all athlete levels, while in a particular 4.1 c or 4.1 d case, where permitted alternatives may have not been tried, could be treated as a 4.3 TUE application.

In addition, SSI would like to highlight again, that general requirement of a clear timeline (diagnostic and prescription prior to start of therapy) is not indicated at all in ISTUE. We acknowledge that there are emergency scenarios (ISTUE Article 4.1 a) where this chronology could be legitimately lacking, however, in all other legitimate TUE scenarios diagnostic and prescription must be the starting point.

## Japan Anti-Doping Agency

Chika HIRAI, Director of International Relations (Japan) NADO - NADO

#### **General Comments**

#### Article 4.2

If we are supportive of the removal of the requirement to trial permitted alternatives from 2023 ISTUE Article 4.2, it is vital that the proposed revision retains the phrase 'appropriate treatment' as depicted in the proposed revision, and that WADA provides more examples of 'appropriate treatment' than currently in the TUE Physician's Guideline.

For example, in the case of 'S3.Beta2 agonist', inhalation use of four prohibited substances (Formoterol, Salmeterol, Salbutamol and Vilanterol) is permitted within the prescribed dosage range. If an athlete is prescribed "procaterol" as the prohibited substance, it is difficult for the TUEC or prescribing physician to determine whether or not it should be judged as "appropriate treatment", even if permitted inhalation use is possible. Before revising, it's important to check for consistency with the Prohibited List.

SUBMITTED

**CHINADA** 

MUQING LIU, Coordinator of Legal Affair Department (CHINA) NADO - NADO

**General Comments** 

**1.Conditions for Granting a TUE** 

We support the removal of the requirement for trial permitted alternatives. Athletes, as patients, may not be able to determine (or may not fully understand) which medications are appropriate for their medical conditions when seeking treatment. For example, some Athletes with severe hypertension may need to change their medications and add diuretic-containing medications to treat their conditions. Removing the requirement for permitted Therapeutic alternatives can better protect the rights and interests of athletes. However, we recommend further refining this Article or providing more examples.

2.Sanctions for Athletes who meet the Article 4.2 criteria but do not meet the criteria for a retroactive TUE (proposed in the Summary of Major Changes, not included in this International Standard)

We believe that Athletes who inadvertently ingest or misuse Prohibited Substances due to therapeutic reasons should be considered to have No Significant Fault or No Significant Negligence. Therefore, a fixed period of Ineligibility between three (3) and six (6) months should not be imposed on them, as this would reduce the differences in positive cases caused by different therapeutic medications, while at the same time creating unfairness to other positive cases caused by No Significant Fault or No Significant Negligence. This in turn would encourage more positive Athletes who do not meet the criteria for granting a TUE to apply for a retroactive TUE at a later time, or even to provide false medical documentation to receive a lesser sanction. This provision could have adverse effects, not only increasing the workload of TUE committees but also posing a serious challenge to the existing TUE system.

Suggested changes to the wording of the Article

## **Conditions for Granting a TUE**

We recommend further refining this Article or providing more examples.

UK Anti-Doping UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

**General Comments** 

4.2 - We have no objections to the reordering of Articles 4.2 (b) and (c).

4.2 (a) - We have no objections to the proposed revisions to Article 4.2 (a).

4.2 (b) - We do not support the removal of the requirement to assess applications on whether permitted alternatives would be as effective as a prohibited substance or method to treat a medical condition. Removing this requisite creates a 'softening' of the rules and has the potential to create a loophole allowing the TUE system to be misused. Indeed, it will make it harder for a TUE Committee (TUEC) to challenge the "appropriateness" of a proposed treatment since this term is subjective and its interpretation will vary amongst practitioners. Furthermore, bypassing reasonable permitted alternatives (when they exist) could conceivably lead athletes to obtaining an unfair advantage by way of overtreatment.

If the proposed revision is trying to afford extra flexibility to lower-level athletes (which was discussed as an issue by stakeholders in the previous consultation phase), then Article 4.3 should be expanded to deal with this issue. That is, lower-level athletes who have a legitimate medical condition but do not retroactively fulfil the conditions outlined in Article 4.2 on account of not having trialled permitted alternatives, should be able to rely on obtaining a fairness TUE under ISTUE Article 4.3.

To be clear, we are not proposing that permitted alternatives must be trialled in every instance (if there is strong clinical justification for not doing so), but the TUEC should have the authority to challenge the "appropriateness" of a proposed treatment when reasonable alternatives do exist.

Comment to 4.2 (b) - We are not in favour of the proposed revision to this comment for two reasons. Firstly, it should be made clear that "appropriate treatment" needs to be evidence-based.

Secondly, if the requirement to assess whether permitted alternatives would be as effective to treat a medical condition is kept within Article 4.2 (b) (see our recommendation above), then the comment that "it is not always necessary to try and fail alternatives before using the Prohibited Substance or Prohibited Method" should be reinstated.

Recommendation to revise the comment to Article 4.2 (b) to j. clarify that justification for the proposed treatment needs to be evidence-based; and ii. reinsert the message that it is not always necessary for an athlete to trial and fail alternatives before seeking to use a prohibited substance or method.

#### Suggested changes to the wording of the Article

4.2 (b) - Recommendation to re-insert the phrase "and there is no reasonable permitted Therapeutic alternative" to Article 4.2 (b).

Also, recommendation to expand the comment to Article 4.3 to mention lower-level athletes who have not trialled permitted alternatives but have a legitimate medical condition. (Suggested wording added to 4.3 section).

Comment to 4.2 (b) - Suggested revision:

[Comment to 4.2 (b): An appropriate treatment could be based on factors such as. The physician must provide clinical justification for why the proposed treatment is the most appropriate. This could be based on factors such as physician 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.]

#### **Sport Integrity Australia**

Andrew McCowan, Assistant Director Project Management Office (Australia) NADO - NADO

SUBMITTED

#### **General Comments**

SIA encourages the Drafting Team to ensure that the Article 4.1, Exceptional Circumstances Criteria can be applied broadly enough to ensure that a mechanism exists for a retroactive TUE to be granted where all other 4.2 criteria are satisfied. For example, to ensure that an Athlete is not improperly penalised where an administrative, or other error, they would have been granted a TUE under Article 4.2.

SIA reconfirms the comments provided as part of the Phase 1 Stakeholder Engagement, and in particular, the principle that if an Athlete satisfies the criteria under Article 4.2 for a TUE then there must be a mechanism under ISTUE for that athlete to be granted a retroactive TUE (if they do not have a TUE in place).

If an Athlete has satisfied the criteria under Article 4.2 but has not complied with the administrative requirements for obtaining a TUE or has made an error in their application, then in these circumstances a retroactive TUE should be granted.

However, the Athlete should be subject to a graded penalty regime that encourages them to follow the correct process for future applications. SIA suggests this could follow a staggered approach for failing to comply with the procedural requirements under the ISTUE. The first failure could result in a reprimand, followed by a period of 2 months Ineligibility for a second procedural offence. This represents a clear regime which is simple to understand and apply.

SIA also supports an appropriate sanctioning flexibility in anti-doping rule violation cases where the criteria for obtaining a TUE in Article 4.2 is met. This includes such cases where an Athlete has a diagnosed medical condition and can produce sound medical evidence (but the athlete has not met the criteria for a retroactive TUE). Noting this is being considered as part of the World Anti-Doping Code review relevant to Article 4.4, SIA agrees a more lenient and flexible sanctioning regime is appropriate, such a reprimand or short period of Ineligibility (two months for example).

#### Suggested changes to the wording of the Article

SIA suggests that if an Athlete is entitled to a TUE but commits an administrative breach a staggered 'penalty' approach could be applied for failing to comply with the procedural requirements under the ISTUE.

The first failure could result in a reprimand, followed by a period of 2 months Ineligibility for a second procedural offence.

#### Reasons for suggested changes

This represents a clear regime which is simple to understand and apply.

#### **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

USADA submits that lower-level athletes should not face the same high expectations for TUEs as international- or national-level athletes. In addition to the lack of anti-doping education and the protection of limited ADO and TUEC resources, USADA also notes that lower-level athletes and their competitors generally do not have as much at stake in their competitions as elite-level athletes (as competition is not professional career choice).

In Article 4.2b: Consider replacing "appropriate treatment" with "standard of care". Standard of care as defined by the US National Institutes of Health is treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by health care professionals.

General comment: Article 4.2c: While removing the need for trialing permitted alternatives is justified (4.2c), it is a worry that this language is removed when considering the potential to abuse medications or obtain false diagnoses simply based on reversible factors or confounders that should be ruled out to prevent abuse of the TUE system (e.g. diet, excessive exercise, use of other medications, poor laboratory testing, ill-timed medical test collections). Therefore, particularly for chronic medical conditions (like hypogonadism), there is a need to continue to strongly consider and rule out functional causes that could lead to a reversible medical condition or resolution without treatment with a prohibited

substance or method. In this way, permitted alternatives that lead to resolution of the medical condition must be properly considered and commented on as part of the overall differential diagnosis.

Recommended change: Ensure wording is included to address the need to require ruling out the use of permitted alternatives as part of the differential diagnosis where appropriate to ensure that the TUE system cannot be abused.

Suggested changes to the wording of the Article

For athletes who are not International or National-Level athletes, please provide ADOs the flexibility to apply different rules (not the TUE rules) to a designated class of lower-level athletes to permit these designated athletes to use otherwise prohibited substances for proper and valid therapeutic purposes, without applying for a TUE. This can be accomplished by adding the following comment to ISTUE Article 4.2: [Comment to Article 4.2: Separate from a TUE, ADOs may develop and implement less stringent (more flexible) standards and processes for authorizing the proper therapeutic use of prohibited substances by Athletes who are not International or National-Level Athletes but over whom the International Federation or National Anti-Doping Organization has chosen to exercise authority, recognizing that they have lower responsibilities under the Code.]

