

# INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS (ISTUE)

## Consultation - Second consultation phase

Showing: All (95 Comments)

### PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS (8)

#### Ministry of sport of Russia

Veronika Loginova, Head of Antidoping Department (Russia)  
Public Authorities - Government

SUBMITTED

1. The main focus of the ISTUE is procedural matters and very little attention is given to practical part (criteria for granting a TUE). The criteria are highly subjective, vague, and can cover a wide range of states. Therefore, at a minimum, the criteria for granting TUEs should be expanded upon and comprehensively described. This is also relevant because the WADA recommendations in support decision making cannot cover all diseases. 2. ISTUE requires the adoption of its provisions (including on the criteria for granting TUEs) by all anti-doping organizations, including international sports federations. Therefore, the provision on the need to confirm permits issued by national anti-doping organizations by international sports federations or major event organizers is unnecessary. These obligations are burdensome for athletes. In any case, TUE requests, medical data and TUE decisions are available in ADAMS. 3. The criteria based on which retroactive TUEs can be issued cannot be the reason for refusing to issue them to athletes who have been or are being treated. The delay in the treatment of any disease for adherence to procedures even for a short time, which is required by the TUEC for the consideration of requests, is unacceptable. 4. The fact that the Prohibited List includes a special category of substances which prohibited in the competition period only implies that athletes may use them to increase their sporting results in that period of time. Therefore, it seems logical to establish specific deadlines for each class of substances in this category, when athletes must submit requests for TUE (i.e. the time from the last use to the start of the competition period). It will allow to optimize the working flow of anti-doping organizations and relieve athletes and doctors from additional unnecessary actions for processing TUE requests. 5. For all substances for which TUE can be issues for in-competition use, studies based on evidence-based medicine should be conducted to confirm that the substance or method does not improve the performance, except for an increase associated with improving health. Research results should be provided to stakeholders for discussion Substances for which there is no information about the studies conducted based on the principles of evidencebased medicine, confirming that this substance or method does not improve the effectiveness of the sport performance, should be grouped together. If an athlete is required to receive these substances, he cannot participate in competitions under the auspices of a national or international federation. An anti-doping organization that has decided to issue TUE for such prohibited substance must also indicate the period during which the athlete is not eligible to participate in the competition, as well as the conditions under which such restriction will be lifted. 6. Inpatient treatment, which is not urgent, requires the use of prohibited substances or methods in accordance with treatment standards adopted in the country, but does not allow the submission of a request within the time limits specified in the Standard.

**Swedish Sports Confederation**

Tommy Forsgren, Results Management Manager (Sweden)  
NADO - NADO

SUBMITTED

The definition of In-Competition in ISTUE does not correspond with the In-Competition definition in ISTI.

**Conseil supérieur des sports**

Matheo TRIKI, Sportif Rugby (Espagne)  
WADA - Others

SUBMITTED

The purpose of the International Standard for Therapeutic Use Exemptions is to establish (a) the conditions that must be satisfied in order for a Therapeutic Use Exemption (or TUE) to be granted, permitting the presence of a Prohibited Substance in an Athlete's Sample or the Athlete's Use or Attempted Use, Possession and/or Administration or Attempted Administration of a Prohibited Substance or Prohibited Method for therapeutic reasons; (b) the responsibilities imposed on Anti-Doping Organizations in making and communicating TUE decisions; (c) the process for an Athlete to apply for a TUE; (d) the process for an Athlete to get a TUE granted by one Anti-Doping Organization recognized by another Anti-Doping Organization; (e) the process for WADA to review TUE decisions; and (f) the strict confidentiality provisions that apply to the TUE process.

**International Paralympic Committee**

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

Comments are submitted by Peter Van de Vliet on behalf of the IPC TUEC and TUE staff

**Institute of National Anti-Doping Organisations**

Graeme Steel, Chief Executive (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

The Standard has improved in a number of ways but still fails to adequately recognise the circumstances of Recreational Athletes. While 4.3 is helpful its limitation to exceptional circumstances is not. There should be explicit relaxation of the requirements for these athletes most particularly for specified substances where; the diagnosis is established, the medication confirms with accepted appropriate medical practice and the capacity for performance enhancement is negligible.

## 2.0 Code Provisions (1)

### 3.0 Definitions and Interpretation (2)

#### 3.1 (2)

##### **NADA**

Regine Reiser, Result Management (Deutschland)  
NADO - NADO

SUBMITTED

Definition TUE:

Please reconsider syntax. Proposal: Replace 'but only where' by 'when' or 'if'.

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

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

SUBMITTED

##### **Definition of a TUE**

UKAD supports the revised definition of a TUE.

#### 3.3 (2)

##### **NADA**

Regine Reiser, Result Management (Deutschland)  
NADO - NADO

SUBMITTED

We propose to reconsider and harmonize the following terms in the ISTUE:

- medical information
- medical history
- medical data
- health information.

It can be concluded from the context that these terms often have got the same or a similar meaning, but they

are not used in a coherent way. None of these terms is included in the definitions of the ISTUE. A harmonization of these terms, where possible and reasonable, could simplify the translation process of the ISTUE into other languages and avoid misinterpretations of these terms.

### Canadian Centre for Ethics in Sport

Elizabeth Carson, Manager, Sport Services (Canada)  
NADO - NADO

SUBMITTED

In the definition of "TUEC," specify that members of these committees are practicing physicians (as specified in section 5.2.a, so the definition reads: "The panel of registered physicians established by an ADO to consider application for TUEs."

In the definition of "WADA TUEC," specify that members of the committee are practicing physicians (as specified in section 5.2.a, so the definition reads "The panel of registered physicians established by WADA to review the TUE decisions of other ADO."

## PART TWO: STANDARDS and Process FOR GRANTING TUEs (7)

### International Cricket Council

Vanessa Hobkirk, Anti-Doping Manager (United Arab Emirates)  
Sport - IF – IOC-Recognized

SUBMITTED

SUBMITTED BY WADA

The ICC supports the introduction of a stand alone Article 4.3 for the specific exemption on the basis of fairness.

### US Olympic Committee

Sara Pflipsen, Senior Legal Counsel (United States)  
Sport - National Olympic Committee

SUBMITTED

The USOC's main suggestion is that it would be helpful for athletes to have more information included in this document relating to retroactive TUEs. In particular, the standards to qualify for retroactive TUE, examples of how one could qualify under the "for fairness" standard for a retroactive TUE, and more clarity on the appeal process for retroactive TUEs. While we recognize that athletes need to be aware of the requirement to apply for TUEs in advance, the individual who validly takes a prescribed medicine and who would otherwise qualify for a TUE is not undermining fair play, and yet can be left with grave consequences with an anti-doping rule violation. More flexibility in granting retroactive TUEs would diminish inadvertent violations and wouldn't harm the integrity of sport nor any other athlete.

### Anti-Doping Norway

Anne Cappelen, Director Systems and Results Management (Norway)  
NADO - NADO

SUBMITTED

### Comment to major proposed changes re point 15

ADNO agree with the proposed introduction of threshold values for the substances prohibited out-of-competition only in in-competition samples. We advise these thresholds to be known to the audience allowing the athlete to be guided of when not to use the substance. (e.g. in questions like "How long time before a competition should I stop

taking prednisolone?"

### Swedish Sports Confederation

SUBMITTED

Tommy Forsgren, Results Management Manager (Sweden)  
NADO - NADO

- SSC support the comment from Denmark that the burden is too heavy for an ADO to translate the TUE application form and relevant clinic information into English or French (article 5.4 ISTUE).

### Conseil supérieur des sports

SUBMITTED

Matheo TRIKI, Sportif Rugby (Espagne)  
WADA - Others

Therapeutic Use Exemptions ("TUEs").

- The presence of a Prohibited Substance or its Metabolites or Markers, and/or the Use or Attempted Use,
- An Athlete who is not an International-Level Athlete should apply to his or her National Anti-Doping Organization for a TUE. If the National Anti-Doping Organization denies the application, the Athlete may appeal

4.4.3 An Athlete who is an International-Level Athlete should apply to his or her International Federation.

- If an Anti-Doping Organization chooses to collect a Sample from a Person who is not an International-Level or National-Level Athlete, and that Person is Using a Prohibited Substance or Prohibited Method for therapeutic reasons, the Anti-Doping Organization may permit him or her to apply for a retroactive TUE.
- WADA must review an International Federation's decision not to recognize a TUE granted by the National Anti-Doping Organization that is referred to it by the Athlete or the Athlete's National Anti-Doping Organization.
- Any TUE decision by an International Federation (or by a National Anti-Doping Organization where it has agreed to consider the application on behalf of an International Federation) that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon review, may be appealed by the Athlete and/or the Athlete's National Anti-Doping Organization, exclusively to CAS.
- A decision by WADA to reverse a TUE decision may be appealed by the Athlete, the National Anti-Doping Organization and/or the International Federation affected, exclusively to CAS.
- A failure to take action within a reasonable time on a properly submitted application for grant/recognition of a TUE or for review of a TUE decision shall be considered a denial of the application.

