

INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTIONS (ISTUE)

Consultation - First consultation phase

Showing: All (91 Comments)

PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS (6)

International Cricket Council

SUBMITTED

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

If a National Sport Federation has the primary authority & responsibility to adopt and implement anti-doping rules, direct the collection of samples, the management of test results and the conduct of hearing at the national level, then the NSF should have the authority to make TUE decisions. Such decisions should be open for scrutiny from the IF, WADA and relevant NADO (where applicable).

Antidoping Switzerland

SUBMITTED

Ernst König, CEO (Switzerland)
NADO - NADO

General remarks: The main issues with the current ISTUE are the following:

- Missing resp. unclear definition and declaration by IFs on "International competition" and ILA. As a consequence neither athletes nor NGBs nor NADOs can clearly determine if an advance TUE is required or a retroactive TUE is possible (ISTUE 4.3 c).
- Lower Level Athletes face challenges obtaining a TUE when they are selected for Int. competitions on short notice (and therefore need an advance TUE on very short notice)
- New approach to be considered (not further elaborated below): Junior athletes up to their 18th birthday may apply for retroactive TUE (ISTUE 4.3 c) unless they are declared ILA or NLA by their IF or NADO. The participation in an international competition does not qualify for ILA for athletes under age 18.

Anti-Doping Authority Netherlands

SUBMITTED

Olivier de Hon, Scientific Manager (Netherlands)
NADO - NADO

On behalf of the four Dutch stakeholders, being the Ministry (Health, Welfare and Sports), the NOC (NOC*NSF), the Athlete's Committee, and the NADO (Dopingautoriteit):

In practice, many IFs still do not clearly publish their rules regarding TUEs on their website. We recommend to tighten the rules in this regard to enforce compliance. This can be done in the Code, but should certainly be addressed in the Standard.

Canadian Centre for Ethics in Sport

SUBMITTED

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

As a general comment for the final version of this Standard, CCES recommends providing hyperlinks to references within the Code, Annexes and other Articles within the Standard.

As a general comment to this Standard, CCES recommends using "their" in place of "his/her" to comply with gender

inclusivity norms.

Institute of National Anti-Doping Organisations

SUBMITTED

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

The current TUE Standard needs to be amended to align itself with the provisions of the new draft of the Code so that it better recognises and provides for Recreational Athletes. It is recognised that the level of education of these athletes is lower and therefore it is not reasonable (for example) for athletes to be expected to know that they should keep a medical file in case of the need to apply for a TUE. Furthermore it is not reasonable to expect recreational athletes to understand the subtleties of some elements of the Prohibited List or for their doctors to realise that the TUE requirements apply in that patient's case. As a broad (part) cure-all to this 4.1 c should not be mandatory for these athletes - and certainly not in the case of specified substances. The obvious example would be a recreational athlete who has appropriately been prescribed terbutaline, and has used it according to "proper" medical practice, should be able to gain an exemption according to a properly considered but more lenient standard better tuned to that circumstance. It is likely, in fact, to be cleaner to have a separate section setting out the requirements for these athletes rather than weaving in additional provisions which will make the Standard more complex and especially for National and international level athletes who need to filter out irrelevant provisions. The new section would continue to appropriately limit the use of prohibited substances but would recognise precisely the reasons why these athletes should be differentiated and make some elements of the requirements more permissive. Generally speaking athletes are likely to accept a trade off which may open a slight window of opportunity to dope but ensure that recreational athletes not setting out to cheat and who, in effect, gain no advantage, are not penalised.

International Testing Agency

SUBMITTED

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

General comment: the ISTUE is a well written document. Daily TUE management difficulties generally arise more from ADAMS lack of capacities than from the regulations.

1.0 Introduction and Scope (1)

Freelance journalist

SUBMITTED

Karayi Mohan, Freelance journalist (India)
Other - Other (ex. Media, University, etc.)

Should a medical prescription suffice to use a banned drug? Or else, should an athlete get a TUE? What happens if the athlete has not got a TUE but has enough prescriptions, investigation reports and hospital records to prove that he/she took the medicine in question under medical advice/supervision? There is no clarity on the subject despite the provision of a TUE and procedures to get such TUEs. Hearing panels, at least in India, tend to view cases sympathetically if the athlete produces a prescription even for a long-term treatment. "I didn't know about a TUE or the requirement" would often be the argument of an athlete. That in many cases have been accepted by panels. Ideally, there has to be as clear statement about the differentiation between a TUE and a medical prescription so that panels are able to assess the importance of a TUE especially in instances where there is long-term use and, despite that, there is sometimes no mention of the medicine in the doping control form.

2.0 Code Provisions (2)

ISU

SUBMITTED

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

CODE 4.4 Therapeutic Use Exemption («TUEs»)

4.4.3.2 If the *National Anti-Doping Organization* considers that the *TUE* does not meet the criteria set out in the International Standard for Therapeutic Use Exemptions, **it has 21 days from such notification to refer the matter to WADA for review**. If the *National Anti-Doping Organization* refers the matter to *WADA* for review, the *TUE* granted by the International Federation remains valid for International-level *Competition* and *Out-of-Competition Testing* (**but is not valid for national-level *Competition***) pending *WADA's* decision. If the *National Anti-Doping Organization* does not refer the matter to *WADA* for review, the *TUE* granted by the International Federation **becomes valid for national-level *Competition* as well when the 21-day review deadline expires**.

ISU Question:

Could an athlete be considered as having committed an ADRV within the 21 days if he/she is competing at national competition and his/her testing result being reported as AAF?

4.4.9

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**.

ISU Proposal 1:

Why a properly submitted TUE would be denied when the fault lies to the organization not properly reviewing TUE; the athlete should not bear the fault of denied treatment when it is the organization fault

ISU Proposal 2:

What is reasonable time? Following the guideline, as for WADA review, is it 21 days?

Antidoping Switzerland

Ernst König, CEO (Switzerland)
NADO - NADO

SUBMITTED

4.4.3:

If an International Federation chooses to test an Athlete who is not an International-Level Athlete, it must recognize a TUE granted to that Athlete in advance or retroactively (ISTUE 4.3 c) by their National Anti-Doping Organization and according to the rules of the National Anti-Doping Organization of the Athlete.

4.4.5:

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 must permit him or her to apply for a retroactive TUE.

3.0 Definitions and Interpretation

3.1 (2)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

Drafting Point: 2021 Code instead of 2015 Code.

International Paralympic Committee

SUBMITTED

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

It would be beneficial for Retroactive TUE to be defined in section 3.1. There is a lot of confusion as to what a retroactive TUE is (and is not), and when it may appropriately be applied for.

