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

Showing: All (265 Comments)

# Concept #1 – Clarify when a prospective TUE begins (22)

<b>UEFA</b> Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other	SUBMITTED
UEFA supports the development of this concept. Clarity on the rules is necessary to ensure u	iniformity.
Once a TUE is approved, there should be no issue that it is backdated to the date of application need to penalise an athlete who has commenced taking necessary medication, applied for a subsequently been tested (prior to its approval). It needs to be made clear though that compe- the TUE decision would need to be at the athlete's own risk. The TUE should not be approved medication began (because an athlete could always just wait until they're tested and then app	TUE and then eting whilst waiting for d from the date the
International Tennis Integrity Agency Nicole Sapstead, Senior Director, Anti-Doping (United Kingdom) Sport - Other	SUBMITTED
Backdating a TUE to the date of application would seem like a common sense interpretation viridiculous situation of someone being tested in the interim and having to seek a retroactive TU costs. Clearly any participation in this time would be at the player's risk.	
<b>Council of Europe</b> Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)	SUBMITTED
Supported And with the same concept it would be good to clarify when a TUE ends.	
<b>COCOM</b> Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO	SUBMITTED
La date d'entrée en vigueur de l'AUT devrait être la date de prise du médicament.	
Anti-Doping Agency of Serbia Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO	SUBMITTED
We support the ISTUE Drafting Team for a change the effective date as the date the application when the medication was prescribed.	ion was received or

Anti-Doping Sweden (ADSE) supports that it should be clarified when a prospective TUE begins so that athletes have the same preconditions. ADSE agrees with the current wording of ISTUE, that a prospective TUE should be valid from the day of the decision, as it is not a retroactive application. However, the risk of receiving a sanction during the application process should be low or non-existing given the athlete is approved a TUE. An athlete, and especially an athlete that is suffering from a medical condition, should not be withheld from a legitimate treatment and have a minimal risk of getting a sanction. Not without saying, that medical documentation and other supporting documentation must prove a diagnosis and an appropriate treatment. It is of importance that the ADO's have a continuous dialogue with the athlete and that progress is made in a reasonable time period. The possibility to get in touch with health care providers, and for them to have the time to help athletes, differs between countries, in between regions in countries and if you have health insurance, that must be considered.

# Organizacion Nacional Antidopaje de Uruguay

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

Satisfied. OK

# **Sport Integrity Australia**

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

We support the consideration of changes to the ISTUE to clarify when a prospective TUE should begin in the above circumstances and, more generally, whether any mechanism could be introduced to address the practical concerns while mitigating the risk of this issue.

The current effective date for Australian prospective TUEs is the date of approval by the TUE Committee, and on balance we recommend this option to the Drafting Team for the following reasons.

It is recognised that an effective TUE from the date of approval does create a 'gap' in coverage if an athlete has already commenced use of a prohibited substance prior to receiving approval for use. However, should the athlete return a positive test then they would be eligible to apply for a retroactive TUE as per section 4.1. of the current ISTUE.

This section is designed to address the circumstances giving rise to the 'gap' between use of a Prohibited Substance and granting of a TUE.

For example, an Athlete who requires an in Advance TUE due to a change in circumstance may rely on the exceptional circumstances outlined under Article 4.1 (such as 4.1(b) insufficient time for Athlete to submit or TUEC to consider their application) to obtain a retroactive TUE to cover the 'gap' if they are facing a possible violation.

If an Athlete transitions from a lower-level athlete (subject to the retroactive TUE regime) to a national level athlete (subject to the advance TUE regime) and they have been using a prescribed Prohibited Substance for a legitimate medical purpose, then they will need to apply for a TUE. They will most likely be continuing to use the Prohibited Substance prior to receiving the TUE approval.

The risk to the Athlete is the same for all Athletes not falling within the requirements for an in Advance TUE. That is, the potential for a violation to be recorded if the TUE is not approved by the TUEC.

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To avoid any doubt if would be useful to include a comment explaining the types of situations which could fall within exceptional circumstances. It would also be useful to distinguish between 'exceptional circumstances' arising due to medical circumstances v 'exceptional circumstances' caused by processes or other events.

If an alternative approach is taken, and a TUE is dated from the date of when the application was first received, this could have implications such as if the application is incomplete. As a result, there could be a considerable amount of time that the TUE is backdated once the required information is received.

NADA

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

NADA GER issues a prospective TUE with the date of the TUEC decision as the effective date. If the athlete has already started the treatment before that date on his/her own risk, our TUEC also decides about a retroactive TUE with the effective date being the start date of the treatment or the start date of the athlete's belonging to our testing pool (e.g. if substances are permantently used for chronic diseases).

This approach works very well for us. In order to reflect this approach in the ISTUE, we suggest to amend Article 4.1 (below the comments for this article) with the following: "An Anti-Doping Organization may grant a retroactive TUE in conjunction with a prospective TUE, if the athlete is using a medication for therapeutic reasons before the date of the TUEC decision. If an athlete is using the medication while the Therapeutic Use Exemption Committee (TUEC) is still deliberating, they do so at the risk of an anti-doping rule violation."

# NADA Austria

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

According to the **Concept #1** there should be a clear distinction between a retroactive TUE and a prospective TUE. Both TUE variants follow the same criteria, but there are different considerations to be made for the TUEC. In the scenario described, it would be best to grant a prospective TUE starting with the decision of the TUEC and granting a retroactive TUE starting with the date of first treatment. The easiest thing to clarify would be a comment to ISTUE 4.1.

# Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand) NADO - NADO

# We support the concept – consistency is fundamental.

Our preference is that in-advance (prospective) applications always commence on the date of approval as we always do. However we understand from discussions with other NADOs that this is not consistent globally.

It would be useful to have clearer provision in the ISTUE that ADOs could reference when advising athletes that they risk an ADRV if they compete before receiving the decision of the TUEC. We suggest this be included in the TUE form template as mandatory information alongside guidance that a TUE should not be backdated to the date of application or presecription.

We also consider that additional clarification is required around when Article 4.1(b) of the ISTUE (insufficient time) can be relied upon. We understand that some ADOs may rely upon this Article where a TUEC is slower in their decision making or doesn't have sufficient time to consider the TUE pre-competition.

We don't believe these constitute **exceptional circumstances** such as a last minute promotion into a team/event which results in the athlete needing a TUE in-advance.

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FINADA

Anna Simula, Pharmacist (Finland) NADO - NADO

This should be stated so clearly that everyone acts the same way. In our point of view this is clear, there is no need to assign the effective date back in time if the application is not a retroactive one.

# Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

For practical reasons, this should not be further clarified. It is logical to let a TUE start at the date of the TUEC decision, unless there are other reasons not to do so (such as with a retroactive TUE). The date of a TUEC decision is fixed, the date of receipt is changeable, because it happens a lot that an application is incomplete.

# Anti-Doping Norway

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

From our point of view, there should be no need to assign the effective date back in time. If the treatment is needed to start promptly, it is possible to apply retroactively according to ISTUE 4.1. a) or b). We always advise the athlete to wait until the decision before starting the treatment. We would like to see examples of circumstances where ISTUE 4.1 a) or b) would not provide the sufficient flexibility.

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

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

The CCES agrees with the need to provide further clarity around the start date for an approved TUE. Currently, the CCES uses the date a TUE application was approved by the TUEC as the start date for a prospective TUE, which, from a practical perspective, seems like the most logical start date. The CCES considers that Article 4.1 captures instances of prior use of the medication, and backdating the TUE start date may create more confusion and possibly more issues with respect to results management. Lastly, the CCES reiterates the process should be athlete-centered, taking into consideration medical conditions which may appear suddenly or which are chronic, existing well before an athlete is subject to TUE requirements. That said, the retroactive application process should cover (or should be expanded to at least consider) all of these possibilities, with appropriate remedies provided for.

Regardless of when the prospective TUE begins, we agree with updating Article 4.0 to provide additional clarity to ensure all ADOs implement this provision in the same manner.

### Japan Anti Doping Agency YUICHI NONOMURA, Result Management (??) NADO - NADO

Agree with this concept. To clarify when the Prospective TUE begins, we recommend to confirm the start date of administration.

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

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TUEs are the responsibility of the Athlete, however there is a significant complexity associated with processing TUEs under the ISTUE. Further, 21 days is allowed from the time of application to provide an Athlete with a TUE decision. USADA recommends that a prospective TUE begins on the date a complete TUE application is received by the ADO. This ensures that an athlete remains responsible for applying for a TUE in accordance with the rules and allows them to not be penalized by the TUE administrative process. Often times, it takes dialogue between the ADO and the athlete to ensure a complete TUE application is received. Avoiding the date an incomplete application was submitted avoids the possibility of an athlete purposely submitting an incomplete application in order to try to get an earlier approval date. Due to the allowance for retroactive TUEs under specific situations, and the fact that it may be very difficult to establish the date of first use of the medication, it does not make sense to back-date TUEs to the date the athlete first used (or was prescribed) a medication. Further, some medications may be prescribed, but prescriptions are not always filled on the date of purchase or first use may not always be clear.

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

SSI supports administrative simplification and the possibility of a prospective TUE with an "effective date" before the "decision date". So far, such situations could be in some cases covered with two separate TUEs, i.e. prospective TUE from the approval date and (depending on the situation) retrospective TUE (Art. 4.1 a or b). In addition to the period required by the TUEC for evaluation, the period from the start of use to the receipt of the application by the ADO should also be defined.

# **Anti Doping Danmark**

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

ADD agrees – a clarification on this would be good.

### **RUSADA**

Kristina Coburn, Compliance Manager (Russia) NADO - NADO

RUSADA agrees with the Drafting Team's proposal.

We would also like to consider eliminating the distinction between TUE and retroactive TUE. Our position is that the athlete's doctor should decide whether therapy should begin immediately or can be postponed based on the athlete's health status. The TUE is required in both circumstances, and as previously stated, the TUE application can be examined by TUEC for up to 21 days (including the moment when the treatment has been already started). Thus, the TUE can come in effect from the date when the positive TUEC decision is issued or have a retroactive effective date - the date of when that treatment began.

### **UK Anti-Doping**

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

We have no objections to this concept being developed further. In most instances, a prospective TUE should start on the date that the TUE decision is communicated to the athlete rather than necessarily the date of the TUEC decision (if the two dates are different). However, there are two scenarios that in our experience do not fit this approach: i. renewal applications – that is, when there is a small lapse between the expiry of a TUE and the granting of a new one for an ongoing medical condition; and ii. TUEC decisions that take an unreasonable amount of time (that is, greater than 14 days) to be reached once a complete application has been submitted. One solution to mitigate the risk for athletes in these two scenarios (if a standard start date is adopted for all prospective TUEs)

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could be to clarify that there are no consequences when Use has started during this "between" period if i. the TUE is ultimately approved; and ii. the athlete has submitted their application before being selected for Doping Control.

# RECOMMENDATIONS

1.

A prospective TUE should start on the date that the TUE decision is communicated to the athlete.

2.

ADOs should not pursue an Anti-Doping Rule Violation when therapeutic use of a prohibited substance or method has started before receipt of a TUE decision for a prospective TUE as long as: i. the TUE is ultimately granted; and ii. the athlete has submitted their prospective application before being selected for Doping Control.

# **International Testing Agency**

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

We agree that greater clarity should be brought on this point. We are aware of the practice of backdating the approval date to the start date of the treatment and whilst this approach is pragmatic, we acknowledge that it does circumvent the rules.

We wonder whether article 4.1 b) (insufficient time, opportunity, etc.) should be broken down (insufficient time vs urgent situations/exceptional circumstances) and those scenarios where athletes start treatment as soon as they consult their physicians and then file a TUE request should be funnel under a revised article 4.1 b). The obligation to submit a TUE application as soon as the treatment is prescribed would be a factor to take into consideration.

# Concept #2 – National-level Prioritization (23)

# **World Rugby**

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

We would agree with this proposal to prioritize certain substances.

# NZ Rugby

Rebecca Giordano, Senior Legal Counsel - Regulations & Compliance (New Zealand) Sport - Other

We support the proposal to amend ISTUE Article 4.1(c) to also allow NADOs to prioritize certain substances (in addition to certain sports or disciplines), by only requiring advance TUE applications for certain categories of prohibited substances.

# **UEFA**

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA does not support the development of this concept. The TUE system is already complicated enough for athletes. Furthermore, if you 'reduce down the importance' of some TUEs compared to others, you risk having a two-tier system in terms of what is prohibited.

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

This doesn't really apply to tennis but nevertheless would disagree with the proposal. ITIA think it would serve to confuse things for athletes who reach the level at which the ITIA is looking at.

# **Sport NZ**

Jane Mountfort, Principal Policy and Legal Advisor (New Zealand) Public Authorities - Government

This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.

We suggest that development of this proposal takes into consideration the significance of any unequal treatment between athletes of different countries in the requirements for TUE applications.

<b>COCOM</b> Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO	SUBMITTED
Prioritiser certaines substances pour certains sport sans demander d'AUT au préalable me se pourrait perturber par la suite les médecins lors des demande d'AUT.	emble dangereux et
Anti-Doping Agency of Serbia Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO	SUBMITTED
We agree with this concept and consider it applicable.	
Anti-Doping Sweden Jessica Wissman, Head of legal department (Sverige) NADO - NADO	SUBMITTED
ADSE consider it is enough to prioritize certain sports and disciplines. The rules are complicat also prioritize substances for certain sports will be confusing for the athletes as well as ADO's	
<b>Organizacion Nacional Antidopaje de Uruguay</b> José Veloso Fernandez, Jefe de control Dopaje (Uruguay) NADO - NADO	SUBMITTED
Satisfied. OK	
Agence française de lutte contre le dopage Adeline Molina, General Secretary Deputy (France) NADO - NADO	SUBMITTED
Dien sus nortent duns intention de signification, le spise en souvre de se servent rispus dist	

Bien que partant d'une intention de simplification, la mise en oeuvre de ce concept risque d'être complexe en termes d'éducation. Pour la bonne compréhension des sportifs et des encadrements médicaux, il est préférable que les cas dans lesquels le sportif doit solliciter une AUT préalable ou peut s'en tenir à une AUT rétroactive soient simples et bien distincts. Des critères plus compliqués risquent d'être contraires à l'intérêt du sportif lui-même. Par

ailleurs, il est déjà permis à un sportif de niveau national de solliciter une AUT rétroactive pour raison exceptionnelle, ce qui suffit actuellement à couvrir les hypothèses extrêmes pour lesquelles un assouplissement à l'AUT préalable est requis.

# NADA

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

The TUE application process should be as simple and clear as possible.

For national level athletes (athletes belonging to a testing pool), we do not consent to the suggestion of Conceopt #2.

Prioritizing certain substances by only requiring advance TUE applications for certain categories of prohibited substances may lead to confusion and would make it much harder for the athletes to decide when to apply for a TUE. Furthermore, this would most likely cause resentments among the athletes, who might not be able to understand why a team mate or competitor does not have to apply for a TUE in the same way. In our view, without deeper knowledge about the different classes of prohibited substances, it is not possible for the athletes to understand why different classes of substances are handled differently.