### Swansea University

SUBMITTED

Mike McNamee, Professor of Applied Ethics (Wales, GB)  
Other - Other (ex. Media, University, etc.)

WADA's ISTUE:

Mike McNamee (Swansea University, UK) and Jon Pike (Open University, UK)

## Introduction

Both McNamee (Bloodworth, McNamee, and Jaques 2018) and Pike (Pike 2018) have commented critically on ethical and conceptual problems of the TUE policy. We reject the position of Dimeo and Møller (Dimeo and Møller 2018) who have argued that if TUEs are sought then the athletes ought not to compete on grounds of health. Our concern is about the precision of the formulation of certain of its criteria, including the explicit incorporation of a criterion of 'fairness'. Some of our points are merely terminological, others are more substantive.

## Retroactive TUEs

**4.1** Unless one of the following exceptions applies (in which case an *Athlete* may apply retroactively for approval for his/her Therapeutic Use of a *Prohibited Substance* or *Prohibited Method* under Article 4.2, i.e., a retroactive TUE), an *Athlete* who needs to Use a *Prohibited Substance* or *Prohibited Method* for Therapeutic reasons must apply for and obtain a TUE under Article 4.2 prior to Using or Possessing the substance or method in question:

a) emergency or urgent treatment of a medical condition was necessary; or

b) there was insufficient time or opportunity for the *Athlete* to submit, or for the TUEC to consider, an application for the TUE prior to Sample collection; or

c) the applicable rules required the *Athlete* to apply for a retroactive TUE (see comment to Article 5.1); or

d) if an *Anti-Doping Organization* chooses to collect a Sample from 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, the *Anti-Doping Organization* may permit the *Athlete* to apply for a retroactive TUE.

## Comments

i. **to 4.1(a)** necessary for what?: to recover health status?; to compete at all?; to compete at a desired level?; or "such that the *Athlete* would experience a significant impairment to health" (as in 4.2)?, or *in extremis* for the preservation of life. Further specification is needed here.

ii. **to 4.1(b)** Compare the laxity of "insufficient time or opportunity" with the whereabouts rule. A doping control officer must wait 60 mins and then may leave. A clarification or explanatory comment might be merited here. In addition, it might be that the athlete or coach or physician makes *it the case that* there is insufficient time of opportunity. Who makes the determination, and on what kinds of criteria?

iii. **to 4.1(d)** Is 4.d an additional criterion, or just an example of 4c? Is 5.1 necessary if 4d states the same thing?

The fourfold criteria: 4.2 (a) and (b)

**4.2** An *Athlete* may be granted a TUE if (and only if) he/she can show, on the balance of probabilities, that each of the following conditions is met:

a. The *Prohibited Substance* or *Prohibited Method* in question is needed to treat an acute or chronic diagnosed medical condition supported by relevant clinical evidence, such that the *Athlete* would experience a significant impairment to health if the *Prohibited Substance* or *Prohibited Method* were to be withheld.

b. The Therapeutic Use of the *Prohibited Substance* or *Prohibited Method* is highly unlikely to will not produce any additional enhancement of performance beyond what might be anticipated by a return to the *Athlete*'s normal state of health following the treatment of the acute or chronic medical condition.

## Comments

First, why repeat balance of probabilities? The balance of probabilities is a standard of proof, and a response to constraints on what can be known about the athlete's status that cover all four criteria. It should not be repeated for 4.2(b)

Second, it is important to be clear that there is *arule*: the Prohibited List – and *exemptions*: TUEs. The rule - *no use of items on the prohibited list under conditions of strict liability*- is the default position. The exemptions are in the gift of WADA/NADOs: they are a privilege, rather than a right, and athletes must *apply* for them if ‘something exceptional’ is the case. It is therefore essential to specify that *exceptional circumstances* must apply. This seems not more stringent than, for example, the position of strict liability that is adopted elsewhere in anti-doping policy.

However, we support the changed version of 4.2b, and agree with WADA’s suggested return to the 2011 wording. Calls for a return to the formulation “highly unlikely” follow (we think) from a possible misinterpretation of the proposed rule change.

Whether there is additional enhancement is something that is a fact. It is an important fact because, if there is additional enhancement, then there will be, to some extent, unfairness to other competitors. Moreover, an important aim of a TUE policy is that competitors get no advantage from their use of the policy.

TUECs do not have clear access to that fact of the matter. It may be very difficult to know precisely whether a specific medication led to a performance enhancement. (Pike 2018: 71-73) So, it is the applicant who must demonstrate, *on the balance of probabilities*, that there will be no performance enhancement. The TUEC must decide, *on the balance of probabilities*, whether this is true. We understand and support WADA’s view that on a balance of probabilities (i.e. more than or equal to 51%) TUEs should “not produce any additional enhancement”.

*[Comment to 4.2(b): An Athlete’s normal state of health will need to be determined on an individual basis. A normal state of health for a specific Athlete is their state of health but for the medical condition in question.]*

This comment – and its appeal to a “normal state of health” leaves things underdetermined. So, it now becomes a simple matter of clinical judgement what level of health is taken as normal. That leaves the door open to misinterpretation or abuse. The second sentence tries to tighten it up “but for the medical condition in question”. It is unclear whether the “but for” formulation is clear enough. If “but for” retains the correct concept, then a simple wording change to “*in the absence of*” might be easier for non-native English speakers. When considering normal state of health, we propose that some international standard is applied such as the DSMV and/or ICD 11 to determine normal and pathological conditions for athletes seeking a TUE.

#### 4.2(c)

c. There is no reasonable Therapeutic alternative to the Use of the Prohibited Substance or Prohibited Method.

*[Comment to 4.2(c): Assessing reasonable Therapeutic alternatives may require consideration of geographical and/or cultural differences. Further, it is not always necessary to try and fail alternatives before using the Prohibited Substance or Prohibited Method. However, the physician must explain why the treatment chosen was the most appropriate e.g. based on experience, side-effect profiles.]*

#### Comment

In what ways do the geo-cultural differences help here? In Asia/America/Russia etc we “prefer” to use this rather than that? Again, this seems to open a latitude that might create unfairness.

#### Retroactive TUE Policy

d. Notwithstanding any other provision in this International Standard for Therapeutic Use Exemptions, an Athlete may apply for and be granted retroactive approval for his/her Therapeutic Use of a Prohibited Substance or Prohibited Method (i.e., a retroactive TUE) if it is agreed, by WADA and by the Anti-Doping Organization to whom the application for a retroactive TUE is or would be made, that, considering the purpose of the Code, it would be manifestly unfair if fairness requires the notto grantofa retroactive TUE. If the relevant Anti-Doping Organization (and/or WADA, on a review) does not agree to the application of Article 4.3, that determination may not be challenged either as a defence to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.

[Comment to 4.3(d): 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 the reasons why the Athlete did not apply in advance; the Athlete's experience; 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. If WADA and/or the Anti-Doping Organization do not agree to the application of Article 4.3(d), that may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.]

#### Retroactive TUE Policy: comments

It is important to re-state that a TUE is an exception. A retroactive TUE is an exception to an exception. Clearly this is an extraordinary issue. But how is it invoked? By what criterion? It is a negative one: it has moved from "fairness requires it" (which is very open ended, though not completely so) to "manifestly unfair". There is no account here of the 'fair to whom?' question. For example: it may be manifestly unfair to an athlete, to prevent an athlete competing because of an AAF, when the athlete is no fault. But this is part of the Code, and at the heart of strict liability, in order to ensure fairness to their competitors. What is fair to an athlete in this situation is not fair to their competitors, and what is fair to the competitors is not fair to the athlete, on a straightforward understanding of fairness. Moreover, this points to the issue of needing ethical judgment/or expertise where the relevant committee may have no specific *ethical* training/education/insight. (The same can be said *inter alia* of the use of the spirit of sport criterion elsewhere in anti-doping policy.)

What training or expertise (what guidance even?) do TUECs have in dealing with matters of fairness? It may sometimes be so obvious that it needs no expertise, or negotiation of trade-offs. But we doubt that it can like this in all cases? So, the first challenge is: based on what competence?