3.3 (1)**Canadian Centre for Ethics in Sport**

SUBMITTED

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

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

3.4 (1)**NADA**

SUBMITTED

Regine Reiser, Result Management (Deutschland)
NADO - NADO

Please define the terms shall, should, may, can as it is done in the Draft ISL

PART TWO: STANDARDS and Process FOR GRANTING TUEs (4)**China Anti-Doping Agency**

SUBMITTED

Zhaoqian LUAN, . (China)
Sport - Other

1. Glucocorticoids was removed during the consultation phase of the 2017 International Standard for TUEs. It is recommended to add it back to the revision to address confusion faced with the anti-doping organizations, or specify it explicitly in the new International Standard for Results Management and Hearings.

Commonwealth Games Federation Medical Commission

SUBMITTED

Michele Verroken, Anti-Doping Administrator (UK)
Sport - Other

5.0 TUE responsibilities of ADOs

It is not sufficient to designate athletes as 'international level' and 'national level' without allocating responsibility for making this designation. Has WADA really got time to arbitrate the choice of NADO to process TUEs? International Federations are better placed to decide if an athlete is international level, Any athlete participating in a Major Event must be classes as an international athlete. An example of a NADO determining a young athlete as a national level athlete who should obtain a retrospective TUE almost cost the athlete a medal at a Major Games, Entering an event under a MEO jurisdiction must qualify for applying for a TUE in advance, even from the MEO!

Proposed TUE System Reforms

There appears to have been an erosion of confidence in the TUE system over the last two years. Critics of the system perceive TUEs to be easily misused and offer athletes who obtain them an avenue for gaining a perceived 'legal' advantage over their competition.

However, it is our opinion that the fundamental principles of the TUE system are sound and that the leak of athlete TUE certificates in 2016 showed that there is limited evidence of misuse or contentious applications to warrant the need for wholesale reform of the system. Instead, we view this consultation process as an opportunity to propose a series of subtle reforms that will strengthen confidence in the system.

Enhanced Oversight

We are of the view that a formal framework for the auditing of ADO TUE programmes should be established to expand on the monitoring of ADO TUEC decisions that the WADA Medical Department already conducts. The aim of such auditing and site visits would be to further scrutinise and improve key components of ADO TUE programmes, namely: i. ADO compliance with the ISTUE; ii. the quality of evidence that supports applications; and iii. the outcome of applications (that is, TUEC decision-making).

Recommendation: Expand on current WADA monitoring activities by establishing a formal framework for the auditing of ADO TUE programmes.

Enhanced Transparency

There has been much debate regarding publicly disclosing athlete TUE data. We disagree with moving in this direction as medical confidentiality is of paramount importance to the integrity of the TUE process. However, ADOs could publish annual TUE statistics which includes key metrics of their TUE programme without jeopardising athlete anonymity. Publishing such statistics may improve the wider sporting communities understanding in relation to the prevalence of TUEs across nations and sports, and the types of substances and medical conditions that TUEs are granted for. Monitoring trends over time would also be a useful way to identify policy areas that require review.

Recommendation: ADOs should publish annual statistics regarding agreed key TUE metrics on their website.

Investment in Philosophical Research

One of the limitations that is thought to exist within the current TUE system is that ADOs do not know what the exact intentions of athletes are when they apply for a TUE. It is taken in good faith that athletes require the use of a prohibited medication because they have a legitimate medical condition. For this reason, some critics perceive the TUE system to be open to misuse by athletes who intend to gain a perceived 'legal' advantage over their competition by using a prohibited substance when: i. they have limited therapeutic need to do so (that is, the application is fabricated by the doctor or athlete); or ii. they have a legitimate therapeutic need but use supra-therapeutic doses once they obtain the TUE; or iii. they have a legitimate therapeutic need but use of the medication in any dosage will provide a potential advantage beyond returning the athlete to their 'normal' state of health.

We believe that a global philosophical research study should be commissioned to investigate the intentions (capability, opportunity, and motives) of athletes, coaches and doctors towards the TUE system in order to help inform future developments in TUE policy.

Recommendation: Commission a global research study to investigate the intentions (capability, opportunity, and

motives) of athletes, doctors, and coaches towards the TUE system.

Initiatives to Continually Improve the Knowledge of TUEC Members

We view the TUEC Symposium and medical guidelines created by the WADA TUE Expert Group as excellent initiatives in raising standards of consistency amongst TUECs. However, we feel that the TUEC community would benefit from more frequent interaction to continue to improve the knowledge of the membership.

This could be achieved through the introduction of a newsletter circulated every six months to TUEC members 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).

Recommendation: Consider new initiatives such as a newsletter to continually improve the knowledge of TUEC members.

Institute of National Anti-Doping Organisations

SUBMITTED

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

4.1 c Should not apply to Recreational level athletes who are unlikely to be aware of this and whose doctors may well have appropriately prescribed a prohibited medication (from a good medical practice perspective) but were unaware of the applicability of this provision to the patient in question. Again - suggest a new section for recreational athletes rather than complicating the existing text.

4.0 Obtaining a TUE (10)

China Anti-Doping Agency

SUBMITTED

Zhaoqian LUAN, . (China)
Sport - Other

Article 4.3 It is recommended to revise the wording to further clarify that this Article is a standard to agree to **accept** the application for a retroactive TUE but not a standard to **approve** it. Besides, the circumstances of 4.3(d) need to be illustrated with examples.

Antidoping Switzerland

SUBMITTED

Ernst König, CEO (Switzerland)
NADO - NADO

4.3. b): It would be useful to have additional guidelines as well as examples for this article as it is unclear what "exceptional" circumstances are.

NADA

SUBMITTED

Regine Reiser, Result Management (Deutschland)
NADO - NADO

4.0
What about off-label use of pharmaceutical products? Shall TUEs be possible for substances that are used off-label?

What about dosages that exceed the officially authorized dosages for a particular substance? Shall TUEs be possible for non-authorized dosages?

4.4.2 - 4.4.4

Recognition of TUEs

NADA Germany continuously receives TUE approvals that are granted by other ADOs (e.g. IFs, NADOs) for German athletes or for athletes who become members of German teams or play in German leagues. We frequently observe that the corresponding medical documentation for these TUE applications does not meet the criteria set out in Article 6.2 ISTUE or the criteria set out in WADA's Medical Information to Support the Decisions of TUECs. There are TUEs, which are granted based on incomplete medical histories or granted without diagnostic confirmation.

In addition, ADOs, especially IFs and NADOs, do not have equal rights in the recognition process. Due to these experiences and our aims to achieve comparable standards in granting TUEs and thus to protect clean athletes, we recommend to revise the entire TUE recognition process.