We strongly suggest that testing pool athletes should in general have to apply for a TUE for any prohibited substance in advance, unless one of the exeptions for a retroactive TUE applies. However, for lower level athletes who do not belong to a testing pool, we would welcome a possibility for ADOs to accept prospective TUE applications only for certain classes of prohibited substances (which ADOs could determine themselves) while generally ADOs may decline to consider advance applications from these athletes.

# Sport Integrity Australia

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

We agree in principle to exploring this approach (prioritising by substance) further. However, there is a real risk that adding another category to the national-level 'prioritisation list' will increase complexity to the TUE system and cause additional confusion for athletes. Having a list of athletes who don't need to apply for an in Advance TUE because of their level, but then still do have to apply because of the substance, seems contradictory and difficult to explain through education and online information.

Note: In Australia, any athlete (regardless of prioritisation level) who is prescribed an S1 Prohibited Substance is encouraged to apply to ASDMAC 'in advance' to ensure they do not use such a Prohibited Substance until an approval is granted. This ensures that they are not exposed to the higher risk associated with the use of these substances which would result if they were required to rely on the retroactive TUE process.

# **NADA Austria**

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

According to **Concept #2** the TUE process should be as easy as possible so that every athlete, asp and physician can understand and follow the required rules. The introduction of a different set of requirements for different target groups is complicating the matter. If this concept is implemented, there must be a very clear and concise rule in the ISTUE which substances need a prospective TUE and which substances can be applied retroactively. If this is left to national prioritization this would lead to chaos. NADOs would have other rules than other NADOs and IFs.

### Drug Free Sport New Zealand Nick Paterson, Chief Executive (New Zealand) NADO - NADO

SUBMITTED

**We do not support this concept**. We consider that a discretion for NADOs to require in-advance TUEs only for certain substances adds additional complexity for athletes. Athletes already need to understand inadvance/retroactive criteria, national, international and event TUE requirements. This introduces additional

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inconsistencies in process for athletes and accordingly, introduces additional risk for athletes.

It creates a two-tier system as to what is prohibited, and it may have the consequence of appearing to reduce the importance of some TUEs compared to others.

The main risk is of athletes inadvertently doping due to the complexity of TUE administrative process. Other possible risks include:

- Top level athletes having TUEs declined if medical notes are not sufficient retroactively under 4.2; the athlete would have not taken the medication if they had required the TUE in advance.

- Athletes having only experience with non-prioritised substances, informed these can be applied for retroactively and therefore misunderstanding when to apply for prioritised substance.

- Different NADOs may prioritise different substance groups meaning there is a risk for athletes who travel and compete at national level in other countries. There is already no consistency for the athlete in sport prioritisation among different nations so this would add more complexity and risk.

**FINADA** Anna Simula, Pharmacist (Finland) NADO - NADO

In principle we support this suggestion as it would give us more flexibility (but on the other hand we are also aware of the possible increased complexity for the athletes).

However, in addition to having flexibility to prioritize certain substance categories it would be useful to be able to prioritize also certain subgrups within substance categories. For example, requiring advance TUE for substance category S4. except subgroup S4.4.2 Insulins and insulin-mimetics.

# Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

We disagree with this concept; this might lead to more confusion, both for NADOs, IFs, as well as athletes.

# **Anti-Doping Norway**

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

The suggestion would be a step away from harmonization of the rules, making mobility between countries more difficult for athletes at national-level (including for competitions in neighboring counties with other TUE-requirements). We are also worried about the uncertainty to the athletes whether they would get a retroactive application approved or not. The added value does not seem to be proportional to the increased complexity of the rules.

**Canadian Centre for Ethics in Sport** Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO SUBMITTED

The CCES does not support the addition of substance classes to article 4.1 c) of the ISTUE.

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While the CCES understands how this change could reduce workload for some ADOs with respect to the volume of TUE applications, we believe adding specific substance classes (e.g., S7) to sports and disciplines would create a more complex system, and it already challenging enough for athletes to understand to existing system.

However, should WADA decide to move forward in the manner described, the CCES believes this provision should be limited to certain substance classifications, rather than sport or disciplines.

**USADA** 

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

The use of ISTUE Article 4.1(c) is beneficial to NADOs primarily because of the large number of sport-disciplines for which they may be responsible. Due to limited TUE resources, and the need to develop a comprehensive risk assessment, it may in many instances make sense to develop different testing pools to effectively use resources. USADA's concern with allowance for a new prioritization variable based on prohibited substance and/or method category is that this has the great potential to add another layer of complexity which may be difficult to both communicate to the athlete, as well as further complicate and cause disparity for international and national-level athletes. Thought should be given to exchanging sport disciplines with substance category, which USADA supports for clarity and effectiveness.

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

SSI considers this proposal to be challenging. The application process should be kept as simple and clear as possible. The principle that all NLA must submit an advance TUE application is an understandable regulation for the athletes. With the addition of substances, an additional criterion would be included, which would make it more difficult for athletes to assess their situation, including the risk of ADRV in the event of misinterpretation. The addition of substances as a criterion also brings challenges in communication and training. If the concept is pursued, the substance categories should be standardised. Otherwise, there could be discrepancies between the NADO and IF, which will lead to misunderstandings by athletes.

# **Anti Doping Danmark**

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

A good option – ADD would consider using such a prioritization.

**UK Anti-Doping** 

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

NADOs should not be allowed to prioritise certain substance categories for the following reasons:

It would add unnecessary complexity to the TUE process. Indeed, adding an additional requirement for athletes to check a substance prioritisation list (as well as checking the anti-doping status of the medication and the NADO's "sport prioritisation" list) will likely cause uncertainty amongst athletes and doctors resulting in a greater volume of enquiries for ADOs to deal with and may lead to more Article 4.3 cases.

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The concept would make NADO "sport prioritisation" groups redundant if all national-level athletes using a prioritised substance would need to apply for a TUE in advance. In effect, significantly more athletes would need to apply for a TUE in advance (or at least be aware of their obligation to) as "sport prioritisation" groups currently only capture national-level athletes who are within the NADO test distribution plan rather than every single national-level athlete.

Athletes who are using a non-prioritised substance who transition to international-level would not be able to rely on the recognition process as they will not hold a valid national-level TUE. This could be problematic as athlete selection for international competition can occur at short notice making it conceivable that some athletes may not receive a TUE decision from their International Federation prior to competition. There is also a danger that athletes may think that the same national substance prioritisation rules apply at international level when they do not.

It is unnecessary as Article 4.1(e) already affords NADOs with the flexibility to determine when to review TUE applications following the out-of-competition use of substances prohibited in-competition only (such as S7 substances).

# RECOMMENDATION

1.

NADOs should not be allowed to prioritise certain substance categories.

SUBMITTED

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

We support this additional categorization, even if it may add an additional layer of complexity to the process and to the athletes' understanding as to when to apply prospectively. We believe that this new approach could, amongst others, alleviate the heavy workload related to prospective TUE requests for stimulants used to treat ADHD.

# Concept #3 – Major Event Organizations (MEOs) Prioritization (17)

SUBMITTED

**UEFA** Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA partially supports the development of this concept.

UEFA sees no particular reason the rules need to change on this point, however, if WADA are considering expanding 4.1(c) for MEOs, you should also consider IFs. Some IFs also process TUEs for quite 'low level athletes'. For example, in football, there are youth players from very small countries who simply play at school or in local teams with their friends and then are called up to the National team. Very often, (particularly for youth athletes), a TUE is not required at NADO level and then the athlete needs one from the IF.

<b>Council of Europe</b> Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)	SUBMITTED
Supported WADA should also expand this to IFs.	
Anti-Doping Agency of Serbia Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO	SUBMITTED
We agree with this concept, it should be practical.	
Anti-Doping Sweden Jessica Wissman, Head of legal department (Sverige) NADO - NADO	SUBMITTED
ADSE support a review of the proposal to expand 4.1 (c) to include MEO's.	
<b>Organizacion Nacional Antidopaje de Uruguay</b> José Veloso Fernandez, Jefe de control Dopaje (Uruguay) NADO - NADO	SUBMITTED
Very important decision It should be considered as a priority when dealing with MOE Satisfied	d. OK
NADA NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO	SUBMITTED
no comment	
<b>Sport Integrity Australia</b> Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO	SUBMITTED
We agree with the proposal to expand the ISTUE Article 4.1(c) on retroactive TUEs to MEOs.	
There are a number of examples of MEOs running one-off international events where the maj lower level who are eligible to apply to their NADO for a retroactive TUE under 4.1.c of the cu example, the Pacific Games. As such, it is appropriate to allow the national prioritisation rules circumstances and allow these lower-level athletes to still rely on the retroactive TUE provisio imperative, as with all retroactive TUEs, that the process be supported by education, and athle of the rules and the risks.	rrent ISTUE. For to also apply in these ons. However, it is

Athletes competing at major multi-international events such as the Olympic Games are most likely already required to apply to their NADO or IF for an in-advance TUE.

Drug Free Sport New Zealand Nick Paterson, Chief Executive (New Zealand) NADO - NADO

**We support the concept**. The ability for MEOs to allow retroactive TUEs would assist them if they are smaller organisations without sufficient capability or resource. We presume that this is not intended to capture the Olympic and Paralympic Games.

FINADA Anna Simula, Pharmacist (Finland) NADO - NADO	SUBMITTED
Supported.	
<b>Dopingautoriteit</b> Robert Ficker, Compliance Officer (Netherlands) NADO - NADO	SUBMITTED
This sounds reasonable, but it also depends on what MEOs think about it.	
Anti-Doping Norway Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO	SUBMITTED
Supported	
Canadian Centre for Ethics in Sport Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada)	SUBMITTED

The CCES agrees with WADA's consideration to expand Article 4.1 c) to include MEOs.

The CCES recognizes that lower-level athletes, who are not defined as National or International-level athletes, can be named very late to some major event teams. Allowing athletes who are late nominations to major event teams to apply retroactively allows for an athlete-centered approach and acknowledges the short timelines these athletes are facing, given they are only made aware of the medical exemption requirements shortly before the event.

### USADA

NADO - NADO

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

SUBMITTED

In practice, expanding ISTUE Article 4.1(c) on retroactive TUEs to include MEOs could potentially be quite challenging because it would be difficult to prioritize athletes in certain sports or disciplines without it appearing unfair to other athletes in the sports or disciplines that 4.1(c) didn't apply to. Also, this is up to individual ADOs at the current time to decide; thus, coming to a common approach that would be consistent from a national to international level may be difficult. Athletes attending Major Games should all be subject to international-level athlete TUE requirements. It is far better for the athlete to have a TUE in place before travelling to a Major Event, than having to go through the retroactive TUE process once an AAF has been reported. Further, MEOs are only able to grant short-duration TUEs for the period of the event; thus, the ability and requirement to consider short-term TUEs (retroactive or prospective) should remain in place. It is always still better for an athlete to apply for a TUE in advance, and helps the athlete and Games-time medical team for piece of mind and treatment plan, especially when competing at a Major Games. USADA believes other ISTUE retroactive criteria should address the

retroactive needs of athletes seeking a TUE at a Major Event.

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

SSI does not see the solution in prioritising the sport (and possibly the substance). However, the challenge should be addressed via the athlete level. To be specific, the MEO could use the ILA or NLA definitions rather than independently defining ILAs (= all those participating in the ME).

# Anti Doping Danmark

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

Supported

**UK Anti-Doping** 

SUBMITTED

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

We have no objections to this concept being developed further if MEOs are in favour of the proposal. In our experience, International Federations (IFs) also deal with relatively low-level athletes. In these instances, NADO's are often expected to review such applications even though the athlete is competing at an international competition and is not part of the NADO "sport prioritisation" group. The ISTUE Drafting Team are therefore encouraged to consult with IFs to determine if ISTUE Article 4.1(c) should be expanded to include these organisations as well.

# RECOMMENDATION

1.

The ISTUE Drafting Team should consider expanding Article 4.1(c) to include IFs and MEOs if these organisations support the concept.

# International Testing Agency

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

We support this initiative.

# Concept #4 – TUEC Membership and Operation (20)

World Rugby David Ho, Senior Manager Anti-Doping Operations (Ireland)

Sport - IF – Summer Olympic

We find the current requirements to be workable, however any further clarification would do no harm.

**IBSA - Virtus - World Abilitysport** Mohy Eldin Elgaafary, TUE Committe member (Egypt) Sport - IPC

SUBMITTED

SUBMITTED

to be obligatory and mandatory to include at least two Pharmacists in the TUE committee membership
UEFA Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other
UEFA partially supports the development of this concept.
Updated guidance on TUEC establishment is not necessary in the IS (it could be included in the Guidelines). Operationally, there could be more instructions. For example, the article 'Whenever appropriate, the TUEC should include, or seek the opinion of, a physician with an expertise related to the athlete's condition' could be moved from Guidelines to IS. There could also be instructions on what to do in terms of no consensus, that all members of the selected TUEC must provided with the same password protected documentation etc.
International Tennis Integrity Agency Nicole Sapstead, Senior Director, Anti-Doping (United Kingdom) Sport - Other
This could be useful. At the moment it falls to individual ADOs to canvas views or learnings from other ADOs/NADOs. More guidance would create a more harmonised approach but also assist ADOs in building a TUEC with the correct skills, experience, term levels etc.
Council of Europe Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)
Partly supported
There should still be room for flexibility
COCOM Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO
Selon moi, l'établissement de procédure pour la CAUT est nécessaire dans le but d'harmoniser les prise en charge et de clarifier les fonctionnements/opérations.
Anti-Doping Sweden Jessica Wissman, Head of legal department (Sverige) NADO - NADO
ADSE support that general guidance of TUEC establishment and operation could be of importance to ADO's and could be a part of the ISTUE guideline, but not necessarily a requirement. A suggestion is to send out a survey to 8-10 NADO's and get input how they operate and compile the answers for a general "guidance tool".
ADSE is considering whether it should be specified a minimum of participating TUEC members for each TUE

**Organizacion Nacional Antidopaje de Uruguay** José Veloso Fernandez, Jefe de control Dopaje (Uruguay) NADO - NADO

decision.

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

With regard to TUEC procedures and operations, we consider WADA's TUE committee member Professional Standard (published in May 2023) as very helpful.

To prevent that information on TUEC procedures is placed in different documents, we suggest to add a reference to the Professional Standard in the ISTUE.

# **Sport Integrity Australia**

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

We agree there should be guidance materials on the TUEC establishment and procedures/operations to support these important processes and promote an effective and harmonised approach to managing TUEs under the ISTUE. These materials would need to take into account the differing abilities of TUECs. For example, they would need to be drafted to take into account the way TUECs operate depending on their size, composition, and the way roles and responsibilities are performed.

To ensure that only competent and compliant TUECs are in operation, smaller NADOs lacking resource and expertise could outsource their TUEC to a more established TUEC.