The second challenge is how transparent is this process, and to whom? If there are to be checks and balances who audits this? And WADA has produced data here that are reassuring (so why not refer to the process of checks and balance in the ISTUE?)

A third, broader challenge may be set though. Why is 4.3 needed at all? It seems to be a "catch all" clause (compare professional codes: these are usually comprised of a list of specific rules and then a final general rule about "conduct that would bring the profession into disrepute", which is completely open-ended.)

A final challenge is this: ought competitors to know, as a matter of transparency and justice, where a fellow competitor has been granted a retroactive TUE (an exception to the exception).

This is not a matter of determining whether x position is ethical or not. Rather it is a clash *between* rights: right to privacy, right to fair competition. WADA sets privacy against fair competition in its whereabouts policy. It holds that privacy (to a degree, within the ADAMS) can be overridden in order to preserve fair competition. Ought it to do something similar with respect to Retroactive TUEs, where this would set fairness against confidentiality? i.e. might it be fairer to allow fellow competitors to know when a Retroactive TUE has been given to an athlete and on what basis, than to withhold this information on the grounds of confidentiality? This relates to the age-old dictum that justice must be seen to be done.

What degree of breach of confidentiality would be justified? To include all relevant medical data of the decision making will offend international standards in patient confidentiality (Cox et al, 2018). Clearly physicians cannot be asked to break their own professional codes or they would risk having their licence to practice be withdrawn by their national accrediting body. However, might we not require the athlete to allow some public account to be given of the nature of their application as a contractual obligation (again, compare whereabouts as a precedent). Or might another solution be to publish a list of those TUEs that were applied for and awarded/not awarded?

The underlying point is this: An athlete is entitled to their privacy, and to the privacy of their medical data. But no-one is *entitled* to a TUE, let alone a retrospective TUE, and it may be reasonable, in circumstances where the process is under scrutiny, to say that an athlete who wants to have a retrospective TUE is required to give up some minimal rights to privacy in order to be granted one. They have no duty to give up those minimal rights, (no-one is compelling them to do so) *unless*- if and only if - they seek the award of a retrospective TUE.

Finally, the redrafted rules suggest that, with respect to the application of the fairness criterion, no appeal is permissible (which hardly seems fair). Again, with respect to transparency and fairness, where are these minutes

recorded, and is there a precedent setting mechanism or is every decision *de novo*? In general, we hold that each critical judgement of the TUEC should be open to appeal in a uniform and consistent way, if there are no morally relevant differences.

MM + JP

20.2.19

Bloodworth, A. J., M. J. McNamee, and R. Jaques. 2018. 'Morgan's Conventionalism versus WADA's Use of the Prohibited List: The Case of Thyroxine', *Sport, Ethics and Philosophy*, 12: 401-15.

Cox, L., Bloodworth, A., & McNamee, M. 2017. Olympic Doping, Transparency, and the Therapeutic Exemption Process. *Diagoras: International Academic Journal on Olympic Studies*, 1, 55-74.

Dimeo, Paul, and Verner Møller. 2018. *The Anti-Doping Crisis in Sport* (Routledge).

Pike, Jon. 2018. 'Therapeutic Use Exemptions and the Doctrine of Double Effect', *Journal of the Philosophy of Sport*, 45-01: 68-82.

## 4.0 Obtaining a TUE (1)

### 4.1 (4)

#### Department of Health - National Integrity of Sport Unit

SUBMITTED

Luke Janeczko, Policy Officer (Australia)  
Public Authorities - Government

Article 4(c) and (d) are essentially the same provision in allowing for a lower level athlete to apply for a retroactive TUE after a sample is taken. It is unclear as to the need for both, and if there is a need for both, an explanation about how they are different is required.

One of the most common retroactive scenarios is when an athlete moves up a level and is then required to have an in advance TUE, but has been taking their medication prior to this and it is not an urgent or emergency situation. The most common situations would be Diabetic using Insulin or athlete with ADHD using stimulants as these diagnoses are often made in childhood and medication use is long standing (lifelong for diabetes). There is no criteria for this and it is usually dealt with as a "new" application but perhaps it could be acknowledged.

#### Antidoping Switzerland

SUBMITTED

Ernst König, CEO (Switzerland)  
NADO - NADO

Antidoping Switzerland welcomes the new and separated 4.3 Fairness article, which is a logical consequence since 4.2 must not fully apply in 4.3 cases. We acknowledge the newly under 4.1 d) written paragraph, aiming to clarify the situation for lower level athletes. Our further suggestions concerning 4.1 b) and c) are listed below.

To improve clarity Antidoping Switzerland suggests to reorder the introducing sentence of article 4.1:

*An Athlete who needs to Use a Prohibited Substance or Prohibited Method for Therapeutic reasons must apply for and obtain a TUE under Article 4.2 prior to Using or Possessing the substance or method in*

*question unless one of the following exceptions applies (in which case an Athlete may apply retroactively for approval for his/her Therapeutic Use of a Prohibited Substance or Prohibited Method under Article 4.2, i.e., a retroactive TUE):*

Since ISTUE Art. 4.1 d) is identical to WADA Code Art. 4.4.5, we recommend removing Art. 4.4.5 from the Code in order to remove this redundancy.

#### 4.1 b)

Removing the term “*other exceptional circumstances*” might loosen the definition of situations in which 4.1 b) can apply. Therefore, Antidoping Switzerland recommends the further use of the current wording of this paragraph.

#### 4.1 c)

Clearer declarations by IFs (and MEOs) are needed and these have to be easily available online (no login or contact details required; up to date lists and filters;..). Antidoping Switzerland suggests that WADA holds IFs accountable regarding this matter.

The information available online should include a clear and easily accessible ILA definition. Depending on the used ILA definition a clearer statement should be required to explain if 4.1 c) applies for certain athletes other than ILA athletes. In addition, it is necessary that international competitions are listed for all disciplines and all ages (junior, elite, master). Furthermore, all regional/continental details need to be clarified. We would wish the following points to be clearly stated by the IFs and monitored by WADA (if applicable):

- International friendly matches (elite, junior, master): are they classified as international competitions or does 4.1c) apply if the individual athletes of these teams are not considered to be ILAs?
- Junior and masters championships and international competitions: are they classified as international competitions or does 4.1c) apply if the athletes competing at these competitions are not considered to be ILAs?
- Continental and/or other regional competitions/championships, if there is a continental federation in addition to the IF (or MEO): Comprehensive definitions of “continental competition” and “continental level athlete” are needed (as above). Only referring to the corresponding IF (or MEO) is usually insufficient because the rules and definitions of the IF usually do not refer to the continental level (Example: information on website of a European championship refers to its IF’s rules. These rules available on the IF website only define international competitions like World championships, other worldwide competitions and the ILA definition might even be based on participation at these international events. In this case the rules which apply for the European championship are not available).
- Competitions / tournaments with international participation, which are no official “international competitions” (sometimes a special tour / series): are they classified as international competitions or does 4.1c) apply if the athletes competing at these competitions are not considered to be ILAs?

#### 4.1 d)

WADA needs to clarify “may permit” (especially for situations where the ADO is an IF and the responsible NADO applies 4.1 c) to a lower level athlete. Recommendation: change wording to “must permit” or “permits”)

If the ADO is the responsible NADO, 4.1d) is likely to be redundant because 4.1 c) may apply. However, we welcome the addition of 4.1d) and suggest to use it for further clarification of the rules applied for lower level athletes tested by their IF (or another NADO than their “home”-NADO). In addition, we suggest a reference to Art. 7.6 for national level athletes tested by their IF.

We do not see a reason why lower level athletes should not be allowed to apply retroactively if their use of the substance/method is for therapeutic reasons and therefore only using the word “may permit” is insufficient. “May permit” should either be replaced by “must permit” or “permits” or an alternative wording as suggested below. The change will provide more confidence for these lower level athletes:

*4.1d) if an Anti-Doping Organization chooses to collect a Sample from 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, **the Athlete can apply for a retroactive TUE to the Anti-Doping***

**Comment: 4.1d) If the ADO is an IF a lower level athlete applies retroactively to his IF (process for national level athletes clarified under article 7.6). If the ADO is “another NADO” Art. 5.1 applies),**

## UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

### Article 4.1 Comments

The proposed revision of article 4.1 does not make it clear that athletes must apply for and obtain a TUE before using/possessing a prohibited substance or method as the exceptions to this fundamental principle are introduced first.