Our proposal:

'An Athlete who is not an International-Level Athlete should apply to his or her National Anti-Doping Organization for a TUE. An Athlete who is an International-Level Athlete should apply to his or her International Federation. An Athlete who is not an International-Level Athlete but who will take part in international competitions, e.g. non-testing pool athletes, should apply to his or her International Federation for a TUE.

Each ADO should recognize TUEs granted by other ADOs only, if these TUEs meet the criteria set out in the International Standard for Therapeutic Use Exemptions (Articles 4.1, 6.2.)'

See also comments to Articles 5.5 and 7.0 ISTUE.

Anti Doping Denmark

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

SUBMITTED

ISTUE article 5.4:

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 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" or "Recreational athletes".

Article 5.4 demands that and 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.

RUSADA

Pavel Khorkin, Senior Specialist of Educational Programs Department (Russia)
NADO - NADO

SUBMITTED

The criteria for granting retroactive TUEs, may not be the reasons for refusals of issuing TUEs to athletes who had or are having medical treatment. Delay in treatment of any disease in order to comply with the procedures, even for a short period which TUE Committee needs for considering applications, is unacceptable.

UK Anti-Doping

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

SUBMITTED

Article 4.3d Comments

Article 4.3d outlines that an athlete is permitted to apply for a retroactive TUE if there is agreement between WADA and the Anti-Doping Organisation (ADO) that a retroactive TUE can be granted on the grounds of fairness. The 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 TUE was not applied for in advance. This consultation with WADA must occur before the TUEC of the ADO can determine if the application fulfils the conditions for granting a TUE outlined in article 4.1.

To be able to provide WADA with the medical documentation, the ADO has already commenced the TUE process. Therefore, it would seem logical for the ADO TUEC to review the medical evidence to determine if the application first fulfils the conditions for granting a TUE prior to contacting WADA to determine if the TUE can be granted retroactively on the grounds of fairness. If the medical evidence does not fulfil article 4.1, then the application should be rejected by the ADO at this stage in the proceedings. If the medical evidence does fulfil article 4.1, then the full case file should be sent to the WADA Medical and Legal teams for assessment. In this scenario, the athlete would be only notified of the outcome of their application following the WADA review.

Recommendation: Clarify the process that ADOs should follow for a retroactive application to be considered on the grounds of fairness. We recommend that applications are reviewed against article 4.1 prior to article 4.3d. Suggested addition:

Comment: ADOs should first review such an application against article 4.1 prior to contacting WADA to determine whether a retroactive TUE can be granted on the grounds of fairness.

Agence française de lutte contre le dopage

Adeline Molina, RAQ (France)
NADO - NADO

SUBMITTED

4.3 bComment: We suggest to specify that the exceptional nature of the circumstances should be assessed by the ADO who receives the TUE request rather than by the TUEC.

4.3 dComment: This article suggests that there may be other reasons to grant a retroactive TUE than an emergency treatment (a), exceptional circumstances (b) or applicable rules as defined under c). The cases covered by d) are not clear. Therefore, we suggest either clarifying or deleting this article entirely. (To be consistent, the check box "Other" on the TUE form should be deleted.)

Canadian Centre for Ethics in Sport

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

SUBMITTED

In the Comment to Article 4.3.d) add an additional note clarifying that that Article 4.3.d) requires the ADO to request permission from WADA.

International Testing Agency

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

SUBMITTED

In relation to Art. 4.3(d):

The concept of "fairness" has proven to be difficult to assess and apply.

This has caused practical difficulties and could lead to undue pressure on the TUEC. TUEC members usually possess a medical expertise and do not necessarily have the legal skills required to make such an assessment.

International Paralympic Committee

James Sclater, Director (Germany)

Other - Other (ex. Media, University, etc.)

SUBMITTED

4.3.c- Clauses for retroactive TUE would benefit from more clarity.

4.3.d- The fairness clause is very vague and ADOs would benefit from more advice on the application of such clause. This might either be done through a comment or a reference to a Guideline, but it seems imperative that such reference is provided in the IS TUE (because of its 'mandatory' nature)

4.1 (7)

Department of Health - National Integrity of Sport Unit

Luke Janeczko, Policy Officer (Australia)

Public Authorities - Government

SUBMITTED

Given the importance placed on making a diagnosis by the WADA TUE Expert Group (and all other TUE Committees) Australia proposes an amendment be made to section 4.1 of the International Standard for Therapeutic Use Exemptions (ISTUE) to insert the following criteria.

4.1 a. The athlete has a confirmed diagnosis of a medical condition

b. The Athlete would experience a significant impairment to health if the

Prohibited Substance or Prohibited Method were to be withheld from the treatment of this condition.

NADA

Regine Reiser, Result Management (Deutschland)

NADO - NADO

SUBMITTED

4.1

There are methods (e.g. blood plasma donation with reintroduction of red blood cells to the donor) and

substances (e.g. LHRH in functional tests of the pituitary gland, S0. substances when athletes take part in clinical trials) which are prohibited but do not meet the TUE criteria a.-d.

Our proposal is to add new criteria:

'e. The Prohibited Substance or Prohibited Method is needed for diagnostic reasons.

f. The use of the Prohibited Substance or Prohibited Method is necessary for humanitarian reasons.'

See also proposed changes in Article 6.2.

4.1.b

How is the Athlete's normal state of health defined?

Proposal: Add 'individual': '...to the Athlete's individual normal state of health...'

Comment to 4.1

Full stop at the end of the sentence and modification: '...,i.e., if the athlete has demonstrated by...'

Always refer to both, 'TUE Guidelines' and 'TUE Physician Guidelines Medical Information to Support the Decisions of TUECs'.

RUSADA

Pavel Khorkin, Senior Specialist of Educational Programs Department (Russia)
NADO - NADO

SUBMITTED

In International Standard for Therapeutic Use Exemptions, the focus is on procedural issues. The practical part (the criteria for being granted TUE) is covered to a small extent. The criteria are extremely judgmental, vague and can cover a broad range of conditions.

For this reason, at the very least, criteria for being granted TUEs must be described in detail. This is also relevant because WADA recommendations for supporting decisions by TUE Committee do not cover all the diseases.

Agence française de lutte contre le dopage

Adeline Molina, RAQ (France)
NADO - NADO

SUBMITTED

UK Anti-Doping

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

SUBMITTED

Article 4.1b Comments

It is difficult to objectively assess the extent of enhancement that certain prohibited substances may have on performance when they are used in a therapeutic context to restore health. This means that TUEC decisions related to article 4.1b are often judgement calls based on clinical experience rather than supported by peer-reviewed studies.