In addition to the above, we suggest that remedies could be introduced to deal with any TUEC non-compliance. For example, the responsible NADO could be required to invoke assistance from a compliant NADO/TUEC to undertake their processes and put in place a plan to address issues of non-conformity.

# **NADA Austria**

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

According to **Concept #4** it should be mentioned that this is already in the guidelines and also in the role descriptor in GLDF which is fine. These documents can be adapted more easily if the need arises, changes in the ISTUE are harder. In addition, if this requirement would be implemented in the ISTUE, it would also be a compliance requirement which would mean more pressure for smaller ADOs (who struggle already to keep up with all the regulations and requirements in various areas of the Anti-Doping work). TUEs should only be issued if all the criteria of the ISTUE are fulfilled. If ADOs wait for further medical information and grant a TUE in the meantime, what happens if the second TUE that is bases on the additional information is not granted? This concept creates more problems than solutions.

**Drug Free Sport New Zealand** Nick Paterson, Chief Executive (New Zealand) NADO - NADO SUBMITTED

SUBMITTED

We note that the ISTUE already has requirements around TUEC formation and there are already the <u>Professional</u> <u>Standards</u>, and have concern that being too prescriptive may cause issues for smaller ADOs. The requirements for granting a TUE are already specified, and not everything needs codified.

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

SUBMITTED

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We think that the establishment of TUECs is currently adequately addressed. Further requirements may lead to a lack of flexibility in appointing TUEC members. Generally speaking, this would lead to micromanagement which is not helpful in attaining global harmonization, and this is also the case in this area.

# **Anti-Doping Norway**

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

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SUBMITTED

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

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

# **Canadian Centre for Ethics in Sport**

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

The CCES supports WADA's consideration to provide ADOs with more guidance around the establishment of a TUEC as well as on the procedures/operations to be followed by the TUEC once formalized.

We are also mindful of the impact of adding such additional guiding practices into the ISTUE itself. The CCES therefore believes that additional supporting documentation or guidance be included in a guideline or model of best practice so that all ADOs, independent of resources and size, can review and improve their practices without fearing consequences if they cannot establish all of the newly added procedures/operations.

# USADA

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

USADA's opinion is that ISTUE Article 5.3 is adequate and gives the flexibility necessary recognizing ADO and MEO differences with respect to access to physician TUEC members and expertise. Specific specialist expertise for complex TUE cases should be strongly encouraged (for example, endocrinologists requirement for testosterone and GH cases) beyond a single TUEC member. WADA has done a very good job at providing further guidance on TUEC membership and operation in the Guidelines which maintains a level of flexibility that is warranted. One challenge that must be addressed is the potential bias that may exist between NADO and IF TUECs. In practice, NADO TUEs may not be recognized by an IF because of actual or implied bias that NADO TUECs may be more permissive or biased toward athletes at the national-level. If a TUEC is operating independently and in accordance with the ISTUE, this should not be an issue, and therefore, automatic recognition should be the norm if the NADO is compliant with the Code and ISTUE.

The "TUE committee member Professional Standard" already contains guidance in addition to Art. 5.3 ISTUE. SSI therefore does not currently see the need to provide additional guidance. It is essential to ensure that the "TUE committee member Professional Standard" and ISTUE are consistent.

SUBMITTED

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

Guidelines on procedures and operations would be helpful. Ex how many members of the TUEC needs to evaluate the application and documentation for an approval?

Is it sufficient that the TUEC member who is a psychiatrist evaluates the TUE applications for stimulants and ADHD?

It would be a burden on our resources if the medical expert in a field was not sufficient for an evaluation and approval of an application.

# UK Anti-Doping

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

We believe that such guidance would be best served in a good practice guideline as opposed to the ISTUE so that ADOs are not constrained in their approach (if their current procedures work for them) and so that less developed ADO TUE Programmes can work towards these proven practices.

Notwithstanding this general principle, we would like to see guidance within ISTUE Article 5.3 on whether a TUE Review Panel can grant a TUE if they fail to reach a unanimous decision (for example, two panel members approve, one rejects). In the UK, TUEC Review Panels can only grant a TUE if all three TUEC panel members agree. The application is rejected if this is not the case and the athlete is then given the opportunity to appeal the decision.

We propose that an additional sentence is included in Article 5.3 to establish that there must be unanimity amongst a TUEC Review Panel for a TUE to be granted. We believe that this requirement is an important element of the decision-making process which gives stakeholders confidence in the final decision. It also reduces any external perceptions of doubt over the decision to grant an athlete with a TUE.

# RECOMMENDATIONS

1.

Guidance on the establishment and procedures/operations of a TUEC should be included within a good practice guideline rather than detailed in the ISTUE.

Add an additional sentence to Article 5.3 to establish that there must be unanimity amongst a TUEC Review Panel for a TUE to be granted. Suggested addition:

5.3. c) Regardless of the size of a TUEC Review Panel, a TUEC shall only grant a TUE if their decision is unanimous.

<sup>2.</sup> 

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

We do not believe that this is necessary, however additional guidance is always welcomed.

# Concept #5 – Short term TUEs (22)

### World Rugby

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

We would agree with this proposal, however we wonder whether this may be better defined in the guidance documents rather than the Standard?

### **UEFA**

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA does not support the development of this concept. Short term TUEs shouldn't be necessary if 'prospective TUEs' can be granted back to the date of the application (as in Concept #1).

### International Tennis Integrity Agency

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

ITIA is supportive of this idea. However, it is not clear how this would work where the further evidence requested is medical and is needed to establish whether the ISTUE Article 4.2 criteria are met and, therefore, whether the TUE should be granted.

### Sport NZ

Jane Mountfort, Principal Policy and Legal Advisor (New Zealand) Public Authorities - Government

This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.

Sport NZ is neutral as regards the proposal to formalise short-term TUEs. If provision is to be expressly made for grant of short-term TUEs, with a view to harmonising their use, Sport NZ considers that there should be clarity in the standard on how to use the system. However, this would need to incorporate safeguards to avoid repeated abuse by the same athlete and clarity on the status of an athlete whose short-term TUE was not extended after investigation.

# COCOM

Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO

si la CAUT reconnait que les conditions sont légitime pour l'octroie d'une AUT mais attend des renseignements supplémentaires, celle-ci doit être conditionnée à l'envoi des renseignements supplémentaires.

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We do not agree that ADOs can approve TUEs for a short term without complete medical documentation.

# Anti-Doping Sweden

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

ADSE support that short term TUE's is an option when approving TUE's, especially when there is limited time before a competition. This is easily managed by approving a TUE with a precondition to submit the requested/specified information for the TUE to be valid for a longer period.

# Organizacion Nacional Antidopaje de Uruguay

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

YES Very is important to have this possibility that requires protecting the athlete before a final decision.

# Agence française de lutte contre le dopage

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

Si cette possibilité peut répondre à un besoin opérationnel, elle suscite de très fortes réserves car elle aboutirait à compliquer à l'excès la procédure et à créer deux procédures concurrentes: l'AUT provisoire et l'AUT classique. Plusieurs questions juridiques, en lien avec la gestion des résultats, doivent être sérieusement examinées avant d'envisager cette nouvelle procédure: quelles seraient les conséquences sur l'AUT provisoire si les pièces demandées pour l'AUT classique ne sont jamais fournies ? Que se passe-t-il à l'égard du sportif si l'AUT provisoire est accordée mais l'AUT classique est refusée ? Le refus de l'AUT classique entraîne-t-il l'annulation rétroactive de l'AUT provisoire? Ce sportif encourt-il une sanction ou au vu de la seule AUT provisoire, son dossier peut-il être classé si un RAA intervient avec une AUT provisoire accordée même lorsque l'AUT est refusée postérieurement au contrôle ?

Pour répondre aux situations d'urgence, il est proposé de privilégier une procédure d'urgence pour l'examen d'une demande d'AUT.

# NADA

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

We consider this suggestion to be problematic for different reasons:

1.) What requirements have to be fulfilled for the approval of a short term TUE? If medical information from specialists is missing, which medical information and documentation and from which physicians has to be submitted for the TUEC to be able to decide about short term applications?

2.) This concept would lead to less legal certainty. What if the assessment by a medical specialist for a subsequent longer-term TUE does not confirm a certain medical condition or results in the realization that permitted substances can be used for treatment and leads to a denial of the application by the TUEC? What consequences would that have for the athlete and/or for the short term TUE that was granted before? This may lead to problematic Result Management cases. Seen from a different perspective, such short term TUEs could very well open up opportunities for doping.

3.) If a treatment is already started before assessment by a medical specialist, it could be hard to confirm or establish a diagnosis (remission of symptoms, normalized diagnostic parameters, etc.).

4.) In our view, such short term TUEs would be mainly necessary if the athlete suffers from an acute disease or if

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an urgent treatment is necessary before the medical documentation for a TUE application is complete. Why should these athletes not apply for a retroactive TUE in accordance with 4.1 a) instead? 5.) Issuing such short term TUEs would result in an increase in the administrative work for ADOs and would double the expenses for the assessment by the TUEC for these cases.

# **Sport Integrity Australia**

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

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We agree the granting of 'short term/preliminary TUEs' should be recognised under the ISTUE.

Where there is a very low risk that a TUE will not be granted, however, further verification is required to complete the process resulting in a delay and it is important for the Athlete to be taking the medication. A 'short term/preliminary TUE' could be provided to cover any 'gap'.

This appears to be most relevant to applications for TUEs for ADHD medications.

While this approach is likely to create additional work for a TUE Manager, it is a clear practical way to facilitate the process and reduce uncertainty and risk. There should be a provision for follow up and for the short-term approval to be withdrawn at a point in time if the required information is not forthcoming. It may be prudent to require the Athlete to explain why the information has not been provided and be warned of any possible further investigation of the matter if it appears the athlete may have abused the process.

It may be possible to include wording such as "conditional" TUE in addition to "short term", to more clearly articulate there are conditions attached to the short term approval.

As noted above in relation to retroactive TUEs, information and education are key to ensuring the Athlete is fully informed of the process and any risk. Also, reliance on this approach may need to be limited to certain substances, and this provision needs to be considered against any expansion of other provisions such as Art. 4.1(c) as outlined above as well as and any further expansion or explanation of 'exceptional circumstances'.

This concept has links and similarities to Concept #1 and we support a process that doesn't penalise athletes where clearly a TUE would or should be granted.

# **Drug Free Sport New Zealand**

Nick Paterson, Chief Executive (New Zealand) NADO - NADO

We support the concept. This would formalise the process that some TUECs already use and create a consistent approach.

We consider that this approach may be more appropriate for renewal applications as opposed to first time applications to avoid the risk that athletes use this short-term process (e.g., to cover only a single event) without the intention of completing the full process for a longer term TUE, or alternatively, that safeguards are put in place to ensure that this process is only relied upon in specific and appropriate circumstances (i.e., where there is confidence that the requirements in Article 4.2 of the ISTUE will be met).

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**FINADA** Anna Simula, Pharmacist (Finland) NADO - NADO

Supported. For example, in ADHD cases it is sometimes difficult to get requested relevant medical information. There might be a situation that the athlete has had a one-year TUE and then for renewal they send a new poor application without no sufficient up to date medical information. Then we could get them few extra months TUE / time to provide requested information. It is often same with foreign players/athletes when they arrive to Finland. In

their home country there has been no need to apply in advance but here they are athletes who need to apply for a TUE in advance and sometimes there is same problem to get all the requested information.

# Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

This could be a great addition to the ISTUE, however, the ISTUE gives this possibility already. By specifically mentioning it or trying to establish a "rule" for it, will hinder the flexibility/independency of a TUEC.

# Anti-Doping Norway

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

This is supported. However, we have taken note that this is already reflected in some TUE Physician Guidelines, e.g. for ADHD, where it is recommended a short-term TUE during dose titration.

# Japan Anti Doping Agency

YUICHI NONOMURA, Result Management (??) NADO - NADO

We understand the concept, however, one size fits all approach does not work some time. There are some cases that TUEC has to grant a Short-Term TUE depending on the disease. TUEC may wish to grant a short-term TUE (like 3 month) because the TUEC wishes to further monitor and evaluate the processes of treatment of the athlete concerned, so that TUEC could determine if a long-term TUE could be granted in the future after a short-term one is come to be expired.

# **Canadian Centre for Ethics in Sport**

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

The CCES agrees with the rationale behind the concept of short-term TUEs in two scenarios:

- 1. When an athlete only requires the substance for a short, well-defined, period of time.
- 2. When an athlete might require additional time to gather more extensive documentation to complete their medical file, and the TUEC is reasonably satisfied that the athlete will meet the conditions of the TUE once the additional documentation is submitted.

Should this concept proceed, consideration should be given as to whether or not automatic recognition would extend to a short-term TUE. Clear guidelines for determining when a short-term TUE is granted would be needed.

If the concept is adopted, the CCES recommends WADA monitor temporary TUEs more intentionally and frequently to ensure proper application of the provision.

**USADA** 

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

The concept of a "provisional" or short-term TUE may be appropriate in specific instances where a TUEC

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determines that a TUE should be granted, however there may be a missing piece of information or detail in the medical record that could strengthen the overall determination of meeting the ISTUE 4.2 criteria. As an example, this may happen with ADD/ADHD applications where the athlete has submitted a good psychological evaluation from a primary care physician, however a follow-up evaluation from a specialist is worthwhile. In these cases, a short-term TUE approval of 6 months to 1 year could be appropriate to give the athlete time to obtain further medical evaluation to shore up the diagnosis and treatment plan, then these can be submitted with a renewal application. In these cases, our experience is that the athlete very likely suffers from a legitimate medical condition, and this ultimately results in a longer-term TUE being granted. Short term TUEs could be limited to chronic conditions where a life-long TUE is likely warranted.

Swiss Sport Integrity

Ernst König, CEO (Switzerland) NADO - NADO

SSI agrees that the situation described occurs frequently and that the practice should be reflected in the ISTUE. The condition (e.g. obtaining a second opinion, submission of specific laboratory values, etc.) for the renewal application should be indicated on the short-term TUE. It must be clear that the conditions for obtaining a TUE are highly likely to be met and that the short-term TUE is only necessary because particular information is required. The minimal documentation required should be standardised in order to avoid decisions based on poor data. Variability in the authorisation period should remain as the authorisation period varies between a few weeks and months depending on the condition.

# Anti Doping Danmark

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

Clarification on this would be helpful.

# **UK Anti-Doping**

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

We support the further development of this concept as it reflects the existing challenge that TUECs and athletes can encounter when the evidential burden to obtain a TUE is higher than what is needed to reach a diagnosis within a country's national health service. This provision affords TUECs with the ability to exercise their judgement in specific cases otherwise an athlete could be facing weeks/months of uncertainty if they are waiting for further information from their specialist or there are delays in arranging an appointment to acquire this evidence.

The following practical considerations should be explored when considering this concept further:

The duration of the short-term TUE – this needs to be sufficient to enable the athlete to obtain the required information but not open ended. We suggest that a short-term TUE should be limited to three months or less.