Reasons for suggested changes

1. Many national sport federations and/or governments desire to stop doping at all levels of competition and some even outside of competitions (i.e., fitness centers). National Federations and/or governments require all members of national sport federations to be bound by the Code. These federations/governments also want to deter doping at all levels of competitions through testing, but bringing the full weight of the ISTUE on lower-level athletes, including masters' athletes, is not necessary to protect this level of competition and is not fair/feasible given the number of athletes who compete at these lower levels.

2. Several ADOs, including USADA, have already implemented, without objection from WADA, different rules for a designated class of lowerlevel athletes. The way these rules have been employed is tailored to the needs within the country. ADOs create a more efficient review process but nevertheless maintain sufficiently robust safeguards to ensure doping is not permitted.

USADA is happy to share and discuss its program for lower-level athletes and the fairly extensive experiences we have had over 20 years (including threats of litigation) that have led us to this conclusion and solution.

## Sport Integrity Commission Te Kahu Raunui

Jono McGlashan, GM Athlete Services (New Zealand) NADO - NADO

#### **General Comments**

- We support the changes, however, seek clarification on how to avoid abuse of prohibited substances when non-prohibited substances are available
- A fundamental change is proposed to amend the criteria that an application must meet in order for the TUE Committee to grant the exemption. It removes the "requirement to trial permitted alternatives". The reasoning is to be more athlete-centric and better reflect medical practice.
- In theory, this would allow athletes who are stable on prohibited substances to not shift from the current and long-term treatments when they
  need to consider applying for a TUE e.g. a non-stimulant medication for ADHD. However, our committee already applies common sense to this
  approach if the doctor justifies the original choice of medication as captured in Comment to Article 4.2(c).
- We envision that the change could be problematic in cases of short-acting doses such as analgesics as there is no requirement to demonstrate other choices. For example, tramadol and glucocorticoid injections. This would also apply in cases such as iron infusions.

"This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

SOBINITIE

#### **General Comments**

Agree the flow is more logical. Happy with changes to criteria

The removal of "permitted alternatives" should not be significant but perhaps some refence to the "non- absolute" consideration of alternatives could occur in the comments?

Comment 1: It is noted that the requirement to "trial". permitted alternative has been completely removed from 4.2. There is no objection to removing having to trial a medicine, however it is suggested that a justification as to why a permitted medicine is not suitable should still be included.

Comment 2: With the deletion of the words "the physician must explain" from the previous, 4.2.(c), there is no requirement on the physician to explain their choice of treatment.

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

#### We agree with a defined sanction - 3 months.

If all athletes were to apply for TUEs in an ad hoc manner, looking for retroactive TUEs when it was possible to have a prospective TUE, the situation could potentially be difficult to manage. A structured approach to TUE applications should be maintained.

To easily allow retroactive applications would favour those who have strong legal support to have their TUE defined as retroactive (4.1) or even come under the fairness clause (4.3), and could be unfair overall.

It is not an easy decision but suggest that a fixed sanction (starting from a defined point in time during the competition season for that athlete) for those who are purposefully late and did not attempt to apply for a TUE when there was an opportunity to do so, could be applied.

Suggested changes to the wording of the Article

Suggest updating the wording to comment to Article 4.2(b) "The Physician must explain the appropriateness of the treatment including such factors as why permitted alternatives are not deemed suitable, the physician's own experience, side-effect profiles or other medical justifications, which can include, where applicable, geographically specific medical practice, and the ability to access the medication etc.

#### Reasons for suggested changes

It is important, at the time of application that the physician explain the appropriateness of treatment.

It is fairer for all to put the onus on the doctor to supply this information with the application <u>at the beginning of the process</u> rather than go through an appeals process due to a decision based on incomplete information. An appeal and a decision being overturned will have to be paid for by the NADO/IF if they are not on the winning side. For example, the TUEC reasoned decision might say X is the first line treatments for this, so deny TUE. Then athlete can appeal and say well X is not available in my country. If TUEC had this information available to them from outset then TUEC decision may have been different.

Internationally there are many shortages of medicines and this is a very practical approach.

NADA India NADA India, NADO (India) NADO - NADO SUBMITTED

#### **General Comments**

We recommend that appropriate sanctioning flexibility may be in anti-doping rule violation cases where the criteria for obtaining a TUE in Article 4.2 of the ISTUE are met may be , 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.

#### **Anti-Doping Norway**

Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO

SUBMITTED

**General Comments** 

### General comment for article 4.2. b)

It is important to clarify whether the phrase "...appropriate treatment..." implies that the TUEC should reject the application if they disagree with the selected treatment. Consider a situation where an athlete is using only beta-2-agonists and applies for a Therapeutic Use Exemption (TUE), yet international guidelines advise that inhaled glucocorticoids should form the cornerstone of asthma treatment.

Deletion of "and there is no reasonable permitted Therapeutic alternative": We prefer keeping the reference.

In Norway, there is a therapy tradition for treating allergies with intramuscular injections of triamcinolone acetonide, depot formulas. However, this treatment is not recommended by international guidelines, and our TUEC will not approve TUE applications unless other recommended treatments are tested first. Eliminating the mentioned phrase would complicate arguing against such applications. Another scenario that would become complex with this removal is the use of diuretics. We believe that diuretics, even for medical purposes, should be limited, and we see no other way to refuse TUE applications.

## Chair

Athlete Council, WADA (Canada) Other

**General Comments** 

## 4. 2 Criteria for Obtaining a TUE

We support the change to 4.2 which removes the requirement to trial alternative treatments.

## 4.2 b) Criteria for Obtaining a TUE

We suggest adding the text in blue below to clarify the connection between the treatment and the medical condition:

"b) The Prohibited Substance or Prohibited Method is an indicated and appropriate treatment for the medical condition diagnosed in 4.2 a."

## Article 4.3 (14)

## World Rugby

David Ho, Senior Manager Anti-Doping Operations (Ireland) Sport - IF – Summer Olympic

#### **General Comments**

World Rugby support this clarification. We consider it important that a medical expert is involved.

## **Council of Europe**

Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

#### **General Comments**

Comment to Article 4.3:

To address issues mentioned in 4.2.b (removal of the requirement to trial permitted alternatives), WADA should explore expanding the comment to Article 4.3 to mention lower-level athletes:

For the avoidance of doubt, retroactive approval may be granted under Article 4.3 even if the conditions in Article 4.2 are not met (although satisfaction of such conditions will be a relevant consideration). Other relevant factors might include, without limitation, the reasons why the Athlete did not apply in advance; the Athlete's competition level; the Athlete's experience; the Education previously received by the Athlete; whether the Athlete declared the Use of the substance or method on the Doping Control form; and the recent expiration of the Athlete's TUE.

SUBMITTED

This clause should rather read "ADO and WADA may..." as not all retroactive TUE Applications require another medical expert view.

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO

#### **General Comments**

SSI generally supports the amendment of the commentary on Article 4.3, but emphasizes that, depending on the situation, other experts may also be consulted and therefore recommends replacing "medical expert" with "expert". Obviously, the criteria of Article 4.2 must be evaluated by medical experts. However, other aspects of a fairness application should be assessed by the relevant experts, e.g. questions relating to Article 4.1 by legal experts / TUE managers or ethical questions by ethics experts.

## Canadian Centre for Ethics in Sport

Bradlee Nemeth, Manager, Sport Engagement (Canada) NADO - NADO

#### **General Comments**

Comment to Article 4.3: Consider changing the wording from "must" to "shall" to maintain consistency across requirements.

#### **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

Comment to Article 4.3 - We welcome the extension of this comment to mandate that Anti-Doping Organisations and WADA must consult with an appropriate medical expert when evaluating TUE requests in accordance with Article 4.3.

Suggested changes to the wording of the Article

Comment to Article 4.3 - Recommendation to expand the comment to Article 4.3 to mention lower-level athletes who have not trialled permitted alternatives but have a legitimate medical condition.

Suggested addition:

[Comment to Article 4.3: For the avoidance of doubt, retroactive approval may be granted under Article 4.3 even if the conditions in Article 4.2 are not met (although satisfaction of such conditions will be a relevant consideration). Other relevant factors might include, without limitation, the reasons why the Athlete did not apply in advance; the Athlete's competition level; the Athlete's experience; the Education previously received by the Athlete; whether the Athlete declared the Use of the substance or method on the Doping Control form; and the recent expiration of the Athlete's TUE.

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

**General Comments** 

Agreed.

As noted under Article 4.2, SIA reconfirms the comments provided as part of the Phase 1 Stakeholder Engagement, and in particular, the principle that if an Athlete satisfies the criteria under Article 4.2 for a TUE then there must be a mechanism under ISTUE for that athlete to be granted a retroactive TUE (if they do not have a TUE in place).

If an Athlete has satisfied the criteria under Article 4.2 but has not complied with the administrative requirements for obtaining a TUE (ie applied in advance if they are required to do so) or has made an error in their application, then in these circumstances they are entitled to a retroactive TUE.

However, the Athlete should be subject to a graded penalty regime that encourages them to follow the correct process for future applications.

SIA suggests this could follow a staggered approach for failing to comply with the procedural requirements under the ISTUE. The first failure could result in a reprimand, followed by a period of 2 months Ineligibility for a second procedural offence. This represents a clear regime which is simple to understand and apply.