There are some substances which are widely accepted to enhance performance beyond a return to 'normal' health; examples include the use of testosterone replacement therapy to treat low-normal testosterone levels and the use of beta-blockers in target sports to treat cardiovascular conditions. In contrast, the additional performance enhancement potential of systemic glucocorticoids close to or during competition to treat an

acute medical condition (such as an exacerbation of asthma) or the use of stimulant medication to treat a chronic medical condition (such as attention deficit hyperactivity disorder) are more controversial to assess (1).

Such judgements are further complicated depending on the athlete's sport – that is, a substance may not have the same impact on performance when assessing the demands of different sports. For example, it is unclear whether a request from a cyclist to use a short course of oral prednisolone to treat an exacerbation of asthma close to or during a competition should be considered differently to a curling competitor in the same scenario.

We feel that guidance from the WADA Medical Department and List Expert Group on how to effectively assess glucocorticoid and stimulant applications against 4.1b would be beneficial in terms of improving the consistency of how this criterion is applied amongst TUE review panels.

Recommendation: Provide further guidance on how TUEC review panels should apply criterion 4.1b and whether the substance or sport should affect how this criterion is applied.

References

Reardon, C.L., and Factor, R.M. (2016). Considerations in the Use of Stimulants in Sport. *Sports Med*, **46**, 611-617.

Article 4.1d Comments

There are few medical scenarios where a TUEC would consider using article 4.1d to reject an application. Scenarios may include: i. the need for testosterone replacement therapy to counteract the suppression of the hypothalamic-pituitary-gonadal axis because of anabolic androgenic steroid (AAS) use; ii. the use of tamoxifen to treat gynaecomastia following AAS use; and iii. the use of methadone to treat an opiate addiction. Even in such scenarios, there is no way for a TUEC to determine whether an application meets 4.1d unless an athlete has already received an anti-doping rule violation (ADRV) or has a known drug dependency issue requiring anti-addictive medication. In reality, TUECs grant or reject applications in accordance with three (article 4.1a-c) rather than four criteria making the use of 4.1d redundant.

Article 4.1d also appears to be in conflict with the World Anti-Doping Code since an athlete should only be penalised once for committing an ADRV. In theory, a sanctioned athlete could face an additional period of ineligibility if a TUE request is rejected on the grounds of 4.1d.

Nevertheless, we acknowledge that there is a moral counterargument to deleting 4.1d – that is, 4.1d conveys a clear deterrence message that previous or current dopers will find it difficult to obtain a TUE and compete in sport whilst doping related health complications persist. We also appreciate that the appearance of this criterion in previous versions of the ISTUE has not proved to be problematic. However, it is our opinion that if a TUE decision was contested based on 4.1d it would not stand up to legal scrutiny. On balance, we remain of the view that 4.1d should be deleted.

Recommendation: Consider deleting article 4.1d. Suggested deletion:

d. The necessity for the *Use of the Prohibited Substance or Prohibited Method* is not a consequence, wholly or in part, of the prior *Use* (without a *TUE*) of a substance or method which was prohibited at the time of such *Use*.

Canadian Centre for Ethics in Sport

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

SUBMITTED

In Article 4.1.c) clarify that athletes have the right to use a prohibited medication if there are no alternatives and/or if non-prohibited alternatives have been trialed and failed. Suggested rewording is as follows: "Non-prohibited alternatives are ineffective and/or there is no reasonable Therapeutic alternative to the use of the

prohibited substance or prohibited method.”

Institute of National Anti-Doping Organisations

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

SUBMITTED

4.1 c Should not apply to Recreational level athletes who are unlikely to be aware of this and whose doctors may well have appropriately prescribed a prohibited medication (from a good medical practice perspective) but were unaware of the applicability of this provision to the patient in question. Again - suggest a new section for recreational athletes rather than complicating the existing text.

4.3 c The comment is not applicable to recreational level athletes and again suggests that they should be dealt with in a separate section with its own provisions.

5.0 TUE Responsibilities of Anti-Doping Organizations (2)

UK Anti-Doping

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

SUBMITTED

New Proposal: Liability of TUECs

We have observed circumstances where the pressure on the athlete to be fit to compete within a short timeframe has led to requests to use treatments which are either outside of published medical guidelines or are not advocated by the TUEC to be in the best long-term interest of the athlete.

Whilst it is not the responsibility of the TUEC to offer medical guidance to the athlete applying for a TUE, TUEC members can feel conflicted in their duties when reviewing such applications. We write a “TUEC Comment” directly on the TUE certificate provided to athletes in situations where the application fulfils the conditions for granting a TUE but the UKAD TUEC are uncomfortable with the proposed treatment plan.

Recommendation: Include a clause within article 5 which confirms that TUEC members have no medical responsibility to the athlete applying for a TUE and that the TUEC carry no liability if they grant a TUE for a treatment that subsequently has a detrimental impact on the athlete’s health.

New Proposal: Remuneration for TUEC Members

At present, there is no requirement for ADOs to provide financial compensation to TUEC members for their involvement in reviewing applications. UKAD pays each TUEC member a nominal per application fee. Whilst we acknowledge that TUEC members do not offer their services to ADOs for financial reasons, this remuneration formalises the arrangement between the two parties and adds an element of professionalism. This would also achieve parity with Athlete Biological Passport experts.

Recommendation: ADOs should be encouraged to provide their TUEC members with a nominal fee for the review of each application.

New Proposal: TUE Monitoring

There is no provision in the ISTUE to minimise the risk of medication misuse once a TUE has been granted. This is despite treatment monitoring being referred to in specific WADA medical information documents to support TUEC decisions. Although medication misuse once a TUE has been granted cannot be eliminated, adding an article to the ISTUE would help to remind ADOs that, where practicable, the monitoring of athlete substance use should be occurring. This is particularly important when monitoring long-term TUEs and in cases where the permitted use of a prohibited substance or method, if overused, may lead to an enhancement of performance other than to return an athlete to a state of 'normal' health.

We propose that wording similar to the 2011 IAAF Anti-Doping Regulations should be used in the ISTUE to increase the robustness of the TUE system: "that it is possible without undue difficulty to monitor or control the dose, frequency, method of administration or other aspect of the use of a Prohibited Substance or Prohibited Method that may otherwise permit an enhancement other than a return to a state of normal health."

The ADO responsible for granting the TUE should also be the primary organisation responsible for monitoring the TUE throughout the exemption period. In such cases that an athlete is no longer considered to be of International standard, then the IF can pass the responsibility of monitoring the TUE to the athlete's NADO.

Recommendation: Add an additional article to article 5 outlining that treatment monitoring is a responsibility of Anti-Doping Organisations.