A second short-term TUE should not be granted if the athlete has already obtained a TUE for three months and has failed to acquire the necessary information within this time.

The provision should be limited to applications which are reliant on further information from a specialist rather

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than a team doctor or general practitioner. RECOMMENDATION 1. The ISTUE Drafting Team should continue to develop this concept. SUBMITTED **International Testing Agency** International Testing Agency, - (Switzerland) Other - Other (ex. Media, University, etc.) We agree that this concept should be enshrined in the ISTUE. Concept #6 – Recognition Process (21) SUBMITTED World Rugby David Ho, Senior Manager Anti-Doping Operations (Ireland) Sport - IF – Summer Olympic We would agree with this proposal. SUBMITTED **UEFA** Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other UEFA does not support the development of this concept. The TUE should be fully recognised or refused by the IF. SUBMITTED International Tennis Integrity Agency Nicole Sapstead, Senior Director, Anti-Doping (United Kingdom) Sport - Other ITIA supports this proposal SUBMITTED **Council of Europe** Council of Europe, Sport Convention Division (France) Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.) Not supported This should not be developed any further. SUBMITTED COCOM Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO

Les IF délèguent (trop) souvent cette compétence aux ONAD. Sur quelle base est-ce qu'il serait acceptable qu'elles

posent des conditions supplémentaires alors que la décision est prise par un panel d'experts indépendants? Si cela devait être accepté et que les IF ont cette possibilité, elles devraient seules avoir la charge du suivi. Il faut arrêter de mettre des charges sur les ONAD au profit des IF. Il devrait y avoir reconnaissance mutuelle, point barre. Sinon merci la crédibilité d'une décision et la sécurité juridique ...

# Anti-Doping Agency of Serbia

Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO

We agree with this concept and consider it applicable.

# **Anti-Doping Sweden**

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

ADSE suggest that all TUE's administered at national level pursuant to Code article 4.4 by a Code Compliant ADO are automatically recognized by the IF unless they actively decide not to recognize them. We understand the need for an "emergency break" at international level for TUE's administered at national level, however, recognition should be the rule rather than the exception.

One way to do this could be to require all IF's to actively make a list of ADO's whose TUE's they do not recognize. Otherwise, if automatic recognition is not considered, with regard to article 7.0 (b), it should be included that the IF's must specify in detail their recognition process. Most IF's have poor information on their websites that makes the recognition process difficult and time consuming both for NADO's and athletes.

# **Organizacion Nacional Antidopaje de Uruguay** José Veloso Fernandez, Jefe de control Dopaje (Uruguay)

NADO - NADO

supporting MOE actions in Games. GOOD

# NADA

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

NADA GER does not consent to this suggestion.

The recognition process should be as simple and clear as possible.

Conditions added by IFs during the recognition process and the duty to comply with these conditions would most likely be too much burden for and confuse the athletes who originally applied to their NADO. Our experience shows that it is not easy to get in contact with some IFs and an athlete might additionally face challenges when it comes to communicating in a different language and in different time zones etc.

We suggest that athletes who consider to compete internationally should send their TUE application directly to their IF.

# Sport Integrity Australia

SUBMITTED

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

We agree that an IF be allowed to add certain conditions if necessary, when recognising TUEs. Additionally, we are of the view that there are a number of considerations and further collaboration and actions that should occur if an IF wishes to do so.

However, this approach should only apply where an athlete falls within the jurisdiction of an IF for a period of time longer than a single international event. Where a national level athlete is only an international level athlete for a single event (and not a longer period of time) the NADO TUE should be recognised by the IF and the NADO should remain the custodian of the TUE.

By way of example, the NADO and IF may impose different conditions relating to the duration and monitoring requirements imposed on an athlete granted a TUE.

Foremost there needs to be clear guidelines as to the process and the responsibility of monitoring.

A preferred approach is for the IF and NADO to consult on the conditions and aim to reach agreement. If agreement cannot be reached, then the default position is for the IF to assume responsibility for managing the TUE. Any change required by the IF should then be managed by the IF, where the athlete falls within their jurisdiction, for a period of time (usually greater than a single event). NADOs could assist but the IF should be responsible for liaising with the athlete and ensuring the athlete understands the changed requirements.

We don't agree that it is necessary to expand these considerations to also cover MEOs. Most MEOs are responsible for one-off short term events. As such it is neither practical nor necessary to impose additional conditions on a TUE to cover these occasions. Unless there is a clear discrepancy in the TUE this situation should not arise.

# **NADA** Austria

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

According to **Concept #6** there is currently a disbalance between the rights and responsibilities of NADOs and IFs. For example, NADOs are not allowed to appeal TUEs that were issued by the IF – only the other way round (WADC 4.4). All ADOs are working on the same ISTUE so they should have equal rights and act on eye level. The TUE process should be as easy as possible so that every athlete, ASP and physician can understand and follow the required rules. This concept would only complicate the TUE process. Custodianship is a concept, that works for other areas of the Anti-Doping work but is not fit for purpose in connection with TUEs. NADOs speak the same language, know the culture of the athletes and have shorter ways of communication. If NADOs are often struggling to find the correct contact person at an international federation, how can we ask that from the athletes. If the concept of custodianship is implemented there is a high risk that recognition will be significantly reduced and/or the recognizing ADO needs to dedicate considerable resources to review the quality of the TUE that should be recognized to really make sure everything was correct. According to the recognition for a single event there is currently a disbalance between the rights and responsibilities of NADOs and IFs. For example, NADOs are not allowed to appeal TUEs that were issued by the IF – only the other way round (WADC 4.4). All ADOs are working on the same ISTUE so they should have equal rights and act on eye level. The TUE process should be as easy as possible so that every athlete, ASP and physician can understand and follow the required rules. This concept would only complicate the TUE process. TUEs should be recognized for the whole duration. There are many athletes who don't know if this is a one-time international event. They would need to apply again and again. Custodianship is a concept, that works for other areas of the Anti-Doping work but is not fit for purpose in connection with TUEs. NADOs speak the same language, know the culture of the athletes, and have shorter ways of communication. If NADOs are often struggling to find the correct contact person at an international federation, how can we ask that from the athletes. If the concept of custodianship is implemented there is a high risk that recognition will be significantly reduced and/or the recognizing ADO needs to dedicate considerable resources to review the quality of the TUE that should be recognized to really make sure everything was correct. A concept that might help is the opportunity for IFs to accept retroactive TUEs for their international events. This would result in fewer ADRVs because of a missed deadline to submit a TUE (that would have been granted but was denied since the timing of the application was not right. According to the consequences of the concept this should be dealt within the ISCCS and not in the ISTUE.

# Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand) NADO - NADO SUBMITTED

We agree that there is benefit in resolving conflict between NADO and IF TUE recognition. We also see benefit in an athlete not having to go through a fresh TUE process through an IF because the IF has had to reject the NADOs TUE in full as opposed to adding conditions.

We have concerns around the practicalities due to an athlete not having had any dealings with the IF on the TUE and so there is concern that that NADO then becomes the conduit between the IF and the athlete, and the conditions ultimately become the NADO's to monitor. We note the reference to assistance from the NADO and consider that clarity is required to ensure that any assistance would only be by NADO agreement. We also consider that there should be clarity around appeal rights regarding the imposition of conditions (i.e., where it isn't a straight rejection/recognition of the existing TUE).

### **FINADA**

Anna Simula, Pharmacist (Finland) NADO - NADO

We suggest that all TUEs administered at national level pursuant to Code article 4.4 by a Code Compliant ADO are automatically recognized by the IF unless they actively decide not to recognize them. At the moment it seems sometimes (with some IFs) that it is more difficult to get the TUE recognized than apply for a new one.

# Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

In general, the role of IFs is very much prioritized over that of the NADOs. Often, a TUE from a NADO is simply rejected by IFs without more information, completely neglecting the independent role (and work!) of a NADO TUEC. It is better to regulate IF's decisions more strictly and requiring that they explain their decisions.

# **Anti-Doping Norway**

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

We suggest that all TUEs administered at national level pursuant to Code article 4.4 by a Code Compliant ADO are automatically recognized by the IF unless they actively decide not to recognize them. We understand the need for an "emergency break" at international level for TUEs administered at national level, however, recognition should be the rule rather than the exception.

One way to do this could be to require all IFs to actively make a list of ADOs whose TUEs they do not recognize, preferably with a reason for such a decision not to recognize the TUEs.

# **Canadian Centre for Ethics in Sport**

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO SUBMITTED

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The CCES disagrees with the suggestion that IFs be allowed to add conditions to a TUE which has already been approved by a NADO.

Rather, the CCES advocates for automatic recognition for all approved TUE. When a TUE is granted in accordance with the requirements outlined in the ISTUE, there should be no need to add conditions. If certain conditions are deemed a necessary element for approval, they should instead be added as a requirement for granting the TUE in the first place.

Where there is concern that an ADO may be inappropriately approving TUEs, this issue should be addressed through existing compliance mechanisms.

However, should this concept be retained, it would be imperative for IFs to be responsible for communication and/or action-items related to the additional conditions to the athlete, and the ADO which initially approved the TUE would not be required to be involved in that process.

USADA

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

USADA believes the TUE recognition process between NADOs and IFs should be more efficient and equitable which benefits athletes by making the process less complex. Under the current rules, IFs have disproportionate power when it comes to TUEs. If a given IF or NADO is compliant with the Code and ISTUE as determined by WADA, then TUEs should be automatically recognized or appealed. IFs should not be able to solely determine the recognition of a TUE. In fact, WADA has the ability to review TUEs to look for evidence of non-compliance. Thus, WADA should provide the oversight on TUE quality, not IFs. Alternatively, if the IF has an issue with a NADO TUE, they should refer it to WADA for review (or appeal in some other fashion), rather than being able to solely determine non-recognition. There is no evidence that the IF TUEC standards are universally higher than NADO TUEC standards. We all have to operate under a single standard. It should be an even playing field and automatic recognition so long as the ADO is in good standing with WADA. Additional conditions added at the time of automatic recognition may be appropriate only when consistent with the WADA TUE Physician guidelines, however the mechanics of communicating this to the athlete may need to be considered as typically a new TUE approval certificate is not issued when automatic recognition occurs.

Swiss Sport Integrity

Ernst König, CEO (Switzerland) NADO - NADO

SSI considers this proposal unfavourable for several reasons. Fundamentally, focus should be on the athlete's interests and the application process should be as simple and clear as possible.

- <sup>1</sup>. It further complicates the recognition process. In order to define the condition, the IF must view the entire documentation. This contradicts our basic position that the recognition of NADO TUEs by the IF should be straightforward or automatic.
- 2. It is questionable whether the IF had sufficient insight into the decision-making process to be able to decide on a condition. The NADO TUEC may have previously assessed earlier TUE applications from the athlete or made conditions on previous TUEs. The IF would have the responsibility to review any previous documents to avoid duplication and unnecessary conditions. The IF's TUEC also has no access to the NADO's TUEC discussion.
- 3. At the time of a renewal application, the athlete may no longer be considered an ILA (especially if the definition is based on competition participation). In this case, the NADO would have to evaluate the application but the IF must verify that his condition is met.
- 4. The proposal leads to an additional inequality between NADO and IF and the value of the NADO TUE is reduced. SSI would welcome that the work of both ADOs is appreciated.

Anti Doping Danmark Silje Rubæk, Legal Manager (Danmark) NADO - NADO

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ADD is strongly advocating for a TUE issued by a NADO should automatically be recognized internationally.

In the few cases that the issued TUE does not fulfil the criteria of the ISTUE WADA, or the IF should naturally be able to reject international recognition.

Concept #6 would not be an issue if the stakeholders TUE'es were equalized with the IF's TUE'es.

Custodianship and monitoring should be in the hand of the issuing stakeholder and stay like that for the entire length of the TUE.

# **UK Anti-Doping**

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

The concept should not be developed further as this proposal would add complexity to the recognition process and is unlikely to alleviate tensions between ADOs when they disagree on the conditions attached to a TUE. In such circumstances, we would rather the IF continue to reject such requests to recognise the NADO TUE.

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However, if the concept is to be developed further then the following points should be considered:

The IF would need to be responsible for communicating the decision to the athlete and NADO that additional conditions were being attached to the TUE and that the IF was assuming custody of the TUE.

The athlete would need to have a right of appeal if additional requirements were placed on their TUE.

An athlete's competition status can be fluid meaning that an athlete can often transition between national and international-level multiple times during the duration of a TUE – this concept does not currently accommodate such fluidity of movement (that is, an athlete can return to national-level at which point the IF would be stuck monitoring the TUE as it appears custody cannot be transferred back to the NADO; furthermore, the NADO may not wish to take on the additional monitoring duties imposed by the IF).

Specific provision in the ISTUE would need to be added to instruct ADOs on their monitoring duties (that is, the TUE Custodian is ultimately responsible for monitoring any conditions imposed).

The IF TUEC would need to review the application in its entirety (that is, a three-person panel be convened) as the decision to include conditions when granting a TUE is part of the remit of the TUEC.

The functionality in ADAMS would need to be developed as TUE decisions cannot currently be modified once issued.

RECOMMENDATION

The ISTUE Drafting Team should not develop this concept further.

# International Testing Agency

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

We agree that recognition process should be reviewed and even replaced. However, in our experience, there has been very limited cases of rejection.

Recognition could be replaced by an automatic recognition with a review possibility, whereby an IF/MEO could send a request for review to WADA.

# Concept #7 – TUE Ownership following Recognition (19)

### World Rugby

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

We would not support this change. We consider that this should remain with the NADO as the organisation having approved the original TUE unless the athlete is long-term international level. If the athlete is competing temporarily at IL, it does not seem to make sense for the IF to manage this for a short period.

### UEFA

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA does not support the development of this concept.

TUE ownership following recognition should stay with the granting ADO. In case of automatic recognition or limited IF checking (have all the documents been submitted in line with WADA's checklist etc), the TUEC of the IF may not have analysed the case. It doesn't therefore make any sense that they 'own' the original TUE which has been fully assessed by the NADO TUEC.

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

Whilst mutual recognition of a TUE is absolutely supported, the issuing ADO should remain the custodian of the TUE for its duration. Otherwise, the impact on an IF could be significant.

# **Council of Europe**

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

# Not supported

TUE ownership following recognition should stay with the granting ADO

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We agree with this concept and consider it applicable.

# Anti-Doping Sweden

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

TUE ownership following recognition should stay with the granting ADO to make it easier for the athletes.

# Organizacion Nacional Antidopaje de Uruguay

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

**OK Satisfied** 

# NADA

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

NADA GER does not consent to this suggestion (see also reasoning above, Concept #6). 'Custody' for a TUE should be assigned to the ADO that initially granted the TUE and in order to prevent confusion for the athletes and to have clear responsibilities, should also stay with this ADO, even when the TUE is recognized. The complete and comprehensive medical file should be administrated and be available at only a single Anti-Doping Organization to prevent fragmentation and loop holes for those who cheat.