**Recommendation:** Reorder the wording of article 4.1 to emphasise that the default position is that athletes must apply for a TUE in advance of use/possession of a prohibited substance or method prior to introducing the retroactive exceptions. Suggested revision:

**4.1.** An Athlete who needs to Use a Prohibited Substance or Prohibited Method for Therapeutic reasons must apply for and obtain a TUE under Article 4.2 prior to Using or Possessing the substance or method in question, unless one of the following exceptions applies (in which case an Athlete may apply retroactively for approval under Article 4.2).

### Article 4.1b Comment

The phrase “due to other exceptional circumstances” has been removed from the latest draft. The rationale for removing this wording is unclear, particularly as article 4.1b is only relied upon on rare occasions and we have not experienced any difficulties when considering athlete explanations in relation to this clause over the past 10 years. We propose the re-inclusion of this wording as it clearly sets out that there must be extenuating circumstances (rather than just any circumstance) for why an athlete who should be applying for a TUE in advance has not done so prior to doping control.

**Recommendation:** Reinsert the phrase “due to other exceptional circumstances” within this clause. Suggested revision:

**4.1b:** Due to other exceptional circumstances, there was insufficient time or opportunity for the Athlete to submit, or for the TUEC to consider, an application for the TUE prior to Sample collection.

### Article 4.1d Comment

The proposed inclusion of this new retroactive clause is not necessary as this scenario is already covered by the applicable rules referenced in article 4.1c. At present, article 5.1 (ISTUE, 2019) outlines that a National Anti-Doping Organisation (NADO) can determine which competitors are defined as being national-level and therefore required to obtain a TUE in advance. In our experience, athletes who are not deemed to be national-level are also unlikely to be considered as international-level competitors by their International Federation (IF). As a result, these athletes are permitted to obtain a retroactive TUE if they are subject to doping control under article 4.1c, regardless of the testing authority involved.

We accept that it is useful to highlight how Anti-Doping Organisations (ADOs) should deal with such a scenario. However, it is our view that this information is better served as a comment to article 4.1c rather than as a stand-alone clause.

**Recommendation:** Delete article 4.1d; add the below wording as a new comment to support article 4.1c.

Suggested revision:

Comment to 4.1(c): If an Anti-Doping Organisation chooses to collect a Sample from 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, the Anti-Doping Organisation may permit the Athlete to apply for a retroactive TUE.

Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.2, in case an application for a retroactive TUE is necessary following Sample collection.

**International Paralympic Committee**

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

It is very unusual and confusing that the ISTUE starts with an article on exceptions.

4.1.c. This article has been divided into two sections. The IPC TUE team would suggest this to be confusing as both relate to code article 4.4. - 4.1.d is the main reason why 4.1.c would apply.

Art 4.1.d could be combined with 4.1.c see comment above.

Art. 4.1.d. as well as art. 5.1 ILA and NLA are defined terms but the provision is silent on athletes who belong to neither category. This is particularly confusing for those athletes that are 'fast-tracked' for international competitions (e.g. late replacements, vacant slots in para team sports, ...). This leaves a large group of athletes without the right or opportunity to apply for a TUE. It is problematic they must depend on a retroactive TUE and potentially a doping rule violation because they cannot apply beforehand.

**4.2 (7)**

**Department of Health - National Integrity of Sport Unit**

Luke Janeczko, Policy Officer (Australia)  
Public Authorities - Government

SUBMITTED

With regard to the change in wording in 4.2(b) to 'will not', from 'highly unlikely', this has always been a difficult criteria to evaluate and the more definite statement will make it even more so. To assist in evaluation there should be examples of the considerations for assessment of this criteria in the Medical Guidelines for TUES.

**Antidoping Switzerland**

Ernst König, CEO (Switzerland)  
NADO - NADO

SUBMITTED

Comment 4.2 c)

This comment might reflect the cultural and regional practices and we are aware that there are (big) differences regarding standard treatments worldwide. However, the comment encourages loosening the conditions to approve a TUE especially with the statement that it might not be necessary to try and fail alternatives.

Therefore, we ask WADA to:

1. Clarify the allowed cultural differences (e.g. is a certain prohibited therapy used in some countries or an

authorized alternative not available in others?). The rules and comments should level out the “cultural differences” that may give some athletes advantages over others (e.g. provide guidance for IFs who evaluate and recognize TUEs from all over the world).

2. Clarify in which situation it might *not* be necessary to try and fail alternatives. Will this decision depend on diagnosis and related risk of health issues connected with a change of therapy (e.g. pain management, vs. asthma, vs. cardiovascular conditions); or competition level of athlete; or duration of treatment?

3. Clarify which physicians’ explanations are considered as sufficient argument:

- Is compliance a reasonable explanation? (e.g. to justify the use of vilanterol rather than salmeterol/formoterol without any contraindication of salmeterol/formoterol or even without having tried these alternatives)
- Does a physician’s experience weigh more than national or international treatment guidelines (e.g. NICE, GINA)?

We welcome WADA’s explanatory comments and acknowledge that 4.2c) needs further explanations and comments to respect different situations and provide more clarity. However, if the needed guidance is provided in full detail and without general statements, it might loosen the strength of the rules. Furthermore, the comments section of an ISTUE article is not the right place for this kind of guidance. Antidoping Switzerland therefore suggests to move this comment to the TUE guidelines and/or TUE physician guidelines where applicable and to provide detailed information in these documents.

Comment 4.2

Does this mean that TUEs for off label therapies are possible, as long as 4.2 a-d is fulfilled?

### Anti-Doping Norway

Anne Cappelen, Director Systems and Results Management (Norway)  
NADO - NADO

SUBMITTED

### 4.2.

ADNO agrees with the new comment clarifying that the use may be part of a necessary diagnostic investigation.

ADNO agrees with the new comment clarifying that when assessing reasonable therapeutic alternative, it is not always necessary to try and fail alternatives before using a prohibited substance or method providing that the physician explain why the treatment chosen was the most appropriate.

### Doping Authority Netherlands

Olivier de Hon, Chief Operating Officer (Netherlands)  
NADO - NADO

SUBMITTED

The comment explaining that diagnostic investigations may also be a reason to grant a TUE is much appreciated. In our view, this section could also easily be expanded to include the altruistic act of plasmapheresis as a reason for granting a TUE, for example by adding some extra words to the text of 4.2.a (“The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic diagnosed medical condition supported by relevant clinical evidence, such that the Athlete or another person would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld from the Athlete.”) or to explicitly mention this possibility in the comment, possibly with a requirement that such a procedure should not interfere with any of the existing methods to establish an ADRV and that the treatment is exercised in a legitimate medical setting. As we have argued before, we feel that the act of plasmapheresis cannot be seen as a method to gain an unfair advantage and should be permitted to athletes by either allowing it explicitly in the PLIS, or by allowing TUE-requests for this medical

procedure. As it currently stands, neither way is open to athletes who would like to engage in this altruistic gesture.

## UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

### Article 4.2a Comment

UKAD supports the amendments to article 4.2a as the new wording i. reinforces the fact that a valid diagnosis is an essential component of an application; and ii. acknowledges that requests to use a prohibited substance or method may be part of a diagnostic intervention (e.g. insulin tolerance or adrenocorticotrophic hormone (ACTH) stimulation tests).

### Article 4.2b Comment

The introductory statement to article 4.2 states that an athlete must show that, on the balance of probabilities, each of the conditions for granting a TUE are met. We therefore support the removal of “highly unlikely” from article 4.2b as this standard of proof is different to “on the balance of probabilities”.

Although additional commentary has been inserted to assist how TUE Committee (TUEC) review panels should interpret article 4.2b, we do not think that this guidance goes far enough. We feel that further guidance (which could sit outside of the ISTUE) is warranted from the WADA Medical Department and List Expert Group regarding the sports and/or substances where additional enhancement of performance can be either ruled out *prima facie* or require closer scrutiny when determining if an application fulfils criterion 4.2b. This guidance would be beneficial to improve the consistency of how this criterion is applied amongst TUEC review panels. Further details regarding this matter can be found in our phase I comments.

**Recommendation:** Provide further guidance on the substances and/or sports that TUEC review panels can either rule out *prima facie* or should pay closer attention to when assessing applications against this criterion.

### Article 4.2c Comment

We understand the intention to provide TUEC review panels with commentary on how to assess whether reasonable therapeutic alternatives exist. However, we wish to express our concern over the proposed new wording which states that “it is not always necessary to try and fail alternatives”.