Suggested addition:

Monitor, where applicable and without undue difficulty, the dose, frequency and method of administration of the Prohibited Substance or Prohibited Method for which a TUE has been granted. Any conditions imposed on the TUE during the exemption period should also be monitored to ensure athlete compliance.

Comment: This may mean that the ADO will require Athletes to submit medical evidence (e.g. review letters, blood test results, etc.) during the exemption period to maintain the validity of the TUE. The ADO responsible for granting the TUE should assume the responsibility of conducting such treatment monitoring. In such cases that an athlete is no longer considered to be of International standard, then the IF can pass the responsibility of monitoring the TUE to the athlete's NADO.

Institute of National Anti-Doping Organisations

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

SUBMITTED

TUEs properly issued by an ADO should retain their validity until such time as they are examined and rejected (with good cause) by another ADO. It is wrong for an athlete generally but particularly if, for example, they are a late replacement into a team or event, to by definition have no TUE. Sometimes this involves expensive travel and other costs which should not have to be borne in a situation where no valid TUE exists and they are "in limbo". While occasionally there may be a legitimate reason for not accepting a TUE this should not be the default situation and athletes should be entitled to participate on the understanding that the relevant TUEC has issued the TUE properly.

5.1 (2)

Organizacion Nacional Antidopaje de Uruguay

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

SUBMITTED

On the occasion of the recommendation, the criterion of being able to prove clearly the independent intention with a national athlete to prove the use of the prohibited substance as an authorized drug should be established very rarely. To establish a very strict time and respect the same in terms of the deadline to analyze and provide a sustainable response in the appeal of a TUE between: FI and the NADO or between; the WADA and the NADO

International Paralympic Committee

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

5.1- The comment sections refers to Code art. 4.4.2 in which WADA will decide as to which ADO should deal with a TUE application of an athlete who is not International Level Athlete (ILA). There are numerous occasions why, for different reasons, athletes are not on a national TUE list nor identified as ILA. To our knowledge, WADA systematically ruled that the IF should deal with the TUE application if the athlete competes internationally. If this is the standard practice, it is preferred that the IS TUE is clear on that subject (and thus in such cases, IF to deal with TUE). This is much preferred over the proposed application of retroactive TUE as suggested in the comment to art. 5.1.

The above also seems in line with art. 5.7 and thus this article should be amended accordingly if so required.

5.2 (6)**ISU**

SUBMITTED

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

ISTUE 5.2

b. In order to ensure a level of independence of decisions, at least a majority of the members of a TUEC should have no **political responsibility** in the *Anti-Doping Organization* that appoints them. All members of the TUEC must sign a conflict of interest and confidentiality declaration.

ISU Comments: The meaning of the words “political responsibility” as used in this paragraph should be clarified.

Department of Health - National Integrity of Sport Unit

SUBMITTED

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

Section 5.2 of the (ISTUE) states that the TUE Committee should be composed of a minimum of three physicians. It does not specify how many TUE Committee members should review each TUE application. There is always likely to be some speculation about the integrity of the process if only one TUE Committee member reviews individual applications. Although it may be difficult for smaller and less resourced TUE Committees, the ISTUE should require an applications to be assessed by more than one physician.

UK Anti-Doping

SUBMITTED

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

Article 5.2 Comment

Article 5.2 outlines how a TUEC should be constituted and act. However, it does not state whether a TUEC can grant a TUE if they fail to reach a unanimous decision (for example, two members approve, one rejects). UKAD uses a panel of three TUEC members and unless a decision is unanimous to approve, the review panel reject the application. The athlete is then given the opportunity to appeal the decision and submit further evidence which is considered by an appeals panel formed of three TUEC members that were not part of the original panel.

We believe that the requirement for unanimity is an important element of our review process which ensures confidence in the final decision. It also reduces any external perceptions of doubt over the decision to grant an athlete with a TUE.

Recommendation:

Add an additional sentence to article 5.2 to establish that there must be unanimity amongst a TUEC Review Panel for a TUE to be granted.

Suggested addition:

5.2... Regardless of the size of a TUE Review Panel, a TUEC should only grant a TUE if the decision is unanimous.

Article 5.2a Comment

Article 5.2a goes on to insist that at least one TUEC member shall have experience in the care and treatment of athletes with impairments when reviewing applications involving such athletes. In our experience, having a physician with such experience is desirable, but should not be a mandatory requirement if an expert with in-depth knowledge of the specific medical condition pertaining to the application is on the review panel when the application is not directly relevant to the athlete's impairment. For example, it should not be mandatory for a TUEC review panel to include a physician with experience of treating athletes with impairments, if the application relates to the use of insulin to treat type 1 diabetes. In this example, it would be more appropriate to include an endocrinologist on the review panel.

Recommendation:

Reword the final sentence of article 5.2a to reflect that having a panel member who has experience in treating the specific medical condition (e.g. a specialist) is as important as having a physician with experience in the care and treatment of athletes with impairments when the application is not directly relevant to the athlete's impairment.

Suggested addition:

5.2a... In cases involving *Athletes* with impairments, at least one TUEC member shall possess general experience in the care and treatment of *Athletes* with impairments, possess specific experience in relation to the *Athlete's* particular impairment(s), or have in-depth knowledge of the specific medical condition pertaining to the application.

Comment: The type of physician required to be on a review panel for applications involving *Athletes* with impairments should be decided on a case-by-case basis dependent on the medical condition.

NADA Austria

Alexander Sammer, Head of Legal (Austria)
NADO - NADO

SUBMITTED

According to the proposed change of responsibilities (see NADA Austria's comments on the WADC) there is no need for International Federations and MEO to be informed on TUEs since they shall not be involved in any part of doping control at all.

The current provision that MEO may "outsource" the TUEC to a third party must be changed. We are dealing with highly sensitive health data, so no third party should have access to it. There is no need for MEO at all to know whether an athlete needs a TUE or not. This is solely the responsibility of the responsible NADO and an appeal body (eg. WADA).

Furthermore, it is questionable why every ADO with testing authority has to have access to the TUE-decision (Article 9.2). An international athlete is competing all around the world. Why must every ADO who is responsible for testing at events have access to his medical data? NADA Austria suggests that medical data is only available if there is a specific request (e.g. if there is a ATF or AAF).

According to ISCCS Article 7.2.4. a Signatory may appoint a third party to carry out anti-doping activities in the case of non-compliance, which includes the TUE-process.

According to ICSSC Article 8.3 WADA may cooperate with other relevant bodies in promoting full code compliance by signatories (eg. UNESCO, Council of Europa any other Intergovernmental organisations), which includes the TUE-process.