# **Sport Integrity Australia**

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

We agree guidance material should be provided to inform the circumstances, where it is agreed between the NADO and IF, that the IF should take over responsibility for a TUE (see Concept #6 above).

However, recognition of TUEs by the IF is usually not appropriate for one off international competitions (i.e. an athlete is not in the IF testing pool, has a NADO TUE and is classified as an International Level athlete for a certain competition). The NADO TUE should be recognised, and the custody should stay with the NADO, as once the competition is over the athlete is no longer classed as an International Level athlete.

# **Drug Free Sport New Zealand**

Nick Paterson, Chief Executive (New Zealand) NADO - NADO

We have similar concerns as with Concept #6, around the practicalities where an athlete may not have had any dealings with the IF regarding a TUE which is then taken over by the IF (e.g., where the NADO TUE is automatically recognised by the IF).

WADA statistics show that NADOs complete over 80% of TUEs (it is unclear how many of these required IF recognition). Therefore, this approach would require clear communication from the IF so that the athlete knows who

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they are dealing with in relation to their TUE, including future renewals etc. We note potential issue with time zone differences and language barriers for athletes in dealing with IF managed TUEs.

We also consider that it must be made clear that any NADO assistance is by agreement from the NADO, and we consider that this may confuse the athlete as to who is managing their TUE (in addition to potential time zone issues and language barrier complications).

There would also need to be clear communication between the IF and the NADO where the athlete ceases to be an international level athlete to ensure that the is handed back to the NADO to manage.

# Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

The concept of "monitoring" is in our opinion still unclear. There are no regulations in this regard, so to tackle this we would like to see a shorter period of validity of a TUE (two to four years max) with new recent information with a new application

### **Anti-Doping Norway**

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

This is not supported. The custodianship should normally be held by the ADO issuing the TUE. Not least, in light of the proposal in Concept #8

### USADA

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

USADA disagrees with an IF taking on custodianship or ownership of the TUE once the TUE is recognized. As a NADO, we work extremely closely with US athletes to manage TUEs and are most familiar with the US medical system and processes. TUE custodianship should remain in the hands of the entity that processed and granted the original TUE.

# **Canadian Centre for Ethics in Sport**

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO SUBMITTED

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The CCES disagrees with the concept that an IF should become custodian of TUEs once approved, as this could create confusion for athletes. Many athletes who are granted a TUE are not international-level athletes and therefore may be of little interest to the IF. Such a change could also impact smaller IFs negatively due to the administrative burden it may place on them.

That said, the CCES believes an athlete's TUE should be accessible (with read access granted at a minimum) to all ADOs with jurisdiction over that athlete (e.g. the NADO, the IF, any relevant MEO), with write access retained by the TUE custodian. Should an IF (or other ADO) require access to documentation submitted by the athlete (e.g. monitoring reports, etc.), a clear requirement for the custodian ADO to upload this documentation into ADAMS could be added to the ISTUE.

Not all athletes necessarily become International Level Athletes. We don't understand the necessity of monitoring all TUEs by IF. It is difficult to understand the issues with this concept. Please clarify the meaning of Custodian in TUE.

# Swiss Sport Integrity

Ernst König, CEO (Switzerland) NADO - NADO

As mentioned in Concept #6, SSI considers the proposal to be challenging. Especially since the ILA status is often only effective for a limited time. Example: The NADO approves a TUE for 4 years. After 2 years, the TUE is recognised by the IF for participation in a competition. The athlete then no longer participates in any international competitions and his ILA status expires after one year according to the definition of the IF. Nevertheless, the IF remains the "custodian" for the entire period. In principle, it should be reconsidered whether it is necessary to transfer the concept of the "custodian" from other areas to TUEs.

# Anti Doping Danmark

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

Not supported.

As above in #6 custodianship and monitoring should be in the hand of the issuing stakeholder and stay like that for the entire length of the TUE.

# **UK Anti-Doping**

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

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We oppose this proposal as it would be burdensome to operationalise and ultimately increase the workload of the ADOs involved without necessarily adding value. This especially holds true in scenarios whereby an athlete's competition status is fluid and TUE custody may have to transfer between ADOs on more than one occasion.

We are also not overly enamoured with this concept based on the way that athlete biological passports are often transferred between ADOs without communication meaning that the new Passport Custodian can inherit actions assigned to a passport that they are unaware of (that is, if this occurred with a TUE then the new TUE Custodian may not realise there were conditions to monitor).

It makes much more sense for the ADO who granted the TUE to maintain custody (and therefore responsibility for the monitoring of conditions associated with the TUE) until such a time as it expires. At which point, the IF should consider the renewal application and become 'custodian' if a new TUE is required and granted.

However, if the concept is to be developed further then the following points should be considered:

The resource requirements for monitoring conditions associated with a TUE (including chasing the athlete or their medical team) should not be underestimated by the ISTUE Drafting Team.

The IF would need to be responsible for communicating the change in TUE ownership to the athlete outside of ADAMS as many national-level athletes granted with a TUE do not have access to ADAMS.

An athlete's competition status can be fluid meaning that an athlete can often transition between national and international-level multiple times during the duration of a TUE – this concept does not currently accommodate for such fluidity of movement (that is, an athlete can return to national-level at which point the IF would be stuck monitoring the TUE as it appears custody cannot be transferred back to the NADO).

The functionality in ADAMS would need to be developed to cope with scenarios whereby an athlete's competition level changes from national to international level (or vice versa).

# RECOMMENDATIONS

1.

The ISTUE Drafting Team should not develop this concept further.

# 2.

The ADO who granted the TUE should remain as 'custodian' of the TUE until such a time as it expires (even when another ADO recognises the TUE).

# **International Testing Agency**

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

We believe that the initial granting organization should keep the custody. We do not see the benefit or reason for the shift to the IFs. Moreover, in case of automatic recognition, the IF doesn't even have access to the medical documentation, so it could not monitor the situation

# Concept #8 – Recognition for a Single Event (20)

# World Rugby

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

Please see our comments on concept #7.

# UEFA

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA does not support the development of this concept.

It would complicate things both for athletes and ADOs. If a TUE is recognised, it's recognised. The athlete may come back up to international level in the future and therefore need a second or third recognition for a 'single event'.

As per our comment for Concept #7, UEFA disagrees that the IF should 'own' the TUE following recognition anyway so this should not be an issue.

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

This assumes that the athlete knows to apply for a TUE in advance of playing in a one time international event. If they did not and returned an AAF then they could apply for a retroactive TUE. In these situations should a TUE be granted by the IF – as the athlete will return to a national level, then the mutual recognition should be reversed and the NADO should become the TUE custodian for the duration of the TUE.

# **Council of Europe**

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

# Not supported

This appears to be a database issue that does not require revision of the ISTUE. It will also complicate the process for athletes and ADOs.

# Anti-Doping Agency of Serbia

Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO

We support the ISTUE Drafting Team that IF become the TUE custodian for the duration of the TUE for lower-level athletes.

# **Anti-Doping Sweden**

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

ADSE encourage such a solution. However, since NADO's and IF's/MEO's approve a TUE based on the fulfillment of ISTUE article 4.2, there shouldn't be any problem to get a TUE recognized, lower-level athletes included. Regardless, it would be most appropriate with recognition for a single event and keep the NADO as the TUE custodian.

# Organizacion Nacional Antidopaje de Uruguay

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

ok Yes Allow a temporary authorization only for the Game in question. But oblige the athlete to present it within the days of the Game, the previous dates must remain under the ISTUE

# NADA

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

Recognition for a single event only could mean more administrative work and several formal recognition processes if an athlete participates in a second or in more events during the time his or her TUE is valid.

If this concept should be realized, a written formal process how to communicate this recognition for a single event by the IFs is needed (e.g. written information to the athlete, to the originally issuing NADO and documentation in ADAMS).

We suggest to add a possibility for IFs to recognize TUEs for single events retroactively after doping controls. This would ease the burden for the athletes who often have difficulties finding out if they belong to the group of

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international athletes in terms of their IF and if they have to contact their IF for recognition before an international competition. Furthermore, retroactive recognition will reduce administrative work for the IFs.

# Sport Integrity Australia<br/>Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia)SUBMITTEDWe do not agree the IF should become the TUE custodian for lower level athletes competing at single international<br/>events.at single international<br/>events.We are of the view the NADO TUE should be recognised and the NADO should remain the custodian of the TUE.<br/>However, if the IF jurisdiction over the athlete is ongoing, then the IF should become the custodian, considering the<br/>comments relevant to Concepts #6 and #7.SUBMITTEDDrug Free Sport New Zealand<br/>NADO - NADOSUBMITTED

**We partially support the concept.** We have the same concern around confusion for the athlete and consider that clear communication would be required. We also have reservations that these lower level athletes would have TUEs in-advance, or whether in reality, they will just be seeking an in-advance TUE in order to compete in the event (due to the IF requirement) which could push the administration for the TUE to the NADO when it otherwise wouldn't be required in-advance.

# **FINADA**

Anna Simula, Pharmacist (Finland) NADO - NADO

Supported.

# Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

An interesting issue, but difficult to pursue. A TUE must be "*medically justified*" and in our opinion, it is either that or not. So medically justified for one event is just not possible, because it contradicts the principle of TUEs.

# **Anti-Doping Norway**

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

Supported

### Canadian Centre for Ethics in Sport Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

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The CCES does not consider this concept to be an issue if the recognition process was automatic.

Should automatic recognition by an IF not be implemented, a TUE approval for a single event could be added by the IF as a "stamp" on the TUE certificate, with the event name and the dates for which the recognition would be valid.

Japan Anti Doping Agency YUICHI NONOMURA, Result Management (??) NADO - NADO	SUBMITTED
Agree with this concept.	
<b>USADA</b> Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO	SUBMITTED
In USADA's experience, because IFs have so many different definitions of an international-leal large issue) often lower-level athletes do not fall under their TUE jurisdiction and they want to responsibility down to the NADO. In practice, recognition for a single-event is not necessary, because the TUE is granted for a medical condition and for a specific duration. The TUE eith criteria or it doesn't. It is potentially confusing to ADOs and athletes that TUEs may be valid f for another. And as addressed above, automatic IF recognition should not come with automa Thus, there would be no disproportionate expenditure of resources by IFs if they do not have custodianship. Regarding perception, it is up to the IF to determine how they define internation they do not want lower-level one-time participants to be counted in their TUE numbers, then consider those athletes to be international-level athletes.	o push the TUE and makes no sense her meets the ISTUE for one event and not atic IF custodianship. e automatic onal-level athlete. If
<b>Swiss Sport Integrity</b> Ernst König, CEO (Switzerland) NADO - NADO	SUBMITTED
SSI recognises that certain athletes may only participate in a one-time international-level ever like to point out that athletes cannot foresee whether and how often they will take part in inter (especially with TUEs for several years). Should they participate in another international ever apply for recognition again. In addition to the administrative effort, this poses the risk of not a again, including the risk for an ADRV. Recognising the full duration would protect the athlete. to explain why the IF becomes the "custodian" if it only recognises the TUE for a single comp	rnational competitions nt, they will have to sking for recognition . You are kindly asked
<b>Anti Doping Danmark</b> Silje Rubæk, Legal Manager (Danmark) NADO - NADO	SUBMITTED
ADD does not see the problem – if an IF can recognize for a single event why not the full dur	ration?
<b>UK Anti-Doping</b> UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO	SUBMITTED
Our position remains that when an athlete requires their national-level TUE to be recognised recognition should continue to be given for the full duration of the TUE to avoid athletes need	

recognition request if they unexpectedly compete in more than one international event during the exemption period.

Furthermore, we do not view the issue presented in the concept paper to require revision of the ISTUE – it appears to be an issue created by the way WADA statistically report TUE data. We sympathise with the challenge of accurately determining the competition level of an athlete when they can transition between sub-national, national, and international-level multiple times during the duration of a TUE. However, this is impractical to track based on how the competition level of athletes is currently managed in ADAMS. Please see recommendation #3 below for a possible reporting solution based on this challenge.

Finally, the statement made in the concept paper that "The IF would also become the TUE custodian for the duration of the TUE" is illogical if this concept was to be further developed – that is, the concept proposes that the IF/MEO would only be recognising the TUE for a single event so the IF/MEO could not become TUE custodian in this instance if the TUE was not scheduled to expire immediately after the single event in question without shortening its duration.

# RECOMMENDATIONS

1.

The ISTUE Drafting Team should not develop this concept further.

2.

Recognition of a NADO granted TUE should continue to be for its full duration.

3.

WADA statistics should report on the number of athletes with a recognised TUE as a new group of athletes rather than counting them as either national or international level.

# **International Testing Agency**

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

We would rather propose that an athlete cannot be considered as "international level" for the purpose of TUEs for a single event and that therefore the national TUE is valid. This would entail modifications on the definitions of international level athlete in a harmonized way across the IFs. Moreover, in our experience, the issue rather arises when the national-level athlete does not hold a TUE and participates in an international event and tests positive. These circumstances trigger retroactive TUE issues.

# Concept #9 – Consequences (20)

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

We would agree with this proposal. Appropriate consequences would seem to need to be something like a WADA expert overseeing the TUE committee of the ADO for a set period of time (e.g. 6 months).

# International Tennis Integrity Agency

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

The concept implies that it is the ADO making poor decisions - surely it is the TUEC that is doing this. Punishing the ADO seems unfair. The consequences should be for TUEC which will be enforced by the ADO. A review of what

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drove the TUEC to that decision should clearly be undertaken before an immediate consequence is imposed. Similar to the other compliance approach – a warning should be issued, with remedial action taken by the ADO/TUEC and then consequences if the poor decision making continues.

**UEFA** Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA supports the development of this concept.

UEFA recommends education rather than sanctioning, however, the right to grant TUEs could be removed from an ADO if consistently bad decisions are made.

Sport NZ

Jane Mountfort, Principal Policy and Legal Advisor (New Zealand) Public Authorities - Government

This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.

Sport NZ seeks more information on the likely efficacy of cost consequences as a lever to improve ADO decisionmaking on TUE applications. WADA providing greater support to repeatedly offending ADOs could be a more effective lever.

## Council of Europe

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

# Supported

However, this would be better managed with education as opposed to financial penalties.

#### COCOM

Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO

L'ONAD est le lien entre l'athlete et la CAUT donc je ne comprends pas comment nous pourrions rendre de mauvaises décisions vu que c'est la CAUT qui fixe les décisions.

#### Anti-Doping Agency of Serbia

Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO

We agree with this concept.

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

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

SUBMITTED

SUBMITTED

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SUBMITTED

ADSE agrees that there should be consequences apart from the compliance process. An extension of discretionary reviews according to ISTUE article 8 is a suggestion ADSE supports.