It is our view that the inclusion of such a broad statement within the ISTUE creates unnecessary ambiguity that could be used as a loophole for TUEs to be granted when there is limited medical justification for why a reasonable permitted alternative has not been trialled or considered. We propose that the comment is removed in its entirety and instead placed within specific WADA medical information documents that support the decisions of TUECs (where relevant) and/or within the WADA TUE guidelines document.

**Recommendation:** Delete the comment that accompanies article 4.2c; move the wording to specific WADA medical information documents (where relevant).

### New Proposal: TUEC Liability Comment

UKAD supports the addition of the comment related to article 4.2 as it sufficiently fulfils the request we made in phase I that a clause should be added to clarify that TUECs have no liability for the medical care provided to athletes applying for a TUE.

**International Paralympic Committee**

SUBMITTED

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

Art. 4.2.b. The IPC TUE Team does not think the addition 'on balance of probabilities' adds value. This provision is already captured in the introductory wording of art. 4.2.

Art. 4.2.c. The comment that has been inserted to "consider geographical and/or cultural differences" will cause difficulties in its practical application by international TUEC. The IPC TUE Team is not in favour to list geography/cultural differences as a specific condition as it may lead to inappropriate reference that thus require review by a TUEC. The experience is that the physician can be consulted with in such cases, which is covered under "determination on an individual basis" (see art. 4.2.b). Perhaps such wording is more appropriate over geography/cultural difference

**Institute of National Anti-Doping Organisations**

SUBMITTED

Graeme Steel, Chief Executive (Germany)  
Other - Other (ex. Media, University, etc.)

[Comment to 4.2(b): An Athlete's normal state of health will need to be determined on an individual basis. A normal state of health for a specific Athlete is their state of health but for the medical condition in question.] This is not a satisfactory definition. If the medical condition existed from birth or a very young age it is not possible to determine what their "state of health would be but for the medical condition". In fact their "normal" state includes the condition. While not a perfect solution the following addition might be of some assistance. A normal state of health for a specific Athlete is their state of health (or what that state of health might reasonably be expected to be) but for the medical condition in question.

4.2(c) The explanatory note is a very good addition.

**4.3 (6)****Department of Health - National Integrity of Sport Unit**

SUBMITTED

Luke Janeczko, Policy Officer (Australia)  
Public Authorities - Government

With regard to "it would be manifestly unfair not to grant a retroactive TUE" -

there should be a process to review a TUE granted under this article.

WADA Medical currently does this but they need the resources to ensure that this is monitored and not abused. It should be stated that this is for exceptional cases and will be reviewed/scrutinised by WADA.

**Antidoping Switzerland**

SUBMITTED

Ernst König, CEO (Switzerland)  
NADO - NADO

Comment to 4.3

How can "*whether the Athlete declared the use of the substance or method on the Doping Control form*" be a criterion to decide if 4.3 can be applied or not?

A declaration should not determine the right to apply for a retroactive TUE under 4.3 (Non-declaration does not equal cheating and athletes are sometimes encouraged by their support personnel to renounce

declarations in general, which might be conflicting for (young) athletes.)

### Anti-Doping Norway

SUBMITTED

Anne Cappelen, Director Systems and Results Management (Norway)  
NADO - NADO

#### 4.3

ADNO support this amendment to the ISTUE clarifying the possibility of retroactive TUE in special circumstances.

### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

#### Article 4.3 Comment

We wish to express our deep concern over the introduction of article 4.3 which will allow for a TUE to be granted under the grounds of fairness, without an application needing to be reviewed by the WADA Medical and Legal teams or fulfil any of the conditions for granting a TUE (as outlined in article 4.2).

At present, an ADO must provide WADA with a full case file including all relevant medical documentation and the athlete's explanation of the circumstances for why a retroactive TUE has been submitted under the grounds of fairness. The circumstances surrounding the application are then reviewed by the WADA Medical and Legal teams to consider whether they fulfil the principles of fairness. If WADA subsequently agree that fairness can apply to this application, an assessment by the ADO TUEC must then be made on whether the conditions for granting a TUE have been satisfied

The comments submitted by other stakeholders during the first phase of the ISTUE consultation highlight that uncertainty exists over the application of the current "fairness principle" and that further guidance is required to determine which circumstances are deemed as appropriate. We therefore feel that devolving the responsibility of reviewing such complex ethical cases onto ADOs and their TUEC review panels, without oversight from the WADA Medical and Legal teams, is inappropriate and unhelpful.

Furthermore, it is our view that allowing for retroactive TUEs to be granted under the grounds of fairness without applications fulfilling the conditions for granting a TUE will undermine the integrity of the TUE system. We think that this proposal will open the system to unnecessary criticism regarding whether retroactive TUEs are being granted appropriately and consistently.

We understand that there have been very few cases globally whereby an athlete has applied for a retroactive TUE which has fulfilled the current fairness principle, but their application did not then satisfy the conditions for granting a TUE (for example, the athlete has a legitimate medical condition but had not trialled reasonable alternatives). The introduction of article 4.3 seems to be aimed at introducing a mechanism to avoid such circumstances where it would appear to be manifestly unfair for an athlete to incur an anti-doping rule violation. However, it is our view that such a process no longer represents a TUE as the conditions for granting a TUE have not been met. Furthermore, the fundamental principles of the TUE process should not be manipulated to serve the purpose of resolving such a small number of complex cases.

It is our view that if the conditions of granting a TUE outlined in article 4.2 are not met, the athlete's opportunity for obtaining a TUE should end. Instead, during the results management process, the athlete should be given the opportunity to present their extenuating circumstances and a decision can then be made by the ADO on whether to pursue an anti-doping rule violation. This would allow for the integrity of the TUE system to remain and for the decision to be made by those best placed.

**Recommendation:** Delete article 4.3; reinstate the current clause which outlines that the grant of a retroactive TUE on the grounds of fairness can only occur if i. it is agreed with the WADA Medical and Legal

teams; and ii. the application fulfils the conditions for granting a TUE as outlined in article 4.2. Suggested revision:

4.1d. It is agreed, by WADA and by the *Anti-Doping Organization* to whom the application for a retroactive TUE is or would be made, that fairness requires the grant of a retroactive TUE if article 4.2 is fulfilled.

*[Comment to 4.1(d): If WADA and/or the Anti-Doping Organization do not agree to the application of Article 4.1(d), that may not be challenged either as a defence to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.]*

**Recommendation:** If our recommendation to delete article 4.3 and to reinstate the current fairness clause is accepted, further guidance should be provided to ADOs which clarifies the process for reviewing an application under the grounds of fairness (that is, the timing of when an ADO should contact WADA to discuss such cases and examples of accepted reasons for invoking the fairness clause).

**Recommendation:** WADA should seek to identify an alternative solution for the small number of cases each year which fail to satisfy the criteria for granting a TUE but where an anti-doping rule violation appears to be manifestly unfair on the athlete. One possible avenue would be to explore adding a further step in the results management process prior to proceeding to arbitration.

### **New Proposal: Transparency of AAF Related Retroactive TUEs (Articles 4.1, 4.3 and 5.4)**

We believe that there should be greater transparency surrounding retroactive TUEs that have been granted to athletes following adverse analytical findings (AAF). If an ADO grants such a TUE, the ADO should be required to publish a notice on their website (in addition to adding the decision to ADAMS) which provides reasoning for the grant of the TUE, but does not identify the athlete, their sport, or any other data that would jeopardise the athlete's anonymity. If anonymity is an issue for ADOs who have a small population of athletes, then WADA should publish annual statistics on behalf of all ADOs regarding the number of retroactive TUEs related to AAFs that have been granted and the reasons for each decision.

Furthermore, if our proposal to remove article 4.3 is not accepted, we feel that this public notice of the number and circumstances for the grant of "pseudo-TUEs" will be essential to maintain athlete confidence within the system.

**Recommendation:** Add the requirement that an ADO shall publish a notice on their website explaining the grounds for granting a retroactive TUE following an AAF. This new responsibility would be in addition to ADO responsibilities already listed under article 5.4a.

Comment to Article 5.4a: If an ADO grants a retroactive TUE to an athlete following an AAF in accordance with Article 4.1 or 4.3, they must publish a notice on their website within 21 days which explains the grounds on which the TUE was granted but which does not identify the athlete, their sport, or any other data that would jeopardise the athlete's anonymity.

**Recommendation:** If athlete anonymity is an issue for ADOs who have a small population of athletes, then WADA should publish annual statistics on behalf of all ADOs regarding the number of retroactive TUEs related to AAFs that have been granted and the reasons for each decision (NB. the athlete, their sport, nationality, or any other data that would jeopardise athlete anonymity would not be published).