To summarize: In the current system an athlete who needs a medical treatment has to accept that his TUE-application is sent to persons at (1) NADO, (2) WADA, (3) International Federation (4) every relevant ADO with Testing Authority and, if applicable, (5) MEO and/or the third party entitled by MEO, (6) an appointed third party in the case of non-compliance (ISCCS Article 7.2.4) and (7) other relevant bodies (ICSSC Article 8.3) . If the athlete does not accept this, he is not allowed to compete anymore which means lifetime exclusion if he has a chronic illness / injury. (1) and (2) should be more than enough.

International Testing Agency

SUBMITTED

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

In relation to Comment to Art. 5.2, consider replacing "SportAccord" with "the International Testing Agency"
In relation to Art 5.2(b), consider better defining the term "political responsibility" which could be interpreted in different (wider or narrower) ways.

International Paralympic Committee

SUBMITTED

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

5.2.a- All members of a TUEC that processes a TUE for an athlete with an impairment should meet the provisions of art. 5.2.a

Related to 5.2.a, and likely to be expanded further upon as part of the IPC submission to the WADC review: WADC art. 4.4.7 and 4.4.8 state that TUE decisions can be appealed exclusively to CAS. CAS however adopts a principle of 'de novo' ruling. This effectively applies that a final TUE decision might be taken by CAS arbitrators. These are unlikely to meet the criteria set forth under IS TUE 5.2.a. From that perspective, a CAS panel on TUE matters should therefore only be able to defer a TUE application back to an ADO for an independent assessment by another panel in case they uphold the appeal.

5.2.b- It might be recommended to have a more clear definition of 'political responsibility'. E.g. IPC Medical Committee members are appointed by the IPC GB to advise this GB on all matters related to athlete health and well-being. In addition, they act as the TUEC.

5.4 (3)

World DanceSport Federation

SUBMITTED

Ineke Crijns, Chair anti-doping commission (Nederland)
Sport - IF – Other

Perhaps this is a more general comment, but to the provided information only in English or French may be difficult and a small group to choose from. Because ADAMS is for instance in another language, it invites you to add the information in that language, which will be translated for someone else who looks into ADAMS using a different language.

NADA

SUBMITTED

Regine Reiser, Result Management (Deutschland)
NADO - NADO

5.4

Define 'promptly', e.g. 14 working days, because it is important for the mutual recognition of TUEs (Each National Anti-Doping Organization, 'International Federation and Major Event Organization must promptly report (in English or French) all decisions of its TUEC (...) through ADAMS.')

5.4.a.

Due to practical therapeutic reasons, the dosage for insulins should be variable on the approval. All other medications should at least be granted up to a maximum dosage that should be stated on the approval/in ADAMS.

An exact start date and a stop date should state the duration.

If an approval is modified, the new approval should contain a notice that the old approval is invalid now.

5.4.b

For reasons of the protection of personal medical data according to national data protection regulations, NADA Germany does not upload any medical information into ADAMS.

NADA Austria

SUBMITTED

Alexander Sammer, Head of Legal (Austria)
NADO - NADO

Since there is the principle of mutual recognition it is questionable if there is a need for a mandatory translation of the relevant clinical information since it could be very costly. NADA Austria suggests that this provision is changed in a way that WADA has the right to ask for this translation in certain cases (e.g. when non-specified substances are involved, if the TUE was issued retroactively and there appear to be some irregularities, etc.)

5.5 (3)

Antidoping Switzerland

Ernst König, CEO (Switzerland)
NADO - NADO

SUBMITTED

Needs to be adjusted accordingly depending on changes in Part one 4.4.3.

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

5.5

In connection with our comments to Articles 2.0 and 7.0 we suggest the following modifications:

'When a National Anti-Doping Organization grants a TUE to an Athlete, it must warn him/her in writing that that TUE is valid at national level only and only in that particular country whose NADO has granted this TUE. When an International Federation or a Major Event Organization grants a TUE to an Athlete, it must warn him/her in writing that that TUE is valid at international level only in international competitions that fall under the responsibility of the International Federation or Major Event Organization that has granted the TUE.'

TUEs between any Anti-Doping Organizations should mutually be recognized according Article 7.0 ISTUE.

RUSADA

Pavel Khorkin, Senior Specialist of Educational Programs Department (Russia)
NADO - NADO

SUBMITTED

International Standard for Therapeutic Use Exemptions entails acceptance of its provisions (including by the criteria of obtaining permissions) by all anti-doping organizations, including international sport federations. In this regard, the provision on the requirement to obtain confirmations of TUEs issued by national anti-doping organizations, from international federations or major event organizers, is redundant. These obligations are burdensome for athletes. In any case, applications for TUE, medical data and decisions of TUE Committee are accessible through ADAMS.

5.6 (4)

China Anti-Doping Agency

Zhaoqian LUAN, . (China)
Sport - Other

SUBMITTED

Article 5.6 As far as we know, many signatories such as some IFs, have not observed the requirements of Articles 5.6.2 and 5.6.3 to post them in a conspicuous place on their websites.

Antidoping Switzerland

Ernst König, CEO (Switzerland)
NADO - NADO

SUBMITTED

In addition: define who is responsible for everything in between (nation tournaments, national competitions in other countries...)

RUSADA

Pavel Khorkin, Senior Specialist of Educational Programs Department (Russia)
NADO - NADO

SUBMITTED

International Standard for Therapeutic Use Exemptions entails acceptance of its provisions (including by the criteria of obtaining permissions) by all anti-doping organizations, including international sport federations. In this regard, the provision on the requirement to obtain confirmations of TUEs issued by national anti-doping organizations, from international federations or major event organizers, is redundant. These obligations are burdensome for athletes. In any case, applications for TUE, medical data and decisions of TUE Committee are accessible through ADAMS.

UK Anti-Doping

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

SUBMITTED

Article 5.6 Comment

Article 5.6 outlines that International Federations (IFs) and Major Event Organisations (MEOs) 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: 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 (2)

Antidoping Switzerland

Ernst König, CEO (Switzerland)
NADO - NADO

SUBMITTED

Article needs to be adjusted accordingly if new approach for recognition is proposed in Part one 4.4.3.

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

5.7

We propose to modify the first sentence: 'Any TUE that an Athlete has obtained from a National Anti-Doping Organization shall not be valid in other countries or at international level, if the Athlete becomes an International-Level Athlete or competes in an International Event unless and until the relevant International Federation or other NADO recognizes that TUE in accordance with Article 7.0.'