Organizacion Nacional Antidopaje de Uruguay José Veloso Fernandez, Jefe de control Dopaje (Uruguay) NADO - NADO	SUBMITTED
OK. The proposal is supported	
<b>Sport Integrity Australia</b> Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO	SUBMITTED
We agree in principle that there should be consequences imposed on TUECs for 'poor performance'	
Possible remedies could include training and education from another TUEC at the cost of the TUEC 'poor TUE decisions' or even removing the function to another 'competent' TUEC. However, this solution impacted due to different medical practices around the world.	
Drug Free Sport New Zealand Nick Paterson, Chief Executive (New Zealand) NADO - NADO	SUBMITTED
<b>We support the concept</b> that there needs to be consistency in approach to the quality of TUEs and processes. We consider that the first approach should be education, training and support and followi compliance consequences are appropriate. Out-sourcing of TUEs to a more compliant organisation r possibility but we acknowledge the associated cost for smaller NADOs.	ng this, non-
Dopingautoriteit Robert Ficker, Compliance Officer (Netherlands) NADO - NADO	SUBMITTED
It would be good to do this (see also our extra suggestion).	
Anti-Doping Norway Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO	SUBMITTED
We agree that consequences such as reimbursing WADA for cost incurred by WADA in respect of re (including discretionary reviews) could be an option for poor TUE decisions. However, it is our under this is already an option in today's ISTUE (cf. ISTUE article 8.9). We do recognize that this does not ADOs being non-responsive to WADAs queries and suggestions, and we could support broadening t art. 8.9 to also cover those situations.	standing that cover cases of

If art. 8.9 (possibly in an amended form) does not sufficiently satisfy the need of WADA, we would ask for clarification of what situations would not be covered by today's rules. Consequences of a punitive character (i.e. going beyond reimbursement of incurred costs) should be restricted to consequences for non-compliance, including e.g. supervision and takeover of the TUE-administration by a WADA appointed third party.

## USADA

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

USADA fully supports giving WADA more ability to impose consequences on specific ADOs with regard to poor TUE processes.

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# Japan Anti Doping Agency

YUICHI NONOMURA, Result Management (??) NADO - NADO

We do not agree. Because, there are different languages and medical problems in each country. It is understandable what you are saying, but, it would be better to clarify the issues what WADA is facing with regard to this concept.

# SUBMITTED **Canadian Centre for Ethics in Sport** Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO The CCES does not believe that extending Article 8.8 to discretionary reviews would be the best way to address such actions. While the CCES supports WADA's desire to address repeated poor TUE decisions by ADOs, the CCES believes that the compliance audit process and the related correctives actions should be the mechanism to address such concerns. Depending on the circumstances leading to the repeated poor decisions (e.g. lack of resources or understanding vs deliberate actions or omissions), the CCES suggests WADA initially addresses these issues by providing more guidance and support to the ADO. A monetary fine would not necessarily help organizations with fewer resources to improve their practices, but if the issues stem from a deliberate attempt to abuse the system, then the compliance system should be utilized with fines incorporated as a last resort. SUBMITTED Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NADO This could be covered in the International Standard for Code Compliance instead of the ISTUE. SUBMITTED Anti Doping Danmark Silje Rubæk, Legal Manager (Danmark) NADO - NADO ADD has no problem with consequences if a stakeholder does not respond to WADA's queries and suggestions. SUBMITTED **UK Anti-Doping** UKAD Stakeholder Comments, Stakeholder Comments (United Kingdom) NADO - NADO We support the further development of this concept. However, two issues appear to have been raised by the ISTUE Drafting Team which we believe require different consequences (and solutions):

An ADO TUEC is underperforming - it is likely in this circumstance that the knowledge level of the TUEC is not to the required standard and would benefit from increased support and education from WADA rather than for the ADO to suffer consequences that are punitive in nature. Expanding ISTUE Article 8.8 to include discretionary reviews by WADA does not go far enough as WADA should review all decisions made by the underperforming TUEC for a defined period to improve standards (without necessarily charging the ADO for this support).

An ADO is unresponsive to WADA queries and corrective actions/suggestions - WADA should deal with this situation as part of their compliance process.

## RECOMMENDATION

1.

The ISTUE Drafting Team should continue to develop this concept.

# International Testing Agency

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

We support the review of the expansion of article 8.8. ISTUE to address the circumstances described.

# Concept #10 – Lower-level Athletes (24)

#### World Rugby

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

We would support the principle of this, however we would need to be careful that we were not trying to capture too many athletes within this lower class of athletes. The definition of 'lower-level' would need clarification and may vary by sport/country etc.

#### NZ Rugby

Rebecca Giordano, Senior Legal Counsel - Regulations & Compliance (New Zealand) Sport - Other

We support allowing ADOs the ability to apply different rules to a designated class of lower-level athletes. The current rules are too onerous for recreational athletes.

#### **UEFA**

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA does not support the development of this concept.

NADOs already have the possibility to allow retroactive approvals for lower-level athletes. Introducing flexibility to the submission of medical information would complicate things. It is unclear what flexibility lower-level athletes would be permitted. To have a TUE without a diagnosis? To not provide the minimum medical information? It would also be complicated if they progress up the ladder to National/International level.

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

The ITIA is very supportive of the ability to flex the definition of who needs a TUE in advance. Thought would have to be given to the definition/level to which this would apply. As an example, more lenience could perhaps be given about applying for a retroactive TUE for athletes competing at a certain level within the sport. Appreciating that lower level athletes are not frequently tested – there may be conditions that could be imposed on a TUE application that are significantly less onerous but at least discharge the burden that rests with the athlete to demonstrate they were taking the substance legitimately. To now impose any TUE requirement on a lower level athlete undermines the rules and the reasons why TUEs exist.

#### **Sport NZ**

Jane Mountfort, Principal Policy and Legal Advisor (New Zealand) Public Authorities - Government

This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.

Sport NZ supports lower-level athletes being subject to different TUE rules for the reasons suggested (including the more limited reach of anti-doping education).

**Council of Europe** 

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

#### Not supported

This create a "two-tier" system and could result in athletes competing against each other who were subject to a different set of TUE requirements at the time of application. It could also lead to disputes between IFs and NADOs. Furthermore, Article 4.3 already affords this flexibility within the system.

## COCOM

Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO

En faveur

Anti-Doping Agency of Serbia

Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO

We do not agree with this concept, and we believe that the TUE rules apply to all athletes equally.

#### Anti-Doping Sweden

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

ADSE supports this suggestion. When it comes to the ISTUE criteria 4.2 (c), and the discussion regarding

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permitted therapeutic alternatives, this rarely happens for lower-level athletes. Largely due to not receiving any formal anti-doping education. Hence, our suggestion is that a TUE application should be approved with more flexibility to the ISTUE 4.2 criteria or a possibility to apply different rules for this designated class of athletes. Guidance for how to determine the class of lower-level athletes is needed for a harmonized approach in between ADO's.

<b>Organizacion Nacional Antidopaje de Uruguay</b> José Veloso Fernandez, Jefe de control Dopaje (Uruguay) NADO - NADO	SUBMITTED
No comments.	
NADA	SUBMITTED
NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO	
NADA CED would welcome to have the peoplicity to apply different rules to lower level ethet	as in terms of THE
NADA GER would welcome to have the possibility to apply different rules to lower-level athlete applications.	

## **NADO Flanders**

Jurgen Secember, Legal Adviser (België) NADO - NADO

NADOF is not in favor of creating a different TUE for recreational athletes, but is in favor of some added flexibility in assessing a retroactive application in general, and especially for lower level athletes. There should be more flexibility in assessing the criterium of the reasonably permitted alternatives and the necessary diagnostic investigations in cases of lower level athletes. This should especially be seen In light of the potential to enhance performance. An Athlete of lower level who seeks medical advice relies on the assistance of a general practicioner rather than a specialised sports physician. When assessing a retroactive application of a lower level athlete, in particular following an Adverse Analytical Finding, the athlete has already relied on the doctor, and is not able to change the past. It should in exceptional circumstance be allowed that this criterium has some flexibility for lower level athletes. This can be done either by specifying in article 4.2, in a separate provision for athletes who are not under the obligation to apply for a TUE prospectively or are not allowed to do so, or by placing this as a clear case of fairness, which can be elaborated for this purpose.

It should however be conditional: if for example non prohoibited alternatives exist, the athlete should consider reevaluating the treatment, and should only be permitted to use this for a specified short period connected to the AAF finding.

#### **Sport Integrity Australia**

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO

We agree in principle that lower-level athletes should be given more flexibility in the anti-doping system to take into account their level of competition, knowledge and understanding of anti-doping rules and reasons for participation.

However, we disagree that lower-level athletes should be subject to more flexible rules for granting TUEs. Changes would likely impact the standardisation of the process and create another inconsistency or complexity.

If an athlete is subject to anti-doping rules, then they should not be allowed to use a Prohibited Substance unless properly permitted to do so in accordance with Art. 4.2 of the ISTUE. A substance is included on the Prohibited List for strict reasons. It should not then be permitted for use simply due to the athlete competing at a lower level. The prioritising of testing and the sanctioning regime under the Code is the most appropriate way to deal with these situations.

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Any changes would need to consider the recognition process across ADOs – we would be uncomfortable with a change that allowed "lesser" approaches to TUEs but required other ADOs to recognise those decisions.

# Drug Free Sport New Zealand

Nick Paterson, Chief Executive (New Zealand) NADO - NADO

**We support the concept** and will be able to provide further comment as additional information becomes available. These athletes may not have been educated and often do not have access to sport physicians or support personnel with awareness of the anti-doping regime.

We envisage that all elements of ISTUE Article 4.2 need to be met so query where the flexibility would be applied.

Questions arise for us:

- Would it be a question of the quality of medical notes and care? Whether or not there would be flexibility in terms of meeting the medical notes in the TPG to establish diagnosis?

- Would this only apply to recreational athletes only or anyone below NLA/ILA?

- Could it act similarly to fairness TUEs considered at full discretion of the NADO?

Consideration is required around how an approved TUEs for low-level athletes would be treated should the athlete transitions into NLA/ILA level (i.e., would a fresh TUE application be required). There should also be suitable parameters in place to ensure this isn't a provision that can be abused for lower level athletes to dope.

#### **FINADA**

Anna Simula, Pharmacist (Finland) NADO - NADO

This is supported.

#### Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

Again an interesting concept. Positive about it is that I would be easier to deal with lower level athletes and it does give some well-needed flexibility. However, since all TUEs must be recorded into ADAMS there is a risk that this leads to disputes between IFs and NADOs.

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

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

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This is supported. In Norway, we test all athlete levels. When a lower-level athlete tests positive for a prohibited substance due to legitimate use of medication, he/she is allowed to apply retroactively. By the review of the applications, our TUEC follows the same rules and guidelines that apply for national- and international level athletes. However, many lower-level athletes are not aware of the strict rules. They therefore cannot always meet the criteria in ISTUE 4.2 (most notably 4.2 c) related to having tried out permitted therapeutic alternatives, which poses challenges for retroactive applications), and the consequences might be an ADRV. An extra flexibility in the regulations is therefore welcome. Flexibility should, however, entail a condition that the exemption is, for example, only valid at a lower level (not at national/international level) or for a very limited period of time so that the athlete

can have the opportunity to fulfill the four criteria in the future.

# Japan Anti Doping Agency

YUICHI NONOMURA, Result Management (??) NADO - NADO

We agree with this concept.

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

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

The CCES agrees with the concept of affording extra flexibility to lower-level athletes when ISTUE regulations apply.

Again, the CCES has already adopted a similar practice with its Medical Review process, which applies to Student-Athletes in Canada. The Medical Review process is less extensive than the TUE application process, providing athletes with a one-time retroactive medical exemption when the athlete can satisfy all of the following conditions:

- Demonstrates by means of appropriate documentation that they have a medical diagnosis made by a licensed physician prior to sample collection:
- Has a prescription signed by a licensed physician prior to sample collection which is consistent with the finding; and
- Provides appropriate confirmation that they are being followed and monitored by a licensed physician to ensure the treatment plan matches the diagnosis.

While the CCES supports the current TUE regime, when it comes to athletes below the national level, adopting more lenient rules would still provide adequate protection against misuse but would be more athlete-centered.

Lastly, and guite importantly, consideration should be given to whether the full TUE requirements should remain for some substance classifications (e.g. S1 and/or S2), regardless of the athlete's level.

# **Swiss Sport Integrity**

Ernst König, CEO (Switzerland) NADO - NADO

Through the retroactive applications of lower level athletes (Art. 4.1 c/d), limited resources can already be protected. The requirements for obtaining a TUE (fulfilment of Art. 4.2 a-d, physician guidelines and checklists) should be the same for lower level athletes as for ILA or NLA. It would be unfair for NLA and ILA if a lower level athlete had received a prospective TUE (at his own request and not because he was obliged to do so) with reduced requirements and later becomes NLA or ILA and the TUE remains valid.

**USADA** 

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

**USADA Comments:** 

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

# **Proposed Solution:**

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

# Rationale:

- 1. Many national sport federations and/or governments desire to stop doping at all levels of competition and some even outside of competitions (i.e., fitness centers). National Federations and/or governments require all members of national sport federations to be bound by the Code. These federations/governments also want to deter doping at all levels of competitions through testing, but bringing the full weight of the ISTUE on lower-level athletes, including masters' athletes, is not necessary to protect this level of competition and is not fair/feasible given the number of athletes who compete at these lower levels.
- 2. Several ADOs, including USADA, have already implemented, without objection from WADA, different rules for a designated class of lower-level athletes. The way these rules have been employed is tailored to the needs within the country. ADOs create a more efficient review process but nevertheless maintain sufficiently robust safeguards to ensure doping is not permitted.

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

#### Anti Doping Danmark

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

ADD does already use some extra flexibility on lower-level athletes and recreational athletes when these athletes are applying for a retroactive TUE when tested positive for medication.

But with a short-term TUE for the testing date and the athlete is asked to revise his/her medication and try permitted medication if possible.

The problem with concept #10 is what happens if the athlete who has a TUE on 'flexible terms' becomes an elite athlete. ADD always process standard applications without considering the level of the athlete.

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

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

We are not in favour of affording extra flexibility when applying ISTUE Article 4.1 and 4.2 regulations to lower-level athletes as this may unintentionally create a "two tier" system. There is a danger that a lower-level athlete is granted a TUE against a "softer" set of rules, and then they transition to compete at a higher level. This could result in athletes competing at the same level but have been subject to different TUE requirements at the time of their respective applications. Indeed, it is not uncommon in paralympic sports that an athlete can very quickly transition from being relatively unknown to medalling at an elite competition.

We believe that the necessary flexibility already exists within the system to deal with lower-level athletes sensitively. That is, such athletes i. do not need to apply for a TUE if they are not within a NADO "sport prioritisation" group; and ii. can apply for a Fairness TUE under ISTUE Article 4.3 if their TUE application does not fulfil the conditions outlined in Article 4.2.