#### Suggested changes to the wording of the Article

As noted under Article 4.2 SIA suggests a staggered 'penalty' approach could be applied for an administrative error resulting in an Athlete failing to comply with the procedural requirements under the ISTUE. The first failure could result in a reprimand, followed by a period of 2 months Ineligibility for a second procedural offence.

#### Reasons for suggested changes

This represents a clear regime which is simple to understand and apply.

## Australian Sports Drug Medical Advisory Committee

Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

#### **General Comments**

Agree

## **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### **General Comments**

Yes agree with this update, it is appropriate that medical expert(s) is involved in deciding 4.1 and 4.3

**Sport Integrity Commission Te Kahu Raunui** Jono McGlashan, GM Athlete Services (New Zealand) NADO - NADO

#### **General Comments**

- We support the changes
- We always practice that our TUE Committee will review a case where there may be grounds for 4.3 to see if there are areas lacking under 4.2- while a TUE can be granted under 4.3 without meeting all conditions of 4.2, the ISTUE notes that this would be a relevant consideration. We had assumed that this was already common practice.
- We require confirmation as to why TUE Committees are not already reviewing 4.3 applications and what is an 'appropriate expert' medically
- We are seeking clarity on how a medical expert is defined i.e. is this satisfied by the medical experts on our TUEC who meet the ISTUE requirements of 'sound knowledge of clinical, sports and exercise medicine' or is it a specialist for the condition in the case? E.g. psychiatrist for ADHD

#### SUBMITTED

## **FINCIS**

Anna Simula, Pharmacist (Finland) NADO - NADO SUBMITTED

#### **General Comments**

We would like to suggest time limits for WADA decisions regarding approval or rejection of Art. 4.3 retroactive TUEs. Currently, under section 4.3, An ADO may grant an application for a retroactive TUE "only with the prior approval of WADA" for national and international-level athletes. The ADO should make a decision within 21 days as per section 6.8 (ISTUE).

In cases where the WADA decision takes an extended period, this can have a severe impact on athletes. It can significantly affect athlete wellbeing, life planning decisions, mental health, resulting in a very stressful situation for the athlete.

#### **Anti-Doping Norway**

Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO

SUBMITTED

#### **General Comments**

The definition of a "medical expert" needs to be clarified, and whether the TUEC should always be consulted in the use of 4.3.

Suggested changes to the wording of the Article

#### Proposed text in the comments to 4.3.:

For the avoidance of doubt, retroactive approval may be granted under Article 4.3 even if the conditions in Article 4.2 are not met (although satisfaction of such conditions will be a relevant consideration). Other relevant factors might include, without limitation, the reasons why the Athlete did not apply in advance; *the Athlete's competition level*; the Athlete's experience; the Education previously received by the Athlete; whether the Athlete declared the Use of the substance or method on the Doping Control form; and the recent expiration of the Athlete's TUE.

#### Reasons for suggested changes

To address issues mentioned in 4.2.b (removal of the requirement to trial permitted alternatives), WADA should explore expanding the comment to Article 4.3 to mention lower-level athletes.

#### International Testing Agency

International Testing Agency, - (Switzerland) Other - Other (ex. Media, University, etc.)

#### **General Comments**

#### 4.3

Suggested amendment: Comment to Article 4.3: to add as an example of factors to take into consideration when assessing the "fairness" criterion whether the Athlete only recently became "International-Level Athlete" or recently changed status under the applicable rule.

Often, athletes finds themselves in jeopardy as they become International-Level Athlete (and test positive) during their first participation in an International Event.

## Article 5 (4)

Dopingautoriteit Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

5.8 We can't help ourselves to point out once again that this article should be checked for compliance much more rigorously than what is currently happening

#### Reasons for suggested changes

5.8 Many IFs and MEOs fail to clearly publish their Testing Pools, International Events, and all TUE-related obligations for their athletes. This makes our daily work extremely difficult, which is all the more disconcerting as the efforts to monitor compliance by NADOs become more and more strict

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

Comment to 5.1 - We have no objections with part of the current comment to Article 5.1 being moved to its own standalone article within 5.5 of the 2027 ISTUE.

#### **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### **General Comments**

Agree with all other suggestions 5a, 5b, 5c and 5d

Chair Athlete Council, WADA (Canada) Other

#### **General Comments**

#### 5.2, 5.7 Validity of TUE Granted by NADO, TUE recognition by IF or MEO

Article 5.2 states that a TUE granted by a NADO "is valid at a national level on a global basis," and that if the athlete competes in the country of another NADO, that TUE will be valid.

Article 5.7 says TUE granted by a NADO "is valid at a national level only" and if the athlete becomes an International Athlete or competes in an International Event, or becomes subject to the TUE requirements of Major Event Organization, that TUE will not be valid.

Rephrasing is needed to clarify this distinction for athletes.

Further, we question why TUEs approved by one Code-compliant signatory are not automatically approved by other signatories?

## Article 5.3 (7)

Council of Europe Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

#### **General Comments**

The phrase "(which may, for example, be a member of staff or a member of a TUEC)" should be deleted as superfluous.

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO

SSI emphasizes that, in relation to the article 4.1 and 4.3, other experts may also be consulted and therefore recommends replacing "medical expert" with "expert". Obviously, the criteria of Article 4.2 must be evaluated by medical experts. However, questions relating to Article 4.1 by legal experts / TUE managers or ethical questions by ethics experts.

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

General Comment: Article 5.3: Clarification around Article 4.1 and 4.3 evaluations is good.

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

5.3 - We welcome the revision to Article 5.3 on the proviso that TUE Managers based within Anti-Doping Organisations (ADOs) are considered to be "medical experts". If this is not the case, then this article should be re-worded further to explicitly list TUE Managers within ADOs as qualified to assess whether an application fulfils the exceptions outlined in Article 4.1.

We have no objections to the deletion of the Comment associated with Article 5.3 since this comment is already set out in Code Article 4.4.

#### **Sport Integrity Australia**

Andrew McCowan, Assistant Director Project Management Office (Australia) NADO - NADO

#### **General Comments**

SIA suggests Article 5.3(a) be amended to require a TUEC to include at least 3 physicians with experience.

#### Suggested changes to the wording of the Article

## Article 5.3 a

TUEC considering a specific application shall include at least three (3) physicians with experience in the care and treatment of Athletes and a sound knowledge of clinical, sports and exercise medicine. In cases where specific expertise is required (for example, for Athletes with impairments where the substance or method pertains to the Athlete's impairment), at least one (1) TUEC member or expert should possess such expertise. One (1) physician member should act as chair of the TUEC.

#### Reasons for suggested changes

Changing "should" to "shall" mandates minimum of three physicians on TUEC. This ties in with 5.3b) which states: "Decisions should be reached through consensus, with further input from other physicians and/or experts if necessary. However, in case of disagreement, a majority decision may be made."

By mandating a minimum of three physicians on TUEC it results in always being able to get a majority decision in the absence of consensus.

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO SUBMITTED

SUBMITTED

**General Comments** 

## Anti-Doping Norway Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO

#### **General Comments**

#### General Comments to article 5.3.1.

We recognize that experience from sports and exercise medicine and from treating athletes provides added value to a TUEC. However, given that the majority of applications received lies outside the expertise of sports physicians, we would suggest that less emphasis is placed on the sports- and exercise medicine and more on other fields of expertise, e.g. internal medicine, endocrinology, pulmonology, psychiatry in addition to an expert in sports and exercise medicine. Additionally, non-medical expertise, could also be considered, e.g. law.

Furthermore, while we recognize that some TUE applications are so complex that more than one TUEC-member should assess them, in our experience the majority does not require the involvement of three physicians. Having three (or more) members assess all TUE-applications (for ADOs with a large number of applications) will unnecessarily increase the complexity of the assessment and thus risk of missing the deadlines, in many instances without providing added value to the process. On the other hand, when the cases are already complex, an extra set of eyes can be helpful. From a practical point of view, if sufficient expertise is ensured, it may therefore not always be necessary to involve all TUEC-members in the assessment of all applications. We suggest instead a more pragmatic approach, where "simple" assessments are carried out by one TUEC-member, but more complex assessments by two or three TUEC-members, or the entire committee.

We therefore suggest a set-up similar to that of Hearing and Appeal Panels is applied for TUECs as well.

See the practice described in ISRM, comment to art. 8.3, which notes that: "The size and composition of the hearing panel may vary depending on the nature of the charge and the evidence put forward. However, the hearing panel shall be composed of a single adjudicator or of a panel of three."

#### Article 5.3 b) (6)

#### NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

#### **General Comments**

We ask for clarification if an unanimous or a majority decision is necessary.

With a view to Article 5.3 a) a majority decision would mean that a decision of 2 to 1 in a group of three physicians is fine. Is that right?

## Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO

**General Comments** 

In order to prevent premature decisions after evaluation by two TUEC members, SSI suggests the following amendment (addition of "only"): Decisions should be reached through consensus, with further input from other physicians and/or experts if necessary. However, only in case of disagreement, a majority decision may be made.

## Canadian Centre for Ethics in Sport

Bradlee Nemeth, Manager, Sport Engagement (Canada) NADO - NADO

#### **General Comments**

Consider changing this to a comment and not an article.

## **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

**General Comments** 

General Comment: Article 5.3b: This is helpful information.

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

5.3 (b) - We stand by our recommendation from the Stakeholder Engagement Phase that the decision to grant a TUE should be unanimous rather than a majority decision. However, we do not oppose the new wording since it affords us the ability to continue to only grant TUEs when a consensus is reached between members of a TUE Review Panel. We also appreciate that not all TUE Committee's work in the same way.

## Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia)

NADO - NADO

**General Comments** 

Agree

## Article 5.3 d) (5)

**Canadian Centre for Ethics in Sport** Bradlee Nemeth, Manager, Sport Engagement (Canada) NADO - NADO

#### **General Comments**

Consider changing this to a comment and not an article.