6.0 TUE Application Process (2)

Organizacion Nacional Antidopaje de Uruguay

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

SUBMITTED

Reveal the medical criteria especially for the granting of the AUTs for ADHD. More exhaustivos, more ordered and controls to croto term. Specifically assess correctly over time and demonstrate the need to scientifically monitor the time of use of the drug in question

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 6 stating that ADOs must provide their TUECs with redacted applications (application form and supporting medical documents) to ensure that athletes remain unidentifiable.

6.1 (4)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

6.1

When should athletes apply for TUEs for substances and methods that are prohibited at all times?

RUSADA

Pavel Khorkin, Senior Specialist of Educational Programs Department (Russia)
NADO - NADO

SUBMITTED

Including on Prohibited List of the category of substances prohibited in-competition, implies that athletes may use them, inter alia, during that period in order to enhance sport performance. In this regard, it would be logical to set specific timeframes for each class of this category of substances, specifying when athletes must submit applications for TUE (that is, the period from the last use to the competition period). This would optimize the working process of anti-doping organizations, and would remove the need for athletes and doctors to do additional unnecessary actions on preparing applications for TUE.

Institute of National Anti-Doping Organisations

SUBMITTED

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

The suggestion that 30 days is the norm and less than 30 days the exception is, frankly, nonsense. Even in the case of chronic conditions there are many cases where athletes are only elevated into the category of requiring TUEs in advance inside 30 days. More commonly TUEs are for urgent short term conditions where the 30 days does not apply. In other words to suggest that 30 days should be the norm when experience shows it is not, does not make sense and this should be made more realistic. Something like: Application should be made immediately the TUE becomes necessary. Failure to apply in a timely fashion may mean that an Exemption can not be considered and granted in time for an event (where that is applicable).

International Paralympic Committee

SUBMITTED

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

6.1- It is not entirely clear to me why a specific 30-day timeline applies for substances prohibited in-competition only, the general principle 'as soon as possible' should apply here as well.

6.2 (2)

NADA

SUBMITTED

Regine Reiser, Result Management (Deutschland)
NADO - NADO

6.2

According to proposed changes in Article 4.1 add:

'c. In case of the use of a Prohibited Substance or Prohibited Method a statement by a qualified physician, attesting the need for the Athlete to Use the Prohibited Substance or Prohibited Method in question for diagnostic or humanitarian reasons.'

Comment to 6.2(b)

The information submitted in relation to the diagnosis, treatment and duration of validity should be guided by the WADA documents titled 'Medical Information to Support the Decisions of TUECs'. Add: 'and TUE Guidelines'.

International Paralympic Committee

SUBMITTED

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

6.2.a- This clause seems to be covered by section 4 of the template application (p.24) although the term used there is 'medically appropriate' instead of 'for therapeutic reasons'. It is recommended to align the language.

6.4 (1)

Agence française de lutte contre le dopage

SUBMITTED

Adeline Molina, RAQ (France)
NADO - NADO

Comment: WADA publishes “Medical Information to Support the Decisions of TUECs” documents on its website to assist the TUECs in the review the TUE requests. Along the same lines, we recommend that WADA makes available to athletes, for each pathology (whenever possible), a list of medical examinations and/or laboratory evaluations (if applicable) needed when submitting a TUE application. This would contribute to the harmonization of the TUE review process among ADOs and increase equal treatment for athletes.

6.7 (4)

UK Anti-Doping

SUBMITTED

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

Article 6.7 Comment

Article 6.7 outlines that TUECs should make their decisions within twenty-one days of receipt of a complete application. We think that this timeframe is too long to expect an athlete to wait for a decision but appreciate that shortening the timeframe too much would not be feasible for some TUECs. As a result, we propose that TUECs should make their decisions within fourteen days of receipt of a complete application (unless exceptional circumstances apply).

Recommendation: Reduce the timeframe for TUEC decisions from twenty-one days to fourteen days (unless exceptional circumstances apply). If this is not possible, then add a comment to article 6.7 that sets out the expectation that a TUEC, in normal circumstances, should be able to review an application within fourteen days of receipt of a complete application.

Suggested addition:

Comment: The TUEC are expected, in normal circumstances, to review TUE requests within fourteen days of receipt of a complete application.

Agence française de lutte contre le dopage

SUBMITTED

Adeline Molina, RAQ (France)
NADO - NADO

Comment: We suggest moving the sentence below to section 5.0, *TUE responsibilities of Anti-Doping Organizations*: “Where a TUE application is made a reasonable time prior to an Event, the TUEC must use its best endeavors to issue its decision before the start of the Event.” We also suggest adding a note to the effect that it is the ADOs’ responsibility to inform the TUEC of the urgency of the request and to make sure the application can be reviewed in a timely manner.

Canadian Centre for Ethics in Sport

SUBMITTED

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

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

In Article 6.7 CCES 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...”

International Paralympic Committee

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

SUBMITTED

6.7- It might be worth clarifying if these are calendar days or working days.

6.8 (1)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

6.8.a.

Due to practical therapeutic reasons, the dosage for insulins should be variable on the approval. All other medications should at least be granted up to a maximum dosage that should be stated on the approval/in ADAMS.

An exact start date and a stop date should state the duration.

If an approval is modified, the new approval should contain a notice that the old approval is invalid now.

6.9 (2)

ISU

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

SUBMITTED

ISTUE 6.9 Each TUE will have a specified duration, as decided by the TUEC, at the end of which the TUE will expire automatically. If the Athlete needs to continue to Use the Prohibited Substance or Prohibited Method after the expiry date, he/she must submit an application for a new TUE **well in advance of that expiry date**, so that there is sufficient time for a decision to be made on the application before the expiry date.

ISU Comments:

What is the expectation of “well in advance” 2 months or 2 weeks ?

Please provide guidelines or clarify the period of time

International Paralympic Committee

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

SUBMITTED

6.9- It might be worth to address the restricted validity of the jurisdiction of TUEs issued by MEOs during Major Events in the comment section here as well.

6.12 (2)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

6.12

Define 'materially'.

Proposal: Athletes should apply for a new TUE in any cases of changes in the parameters given on the approval.

International Paralympic Committee

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

SUBMITTED

6.12- It might be worth expanding on the term 'materially different'.

There might be value to expand upon the eventual 'suspension' of a TUE in case of non-adherence to the provisions set for for the TUE approval (e.g. monitoring requirements for testosterone).

7.0 TUE Recognition Process (3)

Antidoping Switzerland

Ernst König, CEO (Switzerland)
NADO - NADO

SUBMITTED

Article needs to be adjusted accordingly if new approach for recognition is proposed in Part one 4.4.3.