We propose that a better way to deal with the issues raised in this concept would be to expand the comment to Article 4.3 to include competition level as a relevant factor when assessing TUE applications on the grounds of fairness for lower-level athletes. Furthermore, extra flexibility could be afforded to the sanctioning of lower-level athletes within the Code in instances whereby an application does not satisfy ISTUE Article 4.2 or 4.3 but the athlete has a therapeutic need.

# RECOMMENDATIONS

1.

Lower-level athletes should not be afforded extra flexibility when applying ISTUE Article 4.1 or 4.2 regulations.

2.

The ISTUE Drafting Team should explore expanding the comment to Article 4.3 to mention lower-level athletes.

3.

The Code Drafting Team should explore introducing flexibility to the sanctioning in such cases within the Code (when Use is related to a therapeutic need). Please refer to UKAD's WAD Code submission in relation to concept 4.

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

We agree with the review of this concept and the increased flexibility for lower-level athletes.

# Concept #11 – Appeal Panels (23)

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

We agree that this would seem a logical change.

# UEFA

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA supports the development of this concept.

UEFA agrees with the proposal of WADA to make it mandatory that at least one member of a TUE appeal panel must be a physician.

International Tennis Integrity Agency Nicole Sapstead, Senior Director, Anti-Doping (United Kingdom) Sport - Other
The ITIA supports this proposal.
Sport NZ Jane Mountfort, Principal Policy and Legal Advisor (New Zealand) Public Authorities - Government
This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.
Sport NZ supports physicians being part of a TUE appeal panel.
Council of Europe     SUBMITTED       Council of Europe, Sport Convention Division (France)     Public Authorities - Intergovernmental Organization (ex. UNESCO, Council of Europe, etc.)
Supported An appeal panel should consist of (at least) one physician, so it would be good if this is formally addressed.
COCOM Stephanie Sirjacobs, Legal adviser (Belgium) NADO - NADO
Déjà le cas chez nous, cette pratique devrait être encouragée.
Anti-Doping Sweden Jessica Wissman, Head of legal department (Sverige) NADO - NADO
ADSE support the suggestion to include at least one physician/person with medical expertise in the appeal body. There is a need for this competence to fully understand the medical point of view in a TUE case.
Organizacion Nacional Antidopaje de UruguaySUBMITTEDJosé Veloso Fernandez, Jefe de control Dopaje (Uruguay)NADO - NADO
No comments
Agence française de lutte contre le dopageSUBMITTEDAdeline Molina, General Secretary Deputy (France)NADO - NADO
Ce concept n'est pas pertinent car il ne prend pas en compte la diversité des instances d'appel des décisions d'AUT. En France, l'instance d'appel est le Conseil d'Etat, qui est une juridiction ne comprenant pas de médecin. Si la compétence médicale est importante, elle doit être assurée soit par la présence de médecins dans la formation, soit par la possibilité pour l'instance d'appel de solliciter une expertise médicale pour éclairer sa décision. Les deux options doivent être laissées ouvertes pour s'adapter au contexte national.

NADA SUBMITTED   NADA Germany, National Anti Doping Organisation (Deutschland) NADO - NADO
NADA GER welcome the consideration to include physicians in TUE appeal panels.
Submitted Submit
We agree TUE Appeal Panels should include a physician.
The structure and operation of the Australian National Sports Tribunal (NST) provides a good example of how panels should be constructed and implemented.
Drug Free Sport New Zealand   SUBMITTED     Nick Paterson, Chief Executive (New Zealand)   NADO - NADO
We support this concept.
The TUE application process involves a committee with a full understanding of the ISTUE and we consider that the appeal process will frequently require a similar type of expert knowledge. Otherwise, there is the potential for appeal decisions made that do not properly apply the ISTUE considerations.
FINADASUBMITTEDAnna Simula, Pharmacist (Finland)NADO - NADO
We see the benefit in having a person with a medical background involved in the assessments of TUE appeals, however, they could also be involved by providing expert assessment.
Dopingautoriteit   SUBMITTED     Robert Ficker, Compliance Officer (Netherlands)   NADO - NADO
Robert Ficker, Compliance Officer (Netherlands)
Robert Ficker, Compliance Officer (Netherlands) NADO - NADO It should be required that there is at least a physician in an Appeal Panel. However, for the rest it should be left to the different organizations, since there should also be a place in Appeal panels for (for instance) scientists, lawyers

Canadian Centre for Ethics in Sport Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

The CCES agrees with the recommendation to include physicians on TUE appeal panels.

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Japan Anti Doping Agency YUICHI NONOMURA, Result Management (??) NADO - NADO

It is understandable for this concept. We think that adding a physician for an appeal panel would be a good idea. However, considering the circumstances of each country, it should be made as "strongly recommended" as opposed to "mandatory" at this point. It could be possible to reconsider to make it mandatory for the next edition of update (after 2027)

# **Swiss Sport Integrity**

Ernst König, CEO (Switzerland) NADO - NADO

SSI welcomes the proposal that physicians should be part of the TUE appeal panel (for the evaluation of Art. 4.2). Please specify why the system for appeal bodies should only be harmonised for ILA and NLA. Rejections of retroactive applications also tend to be appealed and the same professional qualification should be applied to these cases.

# USADA

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

USADA does not support having a physician on an appeal panel. It is the role and responsibility of arbitrators and judges around the world every day to assess complex scientific and medical matters based on expert testimony and submissions by the parties. There is no reason that arbitrators in the anti-doping context cannot rise to the challenge with respect to TUEs. Anti-doping arbitrators already address complex scientific matters with respect to anti-doping cases, whether it be challenges to analytical methods at laboratories, ABP cases, or understanding the pharmacokinetics of certain substances. USADA, of course, supports physicians providing their expertise to appeal panels to be able to make well informed decisions on challenges to TUEs. But, generally speaking, physicians are not well versed in the legal aspects of arbitrations, including procedural issues and award drafting. Thus, having a physician as a member may in many respects be wasteful of the physician's time and require extensive training or explanations by the other panel members during the process.

Anti Doping Danmark Silje Rubæk, Legal Manager (Danmark) NADO - NADO

This is a good idea. Maybe the physician could be appointed to the Appeal Panel on an ad hoc basis.

# **UK Anti-Doping**

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

We support the further development of this concept and question how a TUE Appeal Panel, without an experienced

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physician, can i. determine if ISTUE Article 4.2 has been fulfilled; or ii. challenge the original TUEC decision (comprised of three physicians).

We also believe that i. members of a TUE Appeal Panel should be reviewing TUE applications on a regular basis to maintain their proficiency; ii. the composition of the Appeal Panel should ideally mirror the experience and expertise of the first TUEC review panel; and iii. in cases where specific expertise (e.g. psychiatry) is required, at least one member should possess such expertise.

#### RECOMMENDATION

1.

The ISTUE and Code Drafting Teams should continue to develop this concept.

#### **Sports Tribunal New Zealand** Helen Gould, Registrar (New Zealand) Other - Other (ex. Media, University, etc.)

We agree with this in principle but if this requirement is included in the Code, then it might be helpful to specify the level or area of expertise of the physician.

#### International Testing Agency

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

We believe that this is already covered by the possibility to appoint experts to assist the panel. TUE appeals require the expertise of a physician specialized in the field of the disease/treatment at stake. It seems unlikely and ineffective to appoint to panels a wide number of physicians to cover all treatments.

# Concept #12 – Sanctions for athletes who fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE (22)

#### World Rugby

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

We would support any revision that would prevent athletes receiving excessive sanctions for what are technicalities or innocent mistakes where there is clear evidence of medical history/need and appropriate treatment, but the athlete has not met the TUE criteria.

#### **UEFA**

Rebecca Lee, Anti-Doping Team Leader (Switzerland) Sport - Other

UEFA supports the development of this concept.

UEFA agrees that excessive and disproportionate sanctions may be given in cases of non-applicable retroactive TUEs while the conditions for the TUE to be granted are fulfilled. A flexible approach is desirable.

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

Sport - Other

There is a need to strike the right balance of ensuring that players follow the anti-doping rules; however, the impact of an 'administrative' breach needs to be proportionate. In the ITIA's experience, 90% of these cases are due to an administrative failure. Low level players shouldn't be facing up to 4 years for not submitting an ADHD medication application prospectively. There could be a standalone approach to ADHD medication and applications that means that if an athlete meets the criteria for being granted a TUE prospectively but does not have one in place for their AAF a different approach can be taken by the ADO. Sometimes the very nature of ADHD means that athletes forget or are not on top of the need to apply for a TUE in advance of taking their ADHD medication. This also means that the placing of the substances on the WADA Prohibited List should reviewed as some amphetamines sit within the specified stimulant category and others the non-specified stimulant category. This makes a significant difference to the potential sanction a player faces who has not successfully been granted a TUE retroactively for their ADHD medication. All amphetamines used in the treatment of ADHD should be treated the same/fall within the same category/sanction

Sport NZ

Jane Mountfort, Principal Policy and Legal Advisor (New Zealand) Public Authorities - Government

This submission is made on behalf of Sport New Zealand, which is the Crown agency responsible for advising the New Zealand government on anti-doping policy and ensuring New Zealand's compliance with the International Convention against Doping in Sport 2005.

Sport NZ supports a review of sanctions for athletes who would be eligible for a TUE but do not meet criteria for a retroactive TUE, to engender a result more proportionate to the harm.

# **Council of Europe**

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

# Supported

Anti-Doping Agency of Serbia Bojan Vajagic, Director's Assistant (Serbia) NADO - NADO

We agree with this concept and we believe that the sanctions should be lighter for these athletes.

# Anti-Doping Sweden

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

ADSE agrees with the concept. If an athlete has a clear medical condition and appropriate treatment the possible sanction should be lower.

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

SUBMITTED

SUBMITTED

SUBMITTED

SUBMITTED

We understand that it should be discussed in more depth by the Expert Groups.

#### NADA

SUBMITTED

SUBMITTED

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

If ISTUE Article 4.2 conditions are satisfied but an athlete's TUE application does not meet the requirements for a retroactive TUE for their positive test, there is still the possibility to consider a Fairness TUE according to Article 4.3.

**NADO Flanders** 

Jurgen Secember, Legal Adviser (België) NADO - NADO

This should be evaluated toghether with more guidance on how to apply ISTUE article 4.3, since this fairness clause would already allow to consider a TUE under fairness. Only if fairness is not possible, the flexibility can be applied.

# **Sport Integrity Australia**

Chris Butler, Director, Anti-Doping Policy and International Engagement (Australia) NADO - NADO SUBMITTED

We agree there should be flexibility in sanctioning where there is 'no fault/no significant fault'.

For example, there could be leniency in sanctioning if the Athlete has a diagnosed medical condition, can produce sound medical evidence but does not meet any of the retroactive TUE criteria. The NADO could impose a lighter sanction i.e. a warning in the first place followed by a sanction for a second offence.

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

SUBMITTED

Drug Free Sport New Zealand Nick Paterson, Chief Executive (New Zealand) NADO - NADO

**We support this concept**. There are situations where an athlete has not been educated or has otherwise not sufficiently understood their TUE obligations, and a lengthy sanction from sport is disproportionate in the circumstances. We consider that the most robust way to deal with this is through inclusion in the ISRM provisions for sanction reductions (e.g., as an example to qualify for no-significant fault or negligence), as opposed to it being grounds for a retrospective TUE to be granted under the ISTUE. This would involve TUEC evidence that Article 4.2 of the ISTUE is satisfied (and 4.2 must be satisfied as a pre-condition for reprimand and no sanction). This would achieve robustness and increased consistency in its application, and would not undermine the intent behind an in-advance TUE requirement. This sanction reduction flexibility should be available to retrospective or in-advance athletes.

We also consider that clarification is required around when a situation is appropriate for a fairness TUE application under Article 4.3 compared with a reduction in sanction scenario (e.g., where a competition result could also be disqualified).

**FINADA** Anna Simula, Pharmacist (Finland) NADO - NADO

This suggestion is highly supported as in some cases current system doesn't give enough of flexibility - for example in cases where athlete has a legitimate medical reason to use prohibited substance and would satisfy the ISTUE 4.2 requirements but hasn't applied prospective TUE (or TUE has expired). In some cases current sanctions are often undue.

# Dopingautoriteit SUBMITTED Robert Ficker, Compliance Officer (Netherlands) NADO - NADO We will elaborate on this in our comments regarding the Code SUBMITTED Anti-Doping Norway Martin Holmlund Lauesen, Director - International Relations and Medical (Norge) NADO - NADO TUEs are meant to ensure, that those athletes who have a legitimate therapeutic need for substances and methods on the prohibited list, where this would not give them a competitive/performance enhancing advantage above their normal state of health. In light of this, we fully support the proposed increased flexibility in the sanctions for those athletes who would have been eligible for TUEs had they received it proactively but are not eligible for retroactive TUEs. While some sanction may be appropriate, a sanction of up to 4 years seems excessive. SUBMITTED **Canadian Centre for Ethics in Sport** Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO The CCES agrees that when a TUE application meets all 4.2 criteria, but unfortunately does not meet any of the retroactive grounds, the current sanctions are excessive and disproportionate. The CCES suggests that in such cases, an ADRV is still confirmed, but that any corresponding sanction be minimal (with the option for no sanction at all). The CCES wonders whether the provisions similar to those utilized for Substances of Abuse could be replicated in some manner to address such situations. Certainly, the CCES understands the need for consequences when athletes do not follow the rules, but when all proper medical justification has been provided and the athlete's error is "administrative" in nature, applying the same sanction that would apply to an athlete who used a substance for performance enhancing reasons or without any supporting documentation seems disproportionate to the offence. SUBMITTED Swiss Sport Integrity Ernst König, CEO (Switzerland) NADO - NÃDO SSI agrees that in some cases the sanctions might not be appropriate. Consequently, we also support the proposals in Concept #4 of the Code Concept Paper. SUBMITTED USADA Allison Wagner, Director of Athlete and International Relations (USA) NADO - NADO

In cases where the Athlete is clearly not intending to cheat and been prescribed a life-saving medication (e.g., insulin) legitimately by a physician to treat a diagnosed medical condition that happens to be a non-specified substance, the rules require more flexibility to grant retroactive TUEs in these cases without having to go to WADA under 4.3. Athletes should not be penalized disproportionately for honest administrative errors or oversights when clearly there is a therapeutic need and there is no intent to enhance performance. This is particularly important for prescription medications that are for chronic conditions such as insulin (diabetes) and diuretics (hypertension) and for athletes that have received limited education.

As indicated in USADA's comments to Code Concept #4, USADA proposes carving out an exception to the restriction of 10.6.2 (as was done with the addition of Article 10.6.1.3) to allow athletes who have received a prospective TUE to be eligible for at a minimum a reprimand and at a maximum a two-year period of ineligibility.

Japan Anti Doping Agency

YUICHI NONOMURA, Result Management (??) NADO - NADO

We also considers it a matter of concern that the current sanctions in the circumstances referred to are excessive and disproportionate. A reduction in the degree of sanction or a revision of the rules not to treat such scenario case as an ADRV might be desirable. For example, to extend the conditions of application of the rules in paragraph 4.1.b of ISTUE. Other option might be that the case "fulfill the ISTUE Article 4.2 criteria but do not meet the criteria for a retroactive TUE" will be treated as "No Significant Fault or Negligence" under WADC art.10.6.2.