#### **International Paralympic Committee**

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

A few point on "fairness"

-The IPC TUE Team believes it should be noted that this should only be considered in rare circumstances,

for example: "Notwithstanding any other provision in this International Standard for Therapeutic Use Exemptions, *in rare circumstances* an Athlete may apply..."

-it is still unclear as to whether these are required to be reviewed by WADA, or not. Currently it just says "(and/or WADA, on a review)" which sounds as though WADA reserves the right to review but does not have to review. The suggestion is that it should be a requirement, to ensure global harmonization regarding a) how often 4.3 is being invoked, and b) ensure it is being involved fairly and for similar circumstances across different NADOs and IFs. One could see this clause being over-used and over-interpreted very easily.

- examples are provided but the IPC's previous feedback to provide more clarity on the 'fairness' clause remains valid. The term 'fairness' has now been replaced by 'manifestly unfair'. There might be a (legal) reason for the change but that should be clarified.

Art. 4.3. It is problematic that 'declaring the use of the substance/method on the DCF' would qualify under 'fairness'?

#### **Institute of National Anti-Doping Organisations**

SUBMITTED

Graeme Steel, Chief Executive (Germany)  
Other - Other (ex. Media, University, etc.)

The changes to 4.3 and, in particular, the explanatory note are very helpful and assist in achieving fairness. Nevertheless the ability of Recreational athletes to understand the requirements of the Standard remain extremely problematic and their different circumstances should allow for a more explicit level of leniency. This may be limited to specified substances. If, however the application of 4.3 is only for truly exceptional circumstances (Per the notes) the purpose of recognising the different needs of recreational athletes as a category is not met and the TUE Standard remains palpably unfair to them.

## **5.0 TUE Responsibilities of Anti-Doping Organizations (2)**

### **5.1 (8)**

#### **UEFA**

SUBMITTED

Rebecca Lee, Anti-Doping Coordinator (Switzerland)  
Sport - Other

We would recommend that in case of doubt, the jurisdiction should be granted to the NADO of the Athlete's Sport Nationality – ie. where they spend most of their time training and competing. For example Gareth Bale should apply for a TUE to the Spanish NADO (unless he's competing at International level, in which case he would apply to UEFA or FIFA).

**Comment to Art. 5.1, Code Article 4.4.2****We already addressed the geographical validity of TUEs in the 1. consultation phase, and would like to add some arguments:**

In our opinion, a TUE validity at national level on a global basis exceeds the competences of National Anti-Doping Organizations. For legal reasons we regard it as not possible for a NADO's TUEC to make a TUEC decision which is – without any recognition – valid in every other country where the athlete takes part in national level competitions.

As soon as an athlete takes part in purely national level competitions in another country, he/she falls under the TUE-responsibility of the other country's NADO. We propose to regard TUEs at national level to be initially valid only in that particular country whose NADO has granted the TUE. Subsequent mutual recognition of TUEs by different countries' NADOs should be possible and described in the ISTUE as an official process.

Additionally, we observe that medical treatments naturally vary from country to country and, as a consequence, TUEC decisions may vary from NADO to NADO. This can lead to the unfavourable situation that an athlete has got a TUE from one country's NADO, but the approved substance or method does not reflect the medical standards or treatment guidelines in the new country.

In order to make TUEC decisions comparable between different countries, although the medical standards vary in individual countries, we propose to reconsider whether WADA's TUEC Guidelines (WADA's Medical information to support the decisions of TUECs) or parts of them should be made mandatory for all ADOs.

**Proposal for the determination of an athlete's NADO for the purpose of TUE jurisdiction:**

A testing-pool athlete must apply for a TUE at the same NADO where he/she is member of a testing-pool. A non-testing-pool athlete, who is not an International-Level Athlete, should follow the medical anti-doping regulations of the country he is competing at the moment and prospectively for a longer time (e.g. team sports with a contract in a particular country for one season or more). A non-testing-pool athlete who is not an International-Level Athlete and who changes his home or the country he competes in very often (e.g. every few weeks) should apply for a TUE at the NADO of the country in which he spends the predominant time, or, if in doubt, at the NADO of his native country.

**Comment to 5.4**

For data protection reasons in general and for the protection of personal medical data in particular according to national data protection regulations, NADA Germany is not allowed to upload or enter medical information regarding the diagnosis and medical history into ADAMS. In addition, NADA Germany does not upload medical files into ADAMS.

A summary of the key information – translated into English – as well as the full medical file can be received via encrypted e-mail upon personal request to NADA.

Please be aware of the fact, that GDPR in Europe requires strong legal grounds for the exchange of sensitive medical data in web-based databases.

**Antidoping Switzerland**

Antidoping Switzerland welcomes the clarification regarding the validity of NADO TUEs at national level on a global basis.

We propose that NADO responsibility should depend on the national license and/or membership in national sports federations/clubs of an athlete.

Additional point to clarify: Which NADO is responsible for result management and potential retroactive TUE application after sample collection by non-“home” NADO (for lower-level athletes)? Ergo, Result management and TUE authority should always be defined identically.

Additional proposal for travelling lower level athletes (based on 4.1 d): If a lower level athlete is allowed to apply retroactively by their home NADO, then all other NADOs allow for retroactive TUEs as well (or forward result management to “home” NADO).

### Anti-Doping Norway

SUBMITTED

Anne Cappelen, Director Systems and Results Management (Norway)  
NADO - NADO

#### 5.1

Re drafting note and request from feedback to this item: ADNO believes that the NADO in the country where the athlete is residing and training, irrespectively of the athlete’s nationality, should normally be the one handling a TUE application from the athlete (unless the athlete is an international level athlete as defined by the athlete’s International federation).

### c/o Japan Anti-Doping Agency

SUBMITTED

Satomi SUZUKI, Assistant Manager / Education & Information Group (JAPAN)  
NADO - NADO

[Comment to 5.1: See Annex 1 for a flow-chart summarizing the key provisions of Code Article 4.4.....  
-----Our Comment is the following-----

We will agree with the revised comment to 5.1 of ISTUE2021, if these conditions are met:

- The TUE application process is clear.
- It is reviewed by WADA and/or IF.

### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

#### Article 5.1 Drafting Note Comment (related to Code Article 4.4.2)

Feedback has been sought from stakeholders on how an athlete’s NADO (for the purposes of TUE jurisdiction) should be determined when the athlete competes and resides across multiple countries but is not determined to be international-level. It is our view that the athlete’s NADO (for the purposes of TUE jurisdiction) should be determined as the NADO within the country in which the athlete is either a citizen of or a member of a national governing body (e.g. a foreign football player competing in a league within the UK would apply to UKAD for a TUE).

**Recommendation:** An athlete’s NADO (for the purposes of TUE jurisdiction) should be determined as the

NADO within the country in which the athlete is either a citizen of or a member of a national governing body.

### Article 5.1 Global Recognition of National-Level TUEs (related to Code Article 4.4.2)

UKAD supports the proposal that TUEs granted at national-level are valid on a global basis without the need for another NADO to formally recognise the TUE.

#### International Paralympic Committee

SUBMITTED

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

5.1 See as well as art. Art. 4.1.d ILA and NLA are defined terms but the provision is silent on athletes who belong to neither category. This is particularly confusing for those (para) athletes that are 'fast-tracked' for international competitions (e.g. late replacements, vacant slots in para team sports, ...). This leaves a large group of athletes without the **right or opportunity** to apply for a TUE. It is problematic they must depend on a retroactive TUE and potentially a doping rule violation because they cannot apply beforehand.

### 5.2 (4)

#### Department of Health - National Integrity of Sport Unit

SUBMITTED

Luke Janeczko, Policy Officer (Australia)  
Public Authorities - Government

Australia does not agree with the comment to Article 5.2.

This is a significant concern and has not been well considered. There is no doubt that the ADO will need to provide information about the athlete's level of competition for 4.1 (c) and (d), but it is inappropriate for non-medical administrators to decide on what constitutes a medical emergency and urgent treatment.

Nor should an ADO have sole discretion over 4.3 as at least some consideration of the medical treatment should be given and the TUEC is the body that should consider this.

#### Anti-Doping Norway

SUBMITTED

Anne Cappelen, Director Systems and Results Management (Norway)  
NADO - NADO

### 5.2

ADNO support the requirement of impartiality of the TUEC members and would encourage an even stronger requirement of independence to be added to the requirement.

#### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

## Article 5.2a Comment

UKAD supports the amendments to article 5.2a as the new wording reflects the importance of selecting a TUEC review panel member with specific expertise pertaining to the medical condition outlined within an application.