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

7.0 TUE Recognition Process

In connection with our comments to Articles 2.0 and 5.5 we suggest the following modifications:

'TUEs must/should be mutually recognized between all ADOs when they are granted in accordance with Articles 4.1 and 6.2 ISTUE. Mutual recognition of TUEs is highly recommended to ease the burden for the athlete.

In order to check if a TUE requested for recognition is granted in accordance with Articles 4.1 and 6.2 ISTUE, each ADO may request (by athlete or ADO) the comprehensive medical documentation of the original TUE application. Additionally, any medical information according to WADA's Medical Information to Support the Decisions of TUECs may be requested if considered necessary.

If there is no reasonable doubt that a TUE of another ADO is granted according Articles 4.1 and 6.2 ISTUE, it must be recognized. If there is any doubt about the diagnosis or the therapy or any criteria described in Articles 4.1 or 6.2 ISTUE, the TUEC of the ADO, which is asked to recognize this TUE, shall decide whether this TUE is

recognized or whether the recognition is refused.

If the ADO's TUEC refuses the recognition of the TUE, the WADA TUEC must review the TUE and decide whether the TUE is valid and must be recognized by other ADOs or whether the TUE loses its validity everywhere.

Any information about decisions to recognize TUEs or to refuse requests for recognition should be communicated via ADAMS. Each decision not to recognize a TUE must include an explanation of the reason(s) for the non-recognition.'

WADA should have policies in place to inform all ADOs when there are ADOs that grant TUEs without compliance of Articles 4.1 and 6.2 ISTUE. Such TUEs do not fulfil the criteria for a recognition as set out in comment to Article 7.0.

Anti Doping Denmark

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

SUBMITTED

ISTUE Article 7 - TUE Recognition Process:

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, only WADA should have the authority to review and change TUEs that an ADO has issued in accordance with the ISTUE and has registered in ADAMS.

An IF or a Major Event Organizer cannot change a decision made by another ADO in accordance with article 8 of the Code, but must proceed in accordance with the rules of appeal. Why, then, should it have authority to review and change a TUE decision?

This fact 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 (5)

China Anti-Doping Agency

Zhaoqian LUAN, . (China)
Sport - Other

SUBMITTED

Article 7.1b The athlete whose application for a TUE has not been entered into the ADAMS shall submit all the materials as required when he applies for the recognition of the TUE granted by his NADO to the IF or MEO. Procedurally, it does not ease the burden on the athlete. Therefore it is recommended that WADA can effectively monitor the implementation of ISTUE by IF and MEO, and promote IF and MEO to automatically recognize the TUE decision granted by NADO.

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

7.1.a.

We recommend defining or explaining 'automatically' (automatic recognition).

UK Anti-Doping

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

SUBMITTED

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 Code article 4.4.3.1 – 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: Remove the concept of ADO automatic recognition of national-level TUEs.

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.

Institute of National Anti-Doping Organisations

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

SUBMITTED

TUEs properly issued by an ADO should retain their validity until such time as they are examined and rejected (with good cause) by another ADO. It is wrong for an athlete generally but particularly if, for example, they are a late replacement into a team or event, to by definition, have no TUE. Sometimes this involves expensive travel and other costs which should not have to be borne in a situation where no valid TUE exists and they are "in limbo". While occasionally there may be a legitimate reason for not accepting a TUE this should not be the default situation and athletes should be entitled to participate on the understanding that the relevant TUEC has issued the TUE properly.

International Testing Agency

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

SUBMITTED

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.

A solution would to apply automatic recognition for TUEs not appealed by WADA. This would be a “real” automatic recognition, without need for verification of the file.

8.0 Review of TUE Decisions by WADA

8.3 (1)

International Paralympic Committee

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

SUBMITTED

8.3- The appeal process for TUE decisions as a result of WADA review is not appropriate. WADA carefully chose the word ‘review’ instead of ‘appeal’ to not reverse IF decisions, but it does not set aside the argument that WADA is the higher authority that made the final decision on a TUE. In which case, it is this decision that should be subject to Appeal, not the IF one (with the IF sitting on the expenses with an appeal to CAS).

8.8 (1)

International Paralympic Committee

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

SUBMITTED

8.8- WADA should consider disclosing reference monetary values for costs incurred as a result of the review of TUE to avoid surprises by ADOs

9.0 Confidentiality of Information (1)

International Paralympic Committee

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

SUBMITTED

9.3- IPC is in full support of the clauses of this article. At the 2017 Helsinki TUE symposium an argument was made that TUE applications should be de-identified/redacted prior to being processed by a TUEC. Because all TUEC members are bound by confidentiality clauses (IS TUE 5.2.b), such de-identification seems only to add an administrative burden to the ADO without any compromise to the provisions of art. 9.3. For this reason, the IPC does not support a revision to de-identify/redact TUE applications prior to processing.

9.1 (1)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

9.1

Drafting Point: ‘...Privacy and_Personal...’ Remove line after ‘and’.

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

World DanceSport Federation

Ineke Crijns, Chair anti-doping commission (Nederland)
Sport - IF – Other

SUBMITTED

In addition to a flow chart, it would be useful to have the TUE application process in on one page as a listing. At this moment the document is hardly approachable for athletes of small IFs.

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

Annex 1: Code Article 4.4 Flow-Chart

Please adjust flow chart pursuant to changes in Articles 4.4 WADC and 2.0 ISTUE.

ANNEX 2: Template of TUE Application Form (3)

Commonwealth Games Federation Medical Commission

Michele Verroken, Anti-Doping Administrator (UK)
Sport - Other

SUBMITTED

the template could and should be adapted for a Major Event to allow the athlete to request recognition of an existing TUE. See CGF template.

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

3. Medication details:

We propose to add 'methods' in left column. 'Prohibited Substance(s) and Methods'

We propose to add 'volume' in column two: 'Dose or Volume'

Data protection issues:

The consent form (attachment to the TUE Application Form) must be strictly in line with the GDPR.

Due to the fact, that consent as "only" reliable and valid legal basis for processing of sensitive data is very controversial among the data protection authorities in Europe, we strongly recommend to review the consent form.

UK Anti-Doping

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

SUBMITTED

Section 6 of the template TUE application form (Annex 2) requires athletes to state their TUE history. In our experience, this is an unnecessary requirement as these details are often inaccurate (for example, the athlete has forgotten or ticks the wrong box). Furthermore, this section is not used by ADOs to screen an application since the athlete's TUE history can be found on ADAMS. It should be best practice for the TUEC to be sent any relevant TUE history from the ADO's own internal records or from ADAMS. As a result, the mandatory need for this information to be completed by athletes on an application form is unnecessary.

Recommendation: Remove subsection 6 requesting the athlete's TUE history from the template TUE application form.