# Anti Doping Danmark

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

Clarification on sanctions and examples would be helpful.

UK Anti-Doping

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

We support the further development of this concept which would lead to more proportionate sanctioning of such athletes who have not fulfilled their anti-doping obligations (that is, by not obtaining a TUE in advance of Doping Control) but who have a therapeutic need for treatment.

#### RECOMMENDATION

# 1.

The ISTUE and Code Drafting Teams should continue to develop this concept

# International Testing Agency

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

We support this initiative and have filed comments in Concept # 4 of the Code Concept Paper.

# Other Comments / Suggestions (12)

SUBMITTED

SUBMITTED

SUBMITTED

SUBMITTED

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

# Comment #1

Transfer of TUEs between NADOs when athlete jurisdiction changes.

# Comment #2

More clarity on the issue of other organisations (IF's, non-signatories) referring to NADOs for TUEs.

## Comment #3

A lot of the information should be available on the website of IF's (such as Registered Testing Pools, International Events). In practice however, this is not always the case. It is often very hard to find, or not available at all. There are already provisions in the Code and ISTUE that require this, but in practice this is a void where both athletes and NADOs suffer from a lack of compliance monitoring from WADA. We strongly suggest using more imperative wording, and sanctioning, if IFs do not fulfil their obligations.

## Comment #4

Clarification on the end date of a TUE (see also concept #1)

#### Comment #5

Monitoring of TUEs (addition of a new provision within the ISTUE that treatment monitoring if the responsibility of ADOs).

#### Comment #6

The ISTUE only speaks of "physician" and this leads to discussion with non-physician medical practitioners, like psychologists and nurse practitioners) A clarification is needed, or the term "general practitioner" on the form needs to be changed in "physician".

#### Comment #7

Continual professional development for TUECs (WADA task; Potentially something for into the ISE)

#### Comment #8

Informing Laboratories on TUEs; this could potentially be an issue for the ISL.

#### Anti-Doping Sweden

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

#### **ISTUE** article 4.1

Currently it is not expressly stated in ISTUE that an athlete is able to appeal an ADO's decision to NOT let the athlete apply for a TUE according to the 4.1 criteria. The possibility to appeal should be clarified in ISTUE.

# **ISTUE** article 4.3

The review process of retroactive TUE's based on ISTUE article 4.3 should be clarified/specified in more detail, especially with regards to the time limit for WADA to give its reasoned decision (approval/denial) after ADO's conditional approval. More examples of how and when article 4.3 can be applied would be helpful.

## **ISTUE** article 5.2

According to ISTUE article 5.2, a TUE granted by a NADO is valid at national level on a global basis, hence there is mutual recognition of TUE's between NADO's. ADSE suggest the possibility for NADO's to appeal a TUE approved by another NADO similar as with a TUE approved by an International Federation. This process would apply to athletes that is of the same nationality as the NADO but the athlete is living and competing abroad.

# **ISTUE** article 5.7

This article should be amended and emphasize that the IF's are obliged to have easy accessible and clear instructions on their website of what they define as International Level Athlete/automatic recognition. It is time consuming for both NADO's and athletes to navigate IF's websites to find the correct information.

**Organizacion Nacional Antidopaje de Uruguay** José Veloso Fernandez, Jefe de control Dopaje (Uruguay) NADO - NADO

None

#### NADA

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

Proposal for Art. 4.2:

We propose to amend Article 4.2 a) with the information that a TUE may also be granted if an athlete donates tissue or cells for humanitarian reasons and if prohibited substances or methods are routinely used for this donation (e.g. aphereses for the donation of peripheral stem cells).Donations are not yet covered by the ISTUE Article 4.2 as they are not needed to treat a diagnosed medical condition of the athletes themselves and are also not part of a necessary diagnostic investigation.There are already concerns from international organisations such as DKMS Group gGmbH and World Marrow Donor Association that the current provisions may precent athletes from donations for humanitarian reasons.

Proposal for Art. 6.13:

Article 6.13 should be transferred to the ISRM as it deals with the handling of AAFs with respect to expired TUEs and its Consequences in teh Results Management process.

#### **Drug Free Sport New Zealand**

Nick Paterson, Chief Executive (New Zealand) NADO - NADO

We propose the addition of a maximum time permitted for a retroactive TUE application to be submitted after being made aware of an AAF (4.1c & d) (also to be included in ISRM), such as 20 days.

Currently, there is nothing concrete to support the NADO when liaising with an athlete other than a 'reasonable timeframe' in the ISTUE Guidelines to justify pursuing RM when a retroactive TUE is incomplete. Reasonable is subjective and can cause months of waiting for medical information causing stress for all parties.

SUBMITTED

SUBMITTED

We also propose clarification of what sort of practitioner is expected to have diagnosed an athlete of the medical condition in Article 4.2(a).

## Dopingautoriteit

Robert Ficker, Compliance Officer (Netherlands) NADO - NADO

#### • Better monitoring by WADA on the information on IFs websites.

Not specifically a ISTUE problem, but a lot of the information should be available on the website of IFs (such as Registered Testing Pools, International Events). In practice however, this is not always the case. It is often very hard to find, or not available at all. There are already provisions in the Code and ISTUE that require this, but in practice this is a void in compliance monitoring from WADA. We strongly suggest to use more imperative wording, and compliance consequences, if IFs do not fulfil their obligations.

## • Clarification on the "Medical Practitioner"

The TUE Application Form mentions "medical practitioner", but the ISTUE itself speaks only about "physician". It would be good if this would be clarified in the ISTUE, because there are also psychologists or even nurse practitioners who are (in practice) the ones who provide the Medical documentation. If not, please change the medical practitioner on the form in "physician".

# Continual professional development for TUECs

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

# • Recognition of the role of the NADOs

The current ISTUE is very much focused on the position of WADA and the IFs and less so on the (work of) NADOs, where much of the workload lies.

# • Recognition of the roles of TUE managers

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

#### • Solve the problem of situation of non-signatories referring to NADOs

There are some non-signatories who refer their athletes to NADOs to get a TUE, referring to the WADC. In the light of thinking in favor of the athletes this is something that most NADOs do, but it is not mentioned in the ISTUE.

• Introduction provision retroactive dispensation

1. Doping Authority Netherlands has dealt with case in which an athlete used modafinil for a self-diagnosed sleeping disorder. She did not consult a medical doctor and purchased the modafinil online. After she tested positive for modafinil, this athlete applied for a retroactive TUE for the use of modafinil. This application was denied by our TUEC. Afterwards, however, the athlete was diagnosed with ADHD by a psychiatrist and was then prescribed modafinil (!) for her ADHD condition by this psychiatrist. She then appealed the decision of the TUEC to deny her a retroactive TUE. The TUE appeal panel consequently granted this athlete a retroactive TUE for modafinil, which 'covered' her AAF.

2. We felt that this situation was undesirable and contrary to the 'spirit' of the ISTUE. Therefore, Doping Authority introduced the following additional provision in our TUE rules. This provision was accepted by WADA Compliance. This provision reads as follows:

If submitting a request for a retroactive dispensation is permitted according to Article 4.1 ISTUE, the following requirements apply, in addition to what is stated in the ISTUE:

a. the retroactive TUE application must relate to the therapeutic purpose for which the prohibited substance and/or prohibited method in question was originally used; and

b. the retroactive TUE application must be substantiated with medical information dated on or before the date of commencement of the use of the prohibited substance and/or prohibited method in question for the therapeutic purpose referred to under 'a'.

3. Doping Authority recommends that a similar provision is introduced in the ISTUE.

# **Canadian Centre for Ethics in Sport**

Elizabeth Carson, Senior Manager, Canadian Anti-Doping Program (Canada) NADO - NADO

The CCES would like to recognize WADA's efforts to address the important issues raised in the Concept Paper. We would like to reiterate that the ISTUE (and indeed all of the International Standards) should be athlete-centered. Changes to the standards should be focused on those elements that assist in achieving the primary objective of protecting clean athletes.

# Anti-Doping Norway

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

We would welcome a clarification of the athletes' right to appeal an ADO's decision to NOT let an athlete apply for a retroactive TUE according to the 4.1 criteria.

The interpretation of Article 4.3. seems to vary between ADOs, in terms of whether 4.3. can be applicable to situations where 4.1 is applicable but an application would not fulfill all four requirements in 4.2.

We find that the ISTUE guidelines are clearer than the ISTUE on this, but we would encourage making it clearer in the ISTUE itself - e.g. by adding in the comments to ISTUE 4.3, that it can be applicable in situations where 4.1

does not allow for a retroactive application, and/or where the requirements of 4.2 would not be fulfilled (and of course that it at the same time would be manifestly unfair not to grant the TUE).

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

Il serait nécessaire que l'AMA établisse des lignes directrices pour indiquer quelle ONAD doit traiter la demande d'AUT d'un sportif étranger venant participer à un championnat national, en particulier lors d'une demande d'AUT rétroactive suite à un RAA. Il semblerait pertinent que l'ONAD du pays d'origine du sportif, sur le territoire duquel il est soigné, traite ces demandes dans l'intérêt du sportif lui-même. Le sportif bénéficierait ainsi de la facilité de la langue et de l'examen d'un panel de médecins parfaitement informé des habitudes médicales du pays de prescription.

SUBMITTED

SUBMITTED

SUBMITTED

# Anti Doping Danmark

Silje Rubæk, Legal Manager (Danmark) NADO - NADO

We find it crucial that ADO's like for example ITA and International federations should live up to the same criteria for operational Independence as NADO's. As it is now, the criteria that is demanded for the NADO is not the same for the ADO's.

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

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

#### **Article 5.0 Conditions Monitoring**

There is currently no provision in ISTUE Article 5.0 that instructs ADOs to monitor athlete compliance when conditions are imposed on a TUE. We would welcome the next version of the ISTUE to make clear that monitoring of conditions imposed on TUEs is the responsibility of the ADO who granted the TUE throughout the exemption period (unless the responsibility for the TUE is transferred to another ADO due to a change in testing jurisdiction – see proposal titled "Transfer of TUEs between NADOs when athlete jurisdiction changes" for commentary on this matter).

#### RECOMMENDATION

#### 1.

Add an additional provision within ISTUE Article 5.0 that the monitoring of conditions imposed on TUEs is the responsibility of the ADO who granted the TUE.

Article 6.14 Inability to update existing issued TUEs in ADAMS when athlete treatment plans change At present, ISTUE Article 6.14 outlines that athletes are required to update ADOs if their treatment plan materially changes to that specified on their issued TUE certificate (in order to maintain the validity of their TUE). ADOs are currently unable to modify an athlete's existing TUE in ADAMS when this occurs. Instead, the ADO must cancel the TUE and generate a new TUE certificate (which also generates a new TUE reference number). This is an inefficient use of an ADO TUE Manager's time. We therefore encourage WADA to improve the functionality in ADAMS to enable ADO TUE Managers to modify and reissue existing TUEs when notified about treatment plan changes.

# RECOMMENDATION

1

Develop new functionality in ADAMS to enable existing TUEs to be modified when an athlete's treatment plan changes

# Transfer of TUE custody between NADOs when athlete jurisdiction changes

There are occasions (typically in professional team sports) whereby the transfer of a TUE from one NADO to another could be useful. For instance, a football player who is a foreign national in the country who granted the TUE is signed to play for a club in a different country whereby the NADO no longer has testing jurisdiction over the player. Currently, the NADO taking over the testing jurisdiction of the player would ask the first NADO to reject/cancel the TUE they granted in ADAMS so that they can issue a new TUE under their custody. We suggest that a new provision is included in the ISTUE to enable the transfer of a TUE (if both parties agree in advance to the transfer and the new NADO agrees with the original NADOs TUEC decision). The new provision would need to instruct the NADO who is transferring custody of the TUE to inform the athlete of the change in custodianship. The development of new functionality in ADAMS would also be required to enable transfers to occur.

# RECOMMENDATION

# 1.

Add a new provision to the ISTUE to enable the transfer of TUEs between NADOs (if both NADOs agree in advance to the transfer and the new NADO agrees with the original TUEC decision).

# 2.

The NADO transferring custody of the TUE must inform the athlete of the change in custodianship.

# 3.

Develop new functionality in ADAMS to enable TUE custody to be transferred between NADOs.

# **Continual Professional Development for TUEC Members and TUE Managers**

Whilst the TUEC Symposium and medical guidelines created by the WADA TUE Expert Group are useful initiatives in raising standards of consistency amongst TUECs, we feel that TUEC members and TUE Managers would also benefit from more frequent interaction to continue to improve the knowledge within the community. This could be achieved through the introduction of webinars every six to twelve months that contains: i. anonymous examples of good 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). The webinars could also be extended to ISTUE Article 4.3 cases to help build an ADOs proficiency in determining the outcome of these cases as they are infrequent but complex (from a legal, medical, and ethical prospective).

Finally, developing an educational programme in this way would help address the ISTUE Revision Group's concerns outlined in Concept #9 regarding the underperformance of certain TUECs.

# RECOMMENDATION

# 1.

Create a continual professional development programme for TUEC members and TUE Managers to improve the knowledge within the community.

# TUE Physician Guidelines – Testosterone therapy for pre- and postmenopausal age group / masters' athletes

There is a growing number of age group / masters' level athletes who are being prescribed testosterone therapy to

treat symptoms of hormone deficiency that occur in pre- and postmenopausal females. Such athletes are advised to refrain from this treatment should they wish to continue competing at an international (albeit sub-elite / amateur) level given that a TUE cannot be considered based on the WADA TUE Physician Guidelines for Male Hypogonadism. Version 8.0 of the guideline states that "TUEs for androgen (testosterone) deficiency should not be approved in women".

Female athletes (and National Governing Bodies) that we have spoken to view this policy to be i. inequal as it is possible for a male athlete with testosterone deficiency to obtain a TUE (but not a female athlete); and ii. it doesn't consider female specific health issues.

We appreciate that WADA's position is focussed on elite level female athletes and that the ISTUE Drafting Team are suggesting that this issue could be resolved by affording lower-level athletes with extra flexibility when applying the ISTUE regulations (ISTUE Concept #10). We are not entirely in favour of the approach described in Concept #10 but have made some considerations should it be explored further (see response to Concept #10 for further details). This Concept may also not assist all athletes at this level as some age group / masters' athletes can still be selected for doping control by International Federations at international age group events or when age group world records are broken.

At the very least, we encourage WADA to produce a position statement on this topic that addresses the current zero-tolerance policy for women and await to see how Concept #10 is further developed (if it gets enough support).

RECOMMENDATION

1. Publish a position statement specific to testosterone deficiency in females.

## International Testing Agency

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

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

SUBMITTED

- Appeal rights regarding retroactive TUE could be clarified.