### International Paralympic Committee

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

Art. 5.2. The IPC TUE Team has firm reservations to the comment to this article (if understood correctly): this would imply that e.g. the Management Team of an ADO may determine on exemptions/fairness instead of the TUEC? The TUEC should be involved in the process.

Art. 5.2.a. It is the IPC's recommendation that all 3 TUEC members should have expertise in para athletes

## 5.4 (5)

### Anti Doping Denmark

Jesper Frigast LARSEN, Legal Manager (Denmark)  
NADO - NADO

SUBMITTED

The Comment to 5.4 reads: "The process of recognition of TUEs is greatly facilitated by use of ADAMS." We totally agree, and we propose that it is made mandatory for ADOs to register all TUEs in ADAMS for them to be internationally valid.

In addition, when registering TUEs in ADAMS, the system lacks categories for athletes outside of international level and national level athletes for ADOs who also test recreational athletes etc. We propose the introduction of a category called "Other athletes". We refer to our comments to the definition of "Athlete" in the Code.

Article 5.4 demands that an ADO must send the TUE application form and the relevant clinical information translated into English or French.

The obligation to translate documents is a heavy and extremely unfair burden on ADOs who are not from English or French speaking countries. We have to bear in mind that there are 209 official languages in the world, and in only 59 (English) and 29 (French) countries is one of WADA's official languages a national language. This problem should be discussed and addressed.

### NADA

Regine Reiser, Result Management (Deutschland)  
NADO - NADO

SUBMITTED

Art. 5.4 b

What do 'duration of administration' and 'duration of the TUE' mean? The duration of a TUE (validity of a TUE) usually depends on the duration of the administration of a prohibited substance or prohibited method. Therefore, 'duration of administration' and 'duration of the TUE' would be (nearly) the same in most cases.

In our opinion, it is important that a TUE approval contains an exact date (dd.mm.yyyy) when the validity starts and an exact date when the validity ends.

### Swedish Sports Confederation

SUBMITTED

Tommy Forsgren, Results Management Manager (Sweden)  
NADO - NADO

· SSC support the comment from Denmark that the burden is too heavy for an ADO to translate the TUE application form and relevant clinic information into English or French

### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

#### Article 5.4 Comment

The new comment relating to article 5.4 proposes that the full medical file no longer needs to be translated into English or French, but a translated summary of the key information must be entered in ADAMS. We encourage the WADA Medical team to consider developing a network of certified translators who could be used by ADOs when full translations of medical files are required.

**Recommendation:** Consider developing a network of certified translators that ADOs could use when full translations of medical files are required.

### International Paralympic Committee

SUBMITTED

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

Art. 5.4. The comment to this art should also be captured under art 6 (TUE application process)

## 5.6 (2)

### Doping Authority Netherlands

SUBMITTED

Olivier de Hon, Chief Operating Officer (Netherlands)  
NADO - NADO

The text about the rights and responsibilities of IFs and MEOs is supported by us, but we would like to stress that non-compliance to this specific article should be specifically targeted by WADA and its staff. Unclear reporting of the issues specified in this article is still the main reason for delays and uncertainties in the TUE-process.

### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

#### Article 5.6 Comment

Article 5.6 outlines that International Federations and Major Event Organisations must publish a notice of which athletes fall under their jurisdiction and are required to apply to them for a TUE. In our experience, the compliance of IFs and MEOs to publish a clear list of international events or athletes for which a TUE is required varies. This lack of harmonisation creates confusion amongst athletes regarding which ADO to obtain a TUE from, and consequently makes a simple education message difficult to deliver. We also suggest that a comment should be added to article 5.6 to advise ADOs that this public notice should be reviewed on an annual basis (e.g. prior to the start of the new competitive season for each sport or prior to starting a new test distribution plan cycle).

**Recommendation:** WADA should actively monitor ADO compliance in relation to article 5.6 and establish a

reporting mechanism to enable ADOs to report cases of non-compliance.

**Recommendation:** Add the below comment to article 5.6.

Comment to 5.6: This public notice should be reviewed on an annual basis (e.g. prior to the start of the new competitive season for each sport or prior to starting a new test distribution plan cycle).

### 5.7 (3)

#### Department of Health - National Integrity of Sport Unit

Luke Janeczko, Policy Officer (Australia)  
Public Authorities - Government

SUBMITTED

Consideration around allowing an IF rejected NADO TUE to stand at National level only assuming the "ISTUE criteria are met".

If these criteria were met then the IF shouldn't have rejected it in the first place, it should have been appealed.

#### International Paralympic Committee

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

Art 5.7. This article and the explanation provided in the summary is confusing and will give rise to multiple issues: it states that an IF refusal of a TUE implies a possibility of regrating a TUE at national level only. There are plenty of athletes that very occasionally are ILA (because the IF list is restricted by nature of resources and/or lists only few major events), but these athletes compete internationally at multiple occasion. It will be extremely confusing to athletes (and does not contribute to the integrity of the TUE process) when a TUE will ultimately be valid. This comes back to the discussion that both ILA and NLA are defined terms, but that confusion continues to be on those athletes that do not belong to either group

## 6.0 TUE Application Process (2)

### 6.3 (2)

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## Anti-Doping Norway

SUBMITTED

Anne Cappelen, Director Systems and Results Management (Norway)  
NADO - NADO

### 6.3

In the summary of major changes, it is clear that "...an athlete may only apply to one ADO at **the same time**. However, it is not clear in the ISTUE text: "An athlete may not apply to more than one Anti-Doping Organization for a TUE for the use of the same Prohibited Substance or Prohibited Method for the same medical condition." ADNO suggest adding "at the same time" at the end of the sentence.

## International Paralympic Committee

SUBMITTED

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

Art 6.3. This article is understood in its intention, but not manageable in absence of a central TUE clearinghouse

### 6.4 (1)

## NADA

SUBMITTED

Regine Reiser, Result Management (Deutschland)  
NADO - NADO

Any treating physician? Or does it have to be the specialist for the disease in question?

### 6.7 (2)

## GAISF

SUBMITTED

Davide Delfini, Membership Manager (Switzerland)  
Sport - Other

Art 6.7 We would like to suggest exploring the possibility to specify that ADOs TUEC can request the athlete to submit to further exams and examination from a doctor chosen by the ADO. We would propose the following: "The TUEC may request from the Athlete or his/her physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the Athlete's application; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate; *and/or it may request the athlete to*

*submit to further exams or being examined by an independent physician/s determined by the Anti-Doping Organization, practising in the same country of the Athlete's physician."*

**Canadian Centre for Ethics in Sport**

Elizabeth Carson, Manager, Sport Services (Canada)  
NADO - NADO

SUBMITTED

In Article 6.7, CCES requests changing the time frame for a TUEC decision from 21 days to a range of 21 to 30 days to allow for proper review of the application.

CCES also recommends adding a time frame to provide clarification for what may be considered a "reasonable time" in the following sentence: "Where a TUE application is made a reasonable time prior to an Event..."

**6.8 (1)**

**GAISF**

Davide Delfini, Membership Manager (Switzerland)  
Sport - Other

SUBMITTED

Art 6.8 In case our proposed modification of art 6.7 is accepted we would like to suggest specifying that the costs for the independent physicians must be paid by the ADOs. We would propose the following: " Any costs incurred by the Athlete in making the TUE application and in supplementing it as required by the TUEC are the responsibility of the Athlete, *except for the costs linked to the further exams and/or examination from the independent physician as might be required by the TUEC, which must be covered by the Anti-Doping Organization.*

**6.10 (1)**

## UK Anti-Doping

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

SUBMITTED

### Article 6.10 Comment

The change made to this article emphasises that TUEC decisions must now be made available on ADAMS. UKAD supports this amendment as this will give the WADA Medical team more oversight to scrutinise TUEC decisions and enable the collation of accurate global statistics to monitor trends.

## 7.0 TUE Recognition Process (5)

### International Cricket Council

Vanessa Hobkirk, Anti-Doping Manager (United Arab Emirates)  
Sport - IF – IOC-Recognized

SUBMITTED

SUBMITTED BY WADA

The ISTUE does not address what happens if an IF chooses not to recognize a TUE issued by a NADO for an international level athlete who is taking part in a domestic/national league competition. What happens should the IF decide to test the international level athlete out-of-competition just before the start of the domestic league? Is it expected to recognize the NADO's TUE under these circumstances?

