



BULL'S EYE THE ISSF IPOD ON DOPING

THERAPEUTIC USE EXEMPTIONS: WHY RESPECTING THE PROCESS IS CRUCIAL TO MAINTAINING AN EVEN PLAYING FIELD.

WITHIN THE JUSTIFIABLY RIGOROUS REALM OF ANTI-DOPING IN SPORT, THERAPEUTIC USE EXEMPTIONS ARE A MEAN BY WHICH AN ATHLETE CAN BE PERMITTED, EXCEPTIONALLY, TO COMPETE WHILST USING A SUBSTANCE WHICH WOULD OTHERWISE BE PROHIBITED.

THE THERAPEUTIC USE EXEMPTION (TUE) PROCESS IS - IN PRINCIPLE - ACCOMMODATING BECAUSE IT CAN ALLOW AN ATHLETE REQUIRING THE MEDICAL USE OF A PROHIBITED SUBSTANCE AND WHO WOULD NOT OTHERWISE BE ABLE TO COMPETE TO DO SO.

WHILE ON THE ONE HAND THE TUE PROCESS CAN BE OBLIGING FOR THE ATHLETE WHO APPLIES AND IS GRANTED A TUE, ON THE OTHER HAND IT CAN SOMETIMES BE UNACCOMMODATING AND SEEMINGLY HARSH TO THE ATHLETE WHO APPLIES FOR AND IS DENIED A TUE.

IRRESPECTIVE OF ITS OUTCOME THE TUE PROCESS MUST REMAIN FOCUSED ON FAIR PLAY SO THAT NO UNFAIR ADVANTAGE IS GIVEN. IT IS CRUCIAL FOR THE PROCESS TO BE RIGIDLY RESPECTED AND PROPERLY IMPLEMENTED FOR THE BENEFIT OF ALL THE OTHER ATHLETES AGAINST WHOM THE TUE APPLICANT MAY EVENTUALLY COMPETE SO AS TO ENSURE THAT AN EVEN PLAYING FIELD IS MAINTAINED.

THE INTERNATIONAL STANDARD FOR THERAPEUTIC USE EXEMPTION (ISTUE)

The process by which an athlete applies for, and then is either granted or denied, a TUE is outlined in the World Anti-Doping Code and the ISSF Anti-Doping Rules. But more specifically, and exhaustively, TUEs are the focal point of the International Standard for Therapeutic Use Exemptions (ISTUE) whose purpose is to ensure that the process of granting TUEs is harmonized across sports and countries.

The ISTUE is a mandatory International Standard developed as part of the World Anti-Doping Program.

The purpose of the International Standard for Therapeutic Use Exemptions is to establish:

- (a) the conditions that must be satisfied in order for a TUE to be granted, permitting the presence of a prohibited substance in an athlete's sample or the athlete's use or attempted use, possession and/or administration or attempted administration of a prohibited substance or prohibited method for therapeutic reasons;

- (b) the responsibilities imposed on Anti-Doping Organizations (whether an International Federation or a National Anti-Doping Organisation) in rendering and communicating TUE decisions;

- (c) the process for an athlete to apply for a TUE;
- (d) the process for an athlete to get a TUE granted by one Anti-Doping Organization (ADO) recognized by another ADO;

- (e) the process for WADA to review TUE decisions; and

- (f) the strict confidentiality provisions that apply to the TUE process.

THE TUE APPLICATION PROCESS

Each National Anti-Doping Organization (NADO) and International Federation (IF) must have a process in place whereby athletes with documented medical conditions requiring the use of a prohibited substance or a prohibited method, which would otherwise be prohibited in-competition or out-of-competition, may request a therapeutic use exemption.

In order to be granted a TUE an athlete must submit a complete application to his or her NADO or to his or her IF at least 30 days before his or her next competition and, in all circumstances, before or as soon as possible after the use of the substance is commenced, unless it is an emergency or exceptional situation. The application must be submitted on an official form, carefully filled-out and include any and all required medical documentation or other type documentation in its support.

TUE application forms can be downloaded on the athlete's relevant ADO's website. The form is also an Appendix to the ISTUE and can be downloaded from the WADA website as well as the ISSF