#### **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

5.3 (d) - We have no objections to the addition of this new article since we already operate in this way.

## Australian Sports Drug Medical Advisory Committee

Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

**General Comments** 

Agree, with the same requirements for expertise as in 5.3.a.

## SUBMITTED

- This is not something that we would be able to do (have a wide range of TUE experts who are pulled in for each case depending on their level of expertise).
- This is prohibitive for small NADOs based on specialist availability and cost prohibitive. Although as this is guiding best practice rather than
  prescriptive, we could continue with our current committee structure.

"This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

## Sport Integrity Australia

Andrew McCowan, Assistant Director Project Management Office (Australia) NADO - NADO

#### **General Comments**

SIA agrees with this provision. However, SIA suggests a comment be included to note that the experience required under Article 5.3(a) also apply to this Article 5.3(d).

#### Suggested changes to the wording of the Article

SIA suggests a comment be included to note that the experience required under Article 5.3(a) also apply to this Article 5.3(d).

#### Reasons for suggested changes

SIA is of the view any TUEC member must have the requisite qualifications to make decisions under the ISTUE.

## Article 5.4 (7)

**Swiss Sport Integrity** 

Ernst König, CEO (Switzerland) NADO - NADO

#### **General Comments**

"...which athletes to apply to it for a TUE, and when" refers to Code Article 4.4.2 and 4.4.3 (= national- and international-level athletes required to apply for an in advance TUE) and ISTUE Article 4.1 c and d (= lower level athletes required to apply for a retroactive TUE). Therefore, these athlete level terms should be used consistently in ISTUE Article 5.4.

In practice, it can be hard to find these athlete level definitions. Therefore it should be mandatory that they are published in a conspicuous place on ADOs website: IF: ILA definition, NADO: NLA definition, MEO: TUE requirement in connection with event.

#### Suggested changes to the wording of the Article

Each National Anti-Doping Organization, International Federation and Major Event Organization must establish a clear process for applying to its TUEC for a TUE that complies with the requirements of this International Standard. It must also publish details of that process by (at a minimum) posting the information in a conspicuous place on its website, including clearly setting out which Athletes are required to apply to it for a TUE, and when (International Federations must publish their International-Level Athlete definition; National Anti-Doping Organizations must publish their National-Level Athlete Definition and Major Event Organizers must publish their TUE requirements in connection with their event(s)).

## **Obligation of Disclosure**

We support expanding the scope of public disclosure of information related to the TUE process. In addition, we

recommend refining this Article by, for example, including more detailed questions during the consultation phase to

help athletes determine whether they need to apply for a TUE and how to do it, etc.

Suggested changes to the wording of the Article

## **Obligation of Disclosure**

We support expanding the scope of public disclosure of information related to the TUE process. In addition, we recommend refining this Article by, for example, including more detailed questions during the consultation phase to help athletes determine whether they need to apply for a TUE and how to do it, etc.

Reasons for suggested changes

## **Obligation of Disclosure**

It can help athletes determine whether they need to apply for a TUE and how to do it, etc.

#### USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

This is helpful to athletes. One suggestion of best practice is to have all this information as part of an ADO TUE policy that can easily be referenced. In practice, NADOs have trouble finding this information from IFs. Many times, finding up-to-date information buried in IF websites is very hard and time consuming.

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

5.4 - We welcome the extra clarity added to this article making all Anti-Doping Organisations accountable for setting out when an Athlete is required to apply to their organisation for a TUE.

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

General Comments

Agree

#### Agree

**Anti-Doping Sweden** 

Jessica Wissman, Head of legal department (Sverige) NADO - NADO

#### **General Comments**

The issue with poor information from ADO's, especially International Federations (IF), regarding the TUE process has been an issue for several years. ADSE experience that some IF's has clear instructions on their websites regarding which Athletes are under their jurisdiction and clearly specifies who are required to apply to them for a TUE and when, while some IF's struggles with this. To add more pressure on IF's a suggestion is to have direct links to all IF's webpages with information regarding Antidoping/TUE's gathered on WADA's website. This would require more administrative work on behalf of WADA, however, it would put more pressure on the IF's and make it easier for NADO's to engage with IF's processes.

## Article 5.5 (6)

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO

#### **General Comments**

"...which athletes are not required to apply for a TUE in advance not only refers to ISTUE Article 4.1c but also ISTUE Article 4.1d (= lower level athletes). Therfore, these athlete level terms should be used consistently in ISTUE Article 5.5.

What is summariezed in Article 5.5 referring to ISTUE 4.1c applies also to non-international non-national level athletes (ISTUE article 4.1d) and therfore concerns IFs too. It sholud also be clearly indicated on ADOs website that non-international and non-national level athletes apply for a retroactive TUE according to ISTUE Article 4.1d (this was previously included in a comment in the Code, however, this comment will be removed. Therfore we strongly recommend reincluding it in the ISTUE).

#### Suggested changes to the wording of the Article

Anti-Doping Organizations must permit 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, to apply for a retroactive TUE. Anti-Doping Organizations must publish and clearly setting out in a conspicuous place on its website, which Athletes are not required to apply for a TUE in advance.

In addition, where national policy requirements and imperatives lead a National Anti-Doping Organization to prioritize certain sports or disciplines over others in its test distribution planning (as contemplated by Article 4.4.1 of the International Standard for Testing), the National Anti-Doping Organization may decline to consider advance applications for TUEs from Athletes in some or all of the non-priority sports or disciplines, but in that case it must permit any such Athlete from whom a Sample is subsequently collected to apply for a retroactive TUE. The National Anti-Doping Organization must publish any such policy in a conspicuous place on its website, including clearly setting out which Athletes are not required to apply for a TUE in advance.

## **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

Agreed and again, a best practice to include this in a TUE Policy document.

# UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom)

NADO - NADO

SUBMITTED

**General Comments** 

5.5 - We have no objections to the revision of this article.

#### Sport Ireland

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

## **General Comments**

## Agree

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

#### **General Comments**

#### Agree

Can MEOs and/or IFs do the same prioritisation? Particularly smaller sports?

## Chair

Athlete Council, WADA (Canada) Other

#### **General Comments**

#### NADO Prioritization of TUE Approval

This Article says that a "National Anti-Doping Organization may decline to consider advance applications for TUEs from Athletes in some or all of the non-priority sports or disciplines." While this allowance may save a NADO from unnecessary work, we are concerned that it is unfair to athletes, who will not have certainty about the status of their medication or treatment.

#### Article 5.6 (6)

## Tug of War International Federation

Peter Dyer, Senior Vice President (England) Sport - IF – IOC-Recognized

#### **General Comments**

Note below 5.6 C, ref Medical file. It should be made clear that this medical file should be proportionate to the risk, using a risk based proportionate and targeted methodology (see also comments in section 4.2)

## Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

#### **General Comments**

1) The translation of medical documentation in English or French is a big burden for NADO's in non-English or non-French speaking countries.

2) "Comment to article 5.5: If a TUE application form is issued....upon request"

#### Suggested changes to the wording of the Article

1) Maybe rephrasing it with something like: "upon request a translation should be provided"

SUBMITTED

SUBMITTED

2) If we add a translation into Dutch on the Form and keep the original English text, the document is nine pages, but only three of them are "relevant" and contain information of the athlete, the medication or the treatment.

Reasons for suggested changes

1) A lot of TUEs are of lower level athletes and providing translations is hardly necessary. If it is it can be done, but if not, this task should be minimized

2) Not relevant and the overhaul of information leads to athletes ignoring the information.

#### **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

5.6 - We support the extension of this article to make it a mandatory requirement for Anti-Doping Organisations to upload the reasons for a TUE denial in ADAMS.

## Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia)

NADO - NADO

#### **General Comments**

Agree

Reasons for suggested changes

5.8: IFs and MEOs need to say where to apply for a TUE as some don't their have TUECs and push back to NADOs but don't make this clear

# **Sport Ireland** Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

**General Comments** 

Agree

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

SUBMITTED

**General Comments** 

Agreed. Does this also include TUEC physician evaluations that may be shared, or only shared in part, with the athlete? In practice, a summary of the reasons for denial is shared with the athlete, but this may be paraphrased. A comment is given to highlight that the reasons for denial may not be an exhaustive list of all details for the denial.

USADA has experienced situations where IF TUECs appear to have specific biases toward medical practices in the US which have had a detrimental effect on determining whether the IF recognizes a TUE granted by USADA. For example, particularly around the diagnosis of ADHD/ADD and use of stimulants in North America. Efforts should be made to maintain objectivity to the ISTUE criteria and TUE Physician Guidelines rather than focusing personal biases toward medical practices in specific countries.

## International Tennis Integrity Agency

Nicole Sapstead, Senior Director, Anti-Doping (United Kingdom) Sport - Other SUBMITTED

## **General Comments**

The ITIA support the addition made in this Article.

## **Council of Europe**

SUBMITTED

Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

#### **General Comments**

1. Article 6.1 and "TUE Application Form"

The issue of conflicting definitions needs addressing as the ISTUE uses the term "physician" while the TUE application form mentions "Medical Practitioner's Declaration" under 6. This leads to confusion, for instance among psychologists and nurse practitioners. Clarification is recommended.

### 2. Article 6.3:

The phrase "The application must include the physician's signature, in the designated area." could be expanded to reflect the fact that much nonclinical communication between physician and athlete is now digital rather than physical. An alternative validation method could be added (e.g. digital signature, verification).

## NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

#### **General Comments**

Art. 6.15 We propose to transfer the Article 6.15 from the ISTUE to the ISRM or include a link in the ISRM and refer to ISRM in this Article.

Also define "shortly after".

Suggested changes to the wording of the Article

The word 'materially' in Article 6.11 should be removed.

#### Reasons for suggested changes

The comment to Article 6.11 describes clearly that the athlete must contact the relevant ADO with all changes that are not accounted for in the TUE. The word 'materially' in Article 6.11 leaves room for an individual's own interpretation on how severe these changes are. It could happen that ADOs miss out on TUEs that need to be renewed if athletes decide that those changes are not material enough and do not contact their ADO.

## **Swiss Sport Integrity**

Ernst König, CEO (Switzerland) NADO - NADO SUBMITTED

#### General Comments

6.1: SSI supports that in this draft, in contrast to the first concept, the Anti-Doping Organization that granted the TUE will remain responsible for the ongoing monitoring of any conditions attached to the TUE.

Consideration should be given to permit nurse practitioners to fulfill same role as physicians, in countries/jurisdictions where certified to do so. In Canada, the general population has easier access to a nurse practitioner than they do access to physicians. It is becoming increasingly difficult for the general population, which includes athletes, to access a physician.

## Malaysia Anti Doping Agency (ADAMAS)

Muhammad Husmar Afdzal Bin Husin, Senior Assistant Director (Malaysia) NADO - NADO

General Comments

Agree with the change. This reduce bureaucratic burden are to both ADO and Athlete.

## Japan Anti-Doping Agency

Chika HIRAI, Director of International Relations (Japan) NADO - NADO

#### General Comments

#### (Former) Article 6.1

Regarding the deletion of the requirement that the athlete should apply for a TUE at least thirty (30) days before their next competition, the submission of a TUE at least thirty (30) days in advance is not currently a mandatory requirement. Our suggestion is to keep the current wording as it is an easy-to-understand expression for athletes or ASP.

In addition, there are few suggestions:

· We think that changing the requirements of the current proposed ISTUE4.1 could lead to the resolution of this proposal.

• "The TUEC shall decide whether or not to grant the application as soon as possible, and usually within no more than twenty-one (21) days of receipt of a complete application." is written in the Article 6.8. Therefore, it should be clearly stated that a 21-day review period is required.

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

**General Comments** 

Former 6.1: Agree with this deletion.

General comment: Article 6.11: Agree with this change.

#### **Sport Integrity Australia**

Andrew McCowan, Assistant Director Project Management Office (Australia) NADO - NADO

#### **General Comments**

Comment to 6.8

SIA suggests a comment be included to explain that 'exceptional circumstances' under this Article are circumstances that support the principle that where a TUE will be ultimately be granted the Athlete will not suffer any consequences due to the administrative timeframes that must be followed. Examples could also be provided.

Suggested changes to the wording of the Article

SIA suggests that "exceptional circumstances" be further explained and if possible, examples be provided so that NADOs can apply the provision consistently.

#### Reasons for suggested changes

SUBMITTED

SIA relies on the principle that the primary purpose of the ISTUE is to ensure that TUEs are ultimately in place where an Athlete has a legitimate medical condition that warrants the permitted use of a prohibited substance.

# UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO General Comments Removal of 6.1 - We have no objections to the removal of this article. 6.11 - We have no objections to the re-prioritisation of this article as 6.11 rather than 6.14. Dopingautoriteit Robert Ficker, Compliance Officer (Netherlands) NADO - NADO SUBMITED

#### General Comments

**UK Anti-Doping** 

#### 6.3

A signature is not of this time anymore – more and more medical diagnoses are automatically transcribed in digital files and as such not accompanied by a written signature. In our country this is already very common and the mere pursuit of a signature is costing the athlete unnecessary money, and the physician unnecessary time

Suggested changes to the wording of the Article

6.3

Delete the sentence "The application must include the physician's signature, in the designated area", possibly replacing it by words like "The application must be accompanied by obvious original medical information as proven by a physician's signature, the use of official letter headings, sharing official credentials, and/or official medical registry details."

Reasons for suggested changes

6.3

When the new ISTUE comes into force in 2027 the digitalization of medical information will have become even more normal and as such the requirement of a signature is unwanted and quite often simply impossible. We should use other ways to ascertain the authenticity of the provided medical information

#### Sport Ireland

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### SUBMITTED

#### **General Comments**

From an operational aspect, we see the merit in having a suggested application time period. We understand the need to modernise the text but have some reservations about the removal of the text relating to the suggested 30-day time period. Some applications have queries on arrival, or are missing documentation or perhaps the athlete applies to the wrong organisation

## Sport Integrity Commission Te Kahu Raunui

Jono McGlashan, GM Athlete Services (New Zealand) NADO - NADO

## General Comments

ARTICLE 6.11

 Guidance could be provided within the TPG or the TUE guidelines as to WADA's interpretation of materially different dosage as this is subjectiveincluding between ADOs carrying out the tests. "This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

#### General Comments

Common situation

- 1. If MEO and IF require an inadvance TUE and refer athlete back to NADO because they don't have a TUEC
- 2. NADO has categorised the athlete as non national level so no TUE required in advance
- 3. Should the IF/MEO therefore accept the NADO's classification and expect a TUE only if athlete is tested?

This may link in with 7.6.

## Chair

Athlete Council, WADA (Canada) Other

#### **General Comments**

#### 6.1 TUE Application Process

The TUE application deadline of "30 days before [the athlete's] next competition" has been deleted from this version. The absence of a posted deadline could disadvantage athletes because they can't predict when a NADO might say it is too late. Should the deadline be 21 days before competition, to align with the TUE Committee's mandate to decide within a maximum of 21 days (except due to exceptional circumstances)?

#### International Testing Agency

International Testing Agency, - (Switzerland) Other - Other (ex. Media, University, etc.)

#### **General Comments**

6.5 and 7.2/7.4

Based on ITA's experience, 10% of TUE requests are not fully completed by the athletes, therefore cannot be properly processed. We would suggest to clarify that ADOs have the possibility to reject such incomplete applications and issue a decision according to Article 5.6 ISTUE.

6.5 suggested amendment. Similar to 7.2 (recognition) and

A TUE application will only be considered by the TUEC Anti-Doping Organization following the receipt of a properly completed application, accompanied by all relevant documents. Incomplete applications will be returned to the Athlete for completion and re-submission. In the event that the Athlete does not complete and re-submit the application within a reasonable deadline, the TUEC ADO may deny the TUE and issue a decision under Article 5.6 ISTUE.

## Article 6.9 (3)

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

**General Comments** 

Agree with addition, but somewhat repetitive to Article 5.6.

SUBMITTED

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

6.9 - We support the extension to this article to make it a mandatory requirement for Anti-Doping Organisations to notify in writing to the athlete the reasons for the denial of a TUE and to set out their right to appeal.

## Australian Sports Drug Medical Advisory Committee

Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

## **General Comments**

Agree

## Article 6.10 (8)

## World Rugby

David Ho, Senior Manager Anti-Doping Operations (Ireland) Sport - IF - Summer Olympic

## **General Comments**

World Rugby agree with this approach, which seems sensible given the familiarity the granting ADO will have with the athlete and their medical history when considering a TUE.

## NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

## **General Comments**

We appreciate the new Article

## Japan Anti-Doping Agency

Chika HIRAI, Director of International Relations (Japan) NADO - NADO

## General Comments

This revision would be difficult to operate. This is because the content and quality of the monitoring that ADOs are expected to carry out are unclear. Especially, it's challenging for large ADOs to keep track of the athlete's treatment status and competitive level.

## Malaysia Anti Doping Agency (ADAMAS)

Muhammad Husmar Afdzal Bin Husin, Senior Assistant Director (Malaysia) NADO - NADO

**General Comments** 

Agree with the changes but recommend for WADA to establish monitoring system within ADAMS.

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

Strongly agree. Good addition.

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

### **General Comments**

6.10 - We welcome the addition of this article which addresses a recommendation made by UKAD during the Stakeholder Engagement Phase in relation to Concept #7.

## Sport Integrity Australia

Andrew McCowan, Assistant Director Project Management Office (Australia) NADO - NADO

#### **General Comments**

SIA suggests additional wording be added to require information be passed to the TUE custodian to take action where it is known an Athlete is abusing the conditions of the TUE.

#### Suggested changes to the wording of the Article

SIA suggests the following additional wording be added to this Article 6.10.

Unless agreed otherwise, the Anti-Doping Organization that granted the TUE will be responsible for the ongoing monitoring of any conditions attached to the TUE (whether or not the TUE is then recognized by another Anti-Doping Organization under Article 7.0). If an Anti-Doping Organization has evidence that an Athlete is abusing a TUE granted by another Anti-Doping Organisation, that Anti-Doping Organization will advise the custodian Anti-Doping Organization who will be responsible for any subsequent investigation.

#### Reasons for suggested changes

SIA feels this approach will lead to better collaboration between NADO's.

## Australian Sports Drug Medical Advisory Committee

Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

**General Comments** 

What if the IF/MEO recognises but changes the conditions. Is this still a recognition or a whole new TUE?

If considered a "recognition" then the NADO is now obliged to monitor conditions placed on it by a different TUEC.

Could it be clarified that if the IF/MEO changes the conditions then they become responsible for monitoring unless agreed to otherwise?

## Article 6.12 (13)

International Tennis Integrity Agency Nicole Sapstead, Senior Director, Anti-Doping (United Kingdom) Sport - Other SUBMITTED

SUBMITTED

In the context of an AAF related to ADHD medication, this provision seems unnecessarily bureaucratic, requiring effectively 2 TUEs and costing the ADO for 2 TUEs to be reviewed and approved. If the TUE application is made retroactively to cover an AAF it usually follows (for ADHD at least) that a prospective TUE will also be made to cover the Athlete for after the AAF and into the future. It seems odd that as drafted this provision would create a time in which the player was neither covered retroactively or prospectively and the ITIA would question why, if the criteria for meeting the retroactive and prospective TUE criteria were met the date of the TUE could not just be from the date of the retroactive TUE (i.e. the date the Athlete was tested and returned an AAF)

#### **Council of Europe**

SUBMITTED

Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

#### **General Comments**

Article 6.12 (effective dates of TUEs)

Clarification is needed to ensure that an ADO would not have to record two TUEs in ADAMS if treatment has already commenced but the course has not yet finished (i.e. the TUE can be granted retroactively so that it is effective from the date treatment commenced (a date in the past) but does not expire until a date in the future when treatment finishes).

#### EOKAN/HADA

Spyridoula Christopoulou, Scientific Support & Quality Office Assistant (Greece) NADO - NADO

#### **General Comments**

 regarding retrospective TUE applications, obviously the effective date is earlier but what happens in cases where the treatment with the banned substance or method expires much later than the date the test was done and an Adverse Analytical Finding was found?

• in the event that a national-level athlete has begun treatment with the use of a prohibited substance or method one or 2 days before the application for TUE and the duration of treatment is 5 days, and the TUEC's decision arises 20 days later but within those days the athlete has not been tested and an Adverse Finding has not arisen, then what will be the effective date?

#### NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

#### **General Comments**

We appreciate the rules for prospective TUEs.

Regarding retroactive TUEs this article contains - according to the WADC wording and to articles 4.0 and 4.1 b) ISTUE - the new term '...Used or Possessed...', and we ask for clarification.

In principle, a TUE is granted for the therapeutic use and not for the possession of a prohibited substance or method, either prospectively nor retroactively.

In our opinion, a TUE is the wrong instrument to legitimate the possession of a prohibited substance or method, especially the possession alone, without a use which would be possible because of the word 'or' in the term.

If a TUE is necessary for the possession of a prohibited substance or method, this will have serious impact on the period of validity of TUEs.

For example: An athlete gets a prescription for glucocorticoid tablets for the treatment of an acute allergic reaction and purchased the tablets in a pharmacy. After the treatment there are a few tablets left in the package. The athlete keeps them for months in- and out-of-competition for the case that he suffers from a further allergic reaction.

Regarding the new wording in this article the athlete would have to have a TUE for every in-competition day or period he still possesses this tablets. We think this is not the intention of the new wording 'Used or Possessed' and even not practicable. How should a period of validity of a TUE be managed in this case?

Furthermore, Articles 2.6.1 and 2.6.2 WADC and comments to these articles clarify that the possession can also be justified by e.g. evidence that the Prohibited substance or Method was possessed or carried for acute or emergency treatments.
See also our comments to Articles 4.0 and 4.1. b). - To ease the burden for the athlete and to avoid potential ADR violations we would like to address that any 'gaps' between a TUE, a renewal of a TUE, a prospective and a retroactive TUE should be avoided, e.g in the following constellation: An athlete becomes an International Level Athlete and requires a prospective TUE granted from the relevant IF. At the same time the athlete is applying for a retroactive TUE at his\*her NADO after an AAF for the same medical condition. For simplification of the process we suggest that it should be agreed that both, the retroactive and the proactive TUE, are handled by one of the ADOs.

## **Swiss Sport Integrity**

Ernst König, CEO (Switzerland) NADO - NADO

#### **General Comments**

This new article needs flexibility to cover an additional scenario: Timely TUE applications for prelongation of an existing TUE. In this scenario the TUEC will reach a decision while the previous TUE is still valid. Therfore a future date (day after expiry of previous TUE) needs to be the effective date of the new TUE. This also corresponds to current ADAMS functionallity. If the proposed draft wording is retained, the necessary functionality must be provided in ADAMS (for example replacement of previous TUEs since overlapping TUEs not permitted).

## **CHINADA**

MUQING LIU, Coordinator of Legal Affair Department (CHINA) NADO - NADO

**General Comments** 

**Article 6.11 Duration of a TUE** 

Regarding the "short-term application" and "low-level athletes" applying for a TUE, some amateur Athletes

may have chronic conditions requiring long-term medication (such as insulin) but also compete. It is clearly

unnecessary to grant long-term TUEs to such Athletes who participate on a temporary and infrequent basis. We

recommend that the WADA TUE Panel issue relevant provisions regarding the requirements for low-level Athletes to

obtain short-term TUEs during Competition, including different medical documentation and review process.

Suggested changes to the wording of the Article

**Article 6.11 Duration of a TUE** 

We recommend that the WADA TUE Panel issue relevant provisions regarding the requirements for lowlevel Athletes to obtain short-term TUEs during Competition, including different medical documentation and review process.

Reasons for suggested changes

# **Article 6.11 Duration of a TUE**

Regarding the "short-term application" and "low-level athletes" applying for a TUE, some amateur Athletes may have chronic conditions requiring long-term medication (such as insulin) but also compete. It is clearly unnecessary to grant long-term TUEs to such Athletes who participate on a temporary and infrequent basis.

## UK Anti-Doping

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

## **General Comments**

6.12 - We welcome the clarification regarding when the effective date of a prospective TUE begins which is in keeping with how we currently operate.

We also have no objections to the new principle that retroactive TUEs cannot be extended into the future but can be evaluated concurrently with a request for a prospective TUE. This acceptance is on the proviso that an Anti-Doping Organisation would not have to record two separate TUE decisions in ADAMS. In our experience, there are occasions whereby urgent treatment has already commenced at the point of reviewing the request for a TUE, but the course of treatment has yet to finish.

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO SUBMITTED

**General Comments** 

Agree, good to clarify

## **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

Article 6.12: USADA strongly disagrees with this change. It does not reflect reality and best practice in the eyes of the athlete. Our practice has been to make the approval date the date that a complete application has been provided to USADA. This ensures that the athlete is not disadvantaged by the evaluation period of the TUE by the TUEC. It reduces the need for a retroactive TUE in the case an athlete uses the medication before the TUEC decision is rendered but the medication is needed for the medical condition and shouldn't be delayed by the TUEC evaluation process. In the case of a denial, then the athlete can stop the medication or change to another alternative. In practice, athletes don't have the luxury of delaying treatment, especially for in-competition prohibited substances such as narcotics, glucocorticoids, and diuretics when acute medical treatment is necessary. It's our experience that these TUEs are rarely denied, so it reduces stress on the athlete to not have to delay treatment and reduces the need for the ADO to have to also consider a retroactive TUE. USADA recommends that the TUE effective date can be left up to the ADO to decide whether it is the approval date or the date a complete application was received by the ADO.

## **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### General Comments

#### Agree

There is a definition of the date of a prospective TUE in this section. Should there be a comment to this section to define the date(s) of the retroactive TUE?....Should it be valid for the date of testing only or should it be valid for another date/duration depending on the duration of administration of the medication?

#### FINCIS

Anna Simula, Pharmacist (Finland) NADO - NADO SUBMITTED

#### **General Comments**

We agree that the effective date for a prospective TUE will be the date of the TUEC's decision to grant the TUE. No further clarification is needed.

But clarification is needed with regards to a Retroactive TUE – it is vital to ensure that the process is described clearly guaranteeing a harmonized process among all ADOs. And the protocol of recording these TUEs in ADAMS should be made easy (avoiding extra/double-work) and at the same time guides ADOs to do the process correctly. For example, in cases when a TUE can be granted retroactively so that it is effective from the date treatment commenced (a date in the past) but does not expire until a date in the future when treatment finishes.

## Sport Integrity Commission Te Kahu Raunui Jono McGlashan, GM Athlete Services (New Zealand)

NADO - NADO

- We support that prospective TUEs are valid from the day they are approved by the TUE Committee- this is already clear in the ISTUE.
- We do not agree nor understand why a retroactive TUE granted should not be able to have the same TUE carried into the future if it is valid from the day of the test if they applied under 4.1c or 4.1d (for example ADHD medication where a TUE would last for 1-year).
- We need clarity on how this will not be increased admin and not confusing for the athlete. TUE processes can already be overwhelming for the athlete and it is not athlete-centric to increase confusion and administration.

"This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

# **Anti-Doping Norway**

Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO

## **General Comments**

At a first glance, the proposal could be burdensome for ADOs. That being said, if both double applications as well as double entries into ADAMS can be avoided (i.e. that an application for both retroactive and prospective TUE can be sent in and managed/dealt with in one go), then we can accept the proposed amendment.

# Article 7 (16)

**Tug of War International Federation** Peter Dyer, Senior Vice President (England) Sport - IF – IOC-Recognized

## **General Comments**

It is a requirement of the Code, Article 4.4, that IFs and MEO should recognise TUEs that have already been granted in accordance with Article 5.5. It is also a requirement that this is written into their ADRs. Therefore the note in 7.1a "Nevertheless, International Federations and Major Event Organizations should carefully select the Anti-Doping Organizations and/or substances for which they will automatically recognize". is somewhat at odds with that intent. It should be stated that MEOs should provide a robust justification why they do not accept the TUE granted by a IF/NADO, the burden of proof being on the MEO not the athlete.

This also reflects on Article 5.8 in two aspects, recognition should be the accepted default with no list necessary and a list of which TUE decisions of other Anti-Doping Organizations will have to be submitted to it for recognition is all that needs to be provided, and secondly, this MUST be supported by a robust justification of why it isn't accepted, also published on the website.

# Council of Europe

Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)

General Comments

# Art. 7 TUE Recognition Process

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.

Timing of recognition of a TUE doesn't need to be addressed in the ISTUE. This seems to be an unnecessary overcomplication of the recognition process. Why is there a need to apply the 4.1 criteria to a TUE that has already been granted - providing the criteria for granting a TUE have been met then surely the timing of the international recognition doesn't matter? Furthermore, there are multiple factors, out of the athlete's control that may have prevented them from obtaining recognition in advance (such as, the athlete was not informed of the need to obtain international recognition by their granting NADO, the NADO failed to provide relevant access to the IF in time, or the IF didn't respond to the recognition request in time). It would seem unfair to penalise an athlete for something which is largely out of their control.

## NADA

NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO

We propose that athletes should be able to apply for recognition of a TUE at any time and that the possibility of a retroactive recognition should be addressed in the 2027 ISTUE. A valid TUE should give legal certainty to the athlete. Athletes should not be required to satisfy the conditions of 2023 ISTUE Aticle 4.1 b) if applying retroactively. In our opinion Article 4.1 b) is not the right article to deal with recognition processes and criteria.

## **NADA Austria**

Dario Campara, Lawyer (Austria) NADO - NADO

#### SUBMITTED

#### **General Comments**

The whole article on Recognition can be deleted. TUEs are in ADAMS, IFs and WADA have the right to appeal the TUE. What is really needed is the right for NADOs to appeal TUEs issued by International Federations.

Currently there is a disbalance between the rights and responsibilities of NADOs and IFs. For example, NADOs are not allowed to appeal TUEs that were issued by the IF – only the other way round (WADC 4.4). All ADOs are working on the same ISTUE so they should have equal rights and act on eye level. Currently there is no corrective monitoring aside from WADA.

TUEs issued by a NADO can be appealed by the International Federation so there is no need to have a recognition process, it only adds another burden for the athlete.

MEOs should not be involved in the TUE process at all, NADOs and International Federations with the monitoring of WADA are enough to guarantee a solid process. The involvement of MEOs in TUEs is also a matter of Data Protection (need-to-know basis). There is no need for MEOs to know about TUEs of athletes (unless there is an ADRV and the MEO has the results management – but even in this case it is only on-demand for this specific case and not a general all-in information.)

# Swiss Sport Integrity

Ernst König, CEO (Switzerland) NADO - NADO

#### **General Comments**

In principle, SSI holds the opinion that NADO TUEs should automatically (i.e. without recognition) be valid at international level. If NADO TUEs will still need to be recognized by the International Federation, SSI strongly supports allowing athletes to get their TUEs recognized at any time between NADO approval and becoming ILA, rather than only once they are considered ILA. Particularly ILA definitions based on competition participation can otherwise lead to stressful situations. Furthermore, an athlete who becomes ILA several years after the NADO granted a TUE must remember to ask for recognized by the International Federation, a similar sanction as for "athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE (Code Article XXX)" should be established in the event of the administrative mistake of missing international recognition.

If the possibility is given that the TUE can be recognized retrospectively, this should be regulated in Article 7. Even if this is based on the concept of Article 4.1 b, we do not recommend confusing "obtaining" a TUE (Article 4.0) and "recognition" of a TUE (Article 7.0).

In addition, SSI recommends keeping the commentary on Article 4.4.3 of the Code, either as it is or in the ISTUE, as it provides clarity ("If an International Federation chooses to test an Athlete who is not an International-Level Athlete, it must recognize a TUE granted by that Athlete's National Anti-Doping Organization."). Such situation could also be prevented by international validity, automated or at least early international recognition.

## UK Anti-Doping

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

# General Comments

7 - We are in favour of making the recognition process as efficient and straightforward as possible for athletes and Anti-Doping Organisations. It is our position that if a national-level TUE satisfies Article 4.2 following a review by an International Federation (IF) or Major Event Organisation (MEO), then the TUE should be recognised regardless of the timing of the request.

However, it should be made clear to athletes that if they fail to request recognition of their national-level TUE in advance of a competition or Doping Control (after becoming an international-level athlete) then they put themselves at risk of committing an Anti-Doping Rule Violation if the TUE is not recognised by the IF/MEO.

Finally, we would caution against assessing recognition requests against the exceptions outlined in Article 4.1 as this article was never intended to be used in this way. Ultimately, this would be another way for athletes to unintentionally fall foul of the rules.

## Recommendations:

1. Athletes should be able to apply for recognition of a national-level TUE at any time. However, it should be made clear that it is at the athlete's own risk if recognition is not sought in advance of competition or Doping Control (after becoming an international-level athlete).

## SUBMITTED

2. Athletes should not have to re-satisfy the exceptions outlined in Article 4.1 for the purposes of the recognition process once a national-level TUE has been granted.

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

In many cases, athletes are confused as to when they may become international-level athletes and apply for TUE recognition. Maximum flexibility should be given to apply for recognition retroactively, if for example, the athlete tests positive and has a TUE at the national-level. This simplifies the process and has no appreciable impact on clean sport.

FINCIS Anna Simula, Pharmacist (Finland) NADO - NADO

#### **General Comments**

We suggest that all TUEs administered at national level pursuant to Code article 4.4 by a Code Compliant ADO are automatically recognized by the IF unless they actively decide not to recognize them.

#### **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### **General Comments**

#### Agree

## NADA India

NADA India, NADO (India) NADO - NADO

#### **General Comments**

We recommend that the provision of retroactive recognition of the TUE may be added in 2027 ISTUE.

# Sport Integrity Australia SUBMITTED Andrew McCowan, Assistant Director Project Management Office (Australia) SUBMITTED

NADO - NADO

## **General Comments**

SIA notes the ISTUE provides a global standard upon which decisions to grant or deny TUE's are made. It is SIA's position that IFs should be obliged to initially recognise TUEs granted by NADOs. Should the IF have concerns that the NADO has not correctly applied the standards set in the ISTUE, it is the IF's responsibility to appeal to WADA.

Agence française de lutte contre le dopage Adeline Molina, General Secretary Deputy (France) NADO - NADO

Les sportifs doivent continuer à pouvoir solliciter une reconnaissance à tout moment. Imposer une règle supplémentaire n'apporte pas de garantie supplémentaire et constituerait une charge administrative additionnelle pour les sportifs et les organisations antidopage.

De même, par cohérence, il serait préférable d'harmoniser le régime de reconnaissance des AUT entre Signataires : si cette reconnaissance est automatique entre organisations nationales antidopage, elle doit être formalisée par une décision entre une fédération internationale et une organisation nationale antidopage. Il serait plus simple pour les sportifs que la reconnaissance soit automatique dans toutes les hypothèses.

#### Sport Integrity Commission Te Kahu Raunui

SUBMITTED

Jono McGlashan, GM Athlete Services (New Zealand) NADO - NADO

#### General Comments

- The code drafting team seeks further feedback on when an athlete should require recognition and whether this could be retroactive at any time.
  - It would be imperative that the IF/MEO does not see this as an opportunity to only review TUEs retroactively rather than when recognition is requested. The athlete must have the opportunity to know in advance if an ADO is potentially going to decline their TUE or require further info e.g. AIU has published information that they require more than 1 specialist review for ADHD cases which is not a requirement in the TUE Physician Guidelines
  - o As noted above, 4.1b is not clear and could be applied subjectively so without clarification on this, we cannot clarify.
  - An ideal situation would be that recognition can take place retroactively, in order to be more athlete-centric and avoid sanctions based on administrative oversights, but the athlete retains the right to apply for recognition prospectively and this should be reviewed and answered within the 21 day window.
- The MEO or IF should consider automatic recognition if they do not intend to review requests for recognition prospectively.
- Note the suggested inclusion reference to Article 4.0: "Athletes who Use or Possess a Prohibited Substance or Prohibited Method before obtaining a TUE do so at their own risk. A retroactive TUE would be required."

"This feedback was endorsed by the Athlete Commission of the Sport Integrity Commission Te Kahu Raunui."

#### **Anti-Doping Sweden**

Jessica Wissman, Head of legal department (Sverige) NADO - NADO

#### **General Comments**

Regarding recognition of a TUE, ADSE want to repeat our comment on Concept#6 in the Stakeholder engagement phase that suggested that: *all TUE's* administered at national level pursuant to Code article 4.4 by a Code Compliant ADO are automatically recognized by the IF/MEO unless they actively decide not to recognize them. If that is not an alternative, we support the suggestion that a TUE could be recognized at any time.

#### WADA NADO Expert Advisory Group

Martin Holmlund Lauesen, member (Norge) Other - Other (ex. Media, University, etc.)

#### **General Comments**

#### **TUE Recognition Process**

The whole article on Recognition can be deleted. TUEs are in ADAMS, IFs and WADA have the right to appeal the TUE. What is really needed is the right for NADOs to appeal TUEs issued by International Federations.

Currently there is a disbalance between the rights and responsibilities of NADOs and IFs. For example, NADOs are not allowed to appeal TUEs that were issued by the IF – only the other way round (WADC 4.4). All ADOs are working on the same ISTUE so they should have equal rights and act on eye level. Currently there is no corrective monitoring aside from WADA.

TUEs issued by a NADO can be appealed by the International Federation so there is no need to have a recognition process, it only adds another burden for the athlete.

MEOs should not be involved in the TUE process at all, NADOs and International Federations with the monitoring of WADA are enough to guarantee a solid process. The involvement of MEOs in TUEs is also a matter of Data Protection (need-to-know basis). There is no need for MEOs to know

about TUEs of athletes (unless there is an ADRV and the MEO has the results management – but even in this case it is only on-demand for this specific case and not a general all-in information.)

International Testing Agency International Testing Agency, - (Switzerland) Other - Other (ex. Media, University, etc.) SUBMITTED

#### **General Comments**

We reiterate our suggestion shared from the first phase.

Based on ITA's experience, non-recognitions of TUEs represents less than 0.5%. To harmonize the process and simplify the procedure for the Athletes, automatic recognition should be the rule and ADOs should be given the possibility to challenge/review problematic cases. The time limit for doing it should be attached to the moment when the Athlete becomes subject to TUE requirements of the other ADOs. Appeal to CAS or NADO's appeal body does not seem fitting for such a review. A mechanism under the WADA's TUE review process (Article 8) seems like the logical framework.

If TUE recognition is still required, we support that TUE recognitions can be done retroactively.

#### Other comments

The authority to consider the application of a retroactive TUE should be with the Results Management Authority of the AAF. There have been instances where a NADO tested international-level athletes and an AAF was reported. Considering that those athletes were international-level, the decision to issue a retroactive TUE was put on the IF. However, when considering a retroactive TUE, the aspects of the AAF are necessarily taken into consideration. This has led to confusion between the NADO, IF and the athlete as well and responsibilities seemed to have been blurred in some instances. We believe that it would be useful to clarify this.

#### **Retroactive Recognition (8)**

## World Rugby

David Ho, Senior Manager Anti-Doping Operations (Ireland) Sport - IF – Summer Olympic

#### **General Comments**

The TUE recognition process should not be an onerous one and putting restrictions on when one can apply for recognition would seem unfair. Again this is a technical point and in World Rugby's view if the guiding principles of Article 4.2 are met then it should not matter when a TUE was recognised, and we do not believe that athletes should be required to satisfy the conditions of Article 4.1b to apply retroactively when applying for recognition.

SUBMITTED

ISU Christine Cardis, Anti-Doping Director (Switzerland) Sport - IF – Winter Olympic

#### **General Comments**

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.

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

ISU:

- These aspects should clearly be addressed in the 2027 ISTUE
- Athletes should still be required to meet the conditions of article 4.1(b) of the ISTUE 2023 in the event of retroactive application.

#### **General Comments**

I believe that for National Level athletes who are required to apply in advance, if they must apply for TUE retroactively, the provisions of Article 4.1b should apply.

However, for lower level National athletes, I believe that they should be able to apply retroactively without necessarily having to apply the requirements of Article 4.1b

## **Canadian Centre for Ethics in Sport**

Bradlee Nemeth, Manager, Sport Engagement (Canada) NADO - NADO

#### **General Comments**

The automatic recognition of the TUEs (without additional steps) should be strongly considered. As all signatories should be assessing TUEs in accordance with the International Standard, TUEs should have an automatic binding effect.

#### Japan Anti-Doping Agency

Chika HIRAI, Director of International Relations (Japan) NADO - NADO

#### **General Comments**

#### **Article 7: TUE Recognition Process**

We support the statement "Athletes must always satisfy the conditions of 2023 ISTUE Article 4.1(b) if applying retroactively."

Our belief is that altering the requirements of the current proposed ISTUE4.1 could resolve this proposal.

#### **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### **General Comments**

From our limited knowledge we feel that they should be able to apply for TUE recognition at any stage, as that would give clarity to the athlete.

FINCIS

Anna Simula, Pharmacist (Finland) NADO - NADO

#### **General Comments**

We are of the opinion that athletes should be able to apply for recognition at any time and there should be no need to satisfy the conditions of 2023 ISTUE Article 4.1(b) if applying retroactively.

There are several reasons out of the athlete's control that may have prevented them from obtaining recognition in advance. For example, such as, the athlete was not informed of the need to obtain international recognition by their granting NADO, the NADO failed to provide relevant access to the IF in time, or the IF didn't respond to the recognition request in time. Athletes should not suffer from something which is out of their control.

## Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia)

NADO - NADO

SUBMITTED

7.1.a Important to clarify that you cant automatically recognise then later review/overturn.

Comment to 7.1.b may be confusing as refers to 4.2 conditions rather than criteria (these are 2 different things, see below).

7.1.b should also mention about not just changing duration but also conditions of the TUE. Are a request for different conditions on the TUE a denial or a "discussion" with the NADO TUEC.

7.6. If IF must recognise a NADO granted TUE, must they also recognise that the athlete be in a category of not requiring an in advance TUE and this should be specified and athlete then allowed to apply.

Suggested changes to the wording of the Article

Comment to 7.1.b ... Article 4.2 criteria (not conditions)

# Article 8 (3)

#### **USADA**

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

Article 8.5: If WADA requests additional information from an athlete's physician or medical care provider, this should be done with the athlete's expressed written consent. This should be clarified.

Australian Sports Drug Medical Advisory Committee Kim Reynolds, Senior ASDMAC Officer (Australia) NADO - NADO

#### **General Comments**

Agree with suggested changes in all of section 8.

#### **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### **General Comments**

#### Agree

#### Article 8.1 (4)

ONAU JOSE VELOSO, Antidoping Medical Director (Uruguay) NADO - NADO

#### **General Comments**

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

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO SUBMITTED

SUBMITTED

SSI generally supports the amendment of Article 8.1, but emphasises that, depending on the situation, other experts may also be consulted and therefore recommends replacing "medical expert" with "expert". Obviously, the criteria of Article 4.2 must be evaluated by medical experts. However, other aspects should be assessed by the relevant experts, e.g. questions relating to Article 4.1 by legal experts / TUE managers.

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

8.1 - We have no objections to the revision of this article.

#### **Sport Ireland**

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

#### **General Comments**

Agree

## Article 8.8 (5)

Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO

#### **General Comments**

A cost ceiling or at least approximate cost information would be helpful when specifying the positions that can be charged on.

#### Japan Anti-Doping Agency

Chika HIRAI, Director of International Relations (Japan) NADO - NADO

#### **General Comments**

#### Article 8.8 & 8.9

It is necessary to clarify WADA's review criteria (the main points and what kind of applications will be examined).

It is necessary to consider whether the ADO should bear the costs of WADA's internal staff, as review are ultimately carried out by the TUEC and experts.

# USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

Is collecting these fees practically feasible and shouldn't there be some maximum as it's very open-ended now for WADA to charge any amount?

#### **General Comments**

8.8 - We have no objections to the revision of Article 8.8 but encourage WADA to use its discretion when reclaiming TUE decision review costs from Anti-Doping Organisations considering the contributions that governments and the sports movement already make to WADA's annual budget.

<b>Sport Ireland</b> Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO	SUBMITTED
General Comments Agree	
Article 8.9 (4)	
Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO	SUBMITTED

## **General Comments**

A cost ceiling or at least approximate cost information would be helpful when specifying the positions that can be charged on.

## USADA

Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

#### **General Comments**

Is collecting these fees practically feasible and shouldn't there be some maximum as it's very open-ended now for WADA to charge any amount?

SUBMITTED

## **UK Anti-Doping**

UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO

#### **General Comments**

8.9 - We have no objections to the revision of Article 8.9 but encourage WADA to use its discretion when reclaiming TUE decision review costs from Anti-Doping Organisations considering the contributions that governments and the sports movement already make to WADA's annual budget.

## Sport Ireland

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

**General Comments** 

Agree

#### **General Comments**

General comment: Code Article 13.4: This may not be practical as national-level appeal bodies may not have the ability to include physicians on their bodies. Physicians can be brought in to act as experts for either side. See also USADA's Code comments in Article 13.2.2.

General comment: Code Article XX: Sanctions for athletes who fulfill the ISTUE Article 4.2 criteria but do meet any criteria for a retroactive TUE.

USADA recommends that all prospective TUEs apply retroactively, if necessary. Athletes would bear the risk of not obtaining a TUE ahead of time. But if the athlete is able to obtain a prospective TUE, concerns regarding a competitive advantage and legitimate need are allayed. Currently, the process of applying a TUE retroactively is narrow and cumbersome.

Indeed, the retroactive TUE bureaucracy has proved to be confusing, difficult to apply, and virtually impenetrable by athletes. Moreover, it can lead to extremely unjust results for athletes who, for example, receive a prospective TUE for a life-saving medication like insulin or an ADHD medication like Adderall but fail to meet the restrictive retroactive TUE criteria and, therefore, face a minimum one-year period of ineligibility. Such a system is manifestly unfair to athletes and must change immediately.

With respect to the only stated concern for leaving the retroactive TUE regime in place, i.e., the pressure hearing panels would face to grant a prospective TUE, USADA counters that hearing panels face that same pressure in almost every case when athletes argue that x sanction will end their careers. And when a panel makes an incorrect decision, it can be appealed, ultimately to the CAS. A similar process has been established for TUE cases, although some adjustment may need to be made. Allowing all prospective TUEs to apply retroactively simplifies the process for athletes and anti-doping organizations without a negative impact on clean sport.

If the retroactive TUE bureaucracy is too entrenched to be dismantled, USADA would support as an alternative a simplistic sanctioning regime of a fixed three-month sanction (or less) if an athlete has obtained a prospective TUE. There would be no apparent adverse impact on clean sport to allow for such a simplistic resolution when an athlete has demonstrated medical need for a substance that does not enhance the athlete's performance beyond the return to a normal state of health.

Sport	Ireland

Cólleen Devine, Director of Anti-Doping & Ethics (Ireland) NADO - NADO

General Comments

Agree

## International Testing Agency

International Testing Agency, - (Switzerland) Other - Other (ex. Media, University, etc.)

#### **General Comments**

Code Article XX (as per the document "Summary of changes to the ISTUE"): Sanctions for athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE.

We support this initiative. We believe that a standalone sanctioning regime for such therapeutic use cases would be fitting and a fixed period of time (3 months) and other consequences (such as DSQ if applicable) would be appropriate.