### Organizacion Nacional Antidopaje de Uruguay

José Veloso Fernandez, Jefe de control Dopaje (Uruguay)  
NADO - NADO

SUBMITTED

In the definition of "TUEC" specify that members reads: "The panel of registered physicians established by an ADO to consider application for TUEs

### Anti Doping Denmark

Jesper Frigast LARSEN, Legal Manager (Denmark)  
NADO - NADO

SUBMITTED

ADD's comments regard article 7.0 - TUE Recognition Process. We refer to our comments to article 4.4 in the Code and would like to add the following:

The current wording opens a window for IFs to not automatically recognize TUE issued by a NADO in accordance with ISTUE and the corresponding guidelines: "To ease the burden on Athletes, automatic recognition of TUE decisions once they have been reported in accordance with Article 5.4 is strongly encouraged. If an International Federation or Major Event Organizer is not willing to grant automatic recognition of all such decisions, [etc.]"

In our opinion, the TUE granted by a NADO (national level) should per default automatically apply on all levels. Nevertheless, the IF, MEO and WADA would still have the possibility to reject the TUE at the international level, if they believe it doesn't fulfill the requirements for obtaining a TUE according to the ISTUE. If so, the IF, MEO and WADA should explain the reason behind the rejection.

The current practice leads to the administration of TUEs being a major burden on ADOs, athletes and the National Health Authorities. Steps should be taken to limit these burdens, thus freeing money and manpower to other important anti-doping tasks.

## 7.1 (4)

### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

#### Article 7.1 Comment

Article 7.1 states that ADOs, in accordance with Code article 4.4.3.1, must recognise TUEs granted by other ADOs if they satisfy the conditions for granting a TUE. However, article 7.1a also introduces the concept of automatic recognition which seems contradictory to this Code article – that is, the recognition process requires an ADO to review the athlete's medical file to be satisfied that the original ADO TUEC decision was correct prior to recognising the TUE. Automatic recognition bypasses this due diligence step for some IFs or MEOs.

We believe that the intention behind the recognition process is apt in that an athlete moving from national to international-level should not need to manually reapply for their TUE. However, we think that automatic recognition should be abolished as the consistency of national-level decisions may vary from country to country. Abolishing automatic recognition would also increase the amount of oversight and scrutiny of national-level TUEs by IFs and MEOs in the cases whereby an athlete progresses from national to international-level.

We therefore propose that it becomes compulsory for at least one member of an IF or MEO TUEC to review national-level TUEs that require recognition. This single reviewer could recommend that the national-level TUE be recognised or that the TUE requires a full review by three members of the IF or MEO TUEC. IFs who want to keep sending TUEs that require recognition to three TUEC members could still do so, but the single reviewer step would improve oversight in a proportionate way for IF or MEO TUECs with less capacity.

**Recommendation:** Introduce a mandatory due diligence step to the recognition process whereby at least one physician from an IF or MEO TUEC must assess whether the conditions for granting a national-level TUE have been satisfied prior to recognising the TUE.

### International Testing Agency

SUBMITTED

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

In relation to Art. 7.1(a):

Automatic recognition is difficult to manage in ADAMS, as ADAMS does not verify that the initial TUE decision is reported in accordance with art 5.4. Hence, automatic recognition (i.e. without any form of scrutiny required by the recognizing ADO) is not attainable until ADAMS provides for automatic verification that a decision has been reported in accordance with art 5.4.

### International Paralympic Committee

SUBMITTED

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

If the Athlete's TUE falls into a category of TUEs that are automatically recognized in this way at the time the TUE is granted, he/she **does not need to take any further action**.

Comment: However, the IF will need to be made aware that the TUE exists and should therefore be notified of the TUE preferably through ADAMS. This will enable the IF to recognise the TUE.

### Institute of National Anti-Doping Organisations

SUBMITTED

Graeme Steel, Chief Executive (Germany)  
Other - Other (ex. Media, University, etc.)

The requirements for granting a TUE are made clear in the Standard and the assumption should be that a TUE granted by any TUEC has met the relevant criteria. Consequently an athlete should not have to re-submit a TUE as a matter of course. The reverse default position should apply and TUEs should be automatically accepted unless an IF specifies ADOs whose TUEs it does not accept (and explains why).

## 7.6 (5)

### NADA

SUBMITTED

Regine Reiser, Result Management (Deutschland)  
NADO - NADO

If the Athlete is a non-testing-pool athlete and his/her NADO offers him/her other possibilities to allow the medical use of prohibited substances or methods (e.g. applying for a retroactive TUE, disposal of a medical certificate) for national-level competitions, an International Federation should be free to accept these national regulations.

### Antidoping Switzerland

SUBMITTED

Ernst König, CEO (Switzerland)  
NADO - NADO

Antidoping Switzerland welcomes the replacement of this statement into a separate article. This emphasizes the need for clarification of the situation of national level and lower level athletes who might be tested by their IF.

If an IF tests an athlete who is not an ILA it is possible that this athlete is not a national level athlete either and thus allowed to apply for a retroactive TUE according to the rules of his NADO. Therefore, we suggest that 7.6 applies to NADO TUEs which have been approved prior to an IF doping control as well as the right to apply retroactively (according to 4.1 c+d).

### UK Anti-Doping

SUBMITTED

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

### Article 7.6 Comments

Article 7.6 states that if an IF chooses to test an athlete who is not international-level, then the IF must recognise a TUE granted by a NADO. This clarification is welcomed. However, we believe that the wording should be expanded to clarify that this applies to both prospective and retroactive TUEs.

**Recommendation:** Clarify that article 7.6 applies to both prospective and retroactive TUEs granted by a NADO. Suggested revision:

7.6 If an International Federation chooses to test an Athlete who is not an International-Level Athlete, it must recognise a TUE granted by that Athlete's National Anti-Doping Organization. This applies to a TUE granted by the Athlete's National Anti-Doping Organization prior to Doping Control and any retroactive TUE that is granted by the National Anti-Doping Organization following the International Federation test.

### International Paralympic Committee

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

7.6 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

Comment: How does this correlate with Article 5.5 Here it mentions that a national TUE is valid at national level only and that if an athlete competes in an International Event that TUE will not be valid for those purposes unless it is recognised? The IPC TUE Team suggests further clarification when 7.6 will apply.

### Institute of National Anti-Doping Organisations

Graeme Steel, Chief Executive (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

This is supported although it is not inconceivable that an athlete competes in multiple sports under different IFs and the Standard appears to be silent here (and elsewhere) as to the implications.

Again, the default position should be one of automatic recognition unless specified otherwise by the IF.

## 8.0 Review of TUE Decisions by WADA (2)

### 8.1 (1)

#### International Paralympic Committee

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

Art. 8.1. See previous comment to art. 5.2

### 8.3 (1)

#### International Paralympic Committee

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

Art. 8.3. WADA is a higher authority than the IF and thus the WADA decision should be subject to appeal and

## 9.0 Confidentiality of Information (2)

### UK Anti-Doping

Samuel Pool, Medical Programmes Officer (United Kingdom)  
NADO - NADO

SUBMITTED

#### New Proposal: Redacted Applications

TUE applications contain personal information (e.g. name, date of birth, address and contact details) and sensitive medical information relating to the athlete. A TUEC is responsible for reviewing the medical documentation provided by the athlete to consider whether a TUE should be granted. It is our view, supported by the newly introduced General Data Protection Regulations (GDPR), that a TUEC does not require knowledge of the identity of the athlete or their other personal information to be able to perform this duty. Redacting this information also adds extra robustness to the TUE review process as it removes any perceived bias towards the athlete.

**Recommendation:** Include an additional article or comment within article 9 stating that ADOs must provide their TUECs with redacted applications (application form and supporting medical documents) to ensure that athletes remain unidentifiable.

## ANNEX 1: Code Article 4.4 Flow-Chart (2)

### Conseil supérieur des sports

Matheo TRIKI, Sportif Rugby (Espagne)  
WADA - Others

SUBMITTED

- Code Changes: Code Article 4.4.2

There is a need for more clarity on who an athlete's NADO is for the purposes of applying for a TUE: for athletes who are not International-Level Athletes.

- Definitions: The TUE definition was clarified.

- Obtaining a TUE

A restructuring of 4.1- 4.3 was undertaken to make it clear that athletes must apply for and obtain a TUE before using/possessing the substance or method unless a specific exception to apply retroactively applies.

- TUE Responsibilities of ADO

■

### International Paralympic Committee

James Sclater, Director (Germany)  
Other - Other (ex. Media, University, etc.)

SUBMITTED

Flowcharts. All charts might benefit from an additional reference to the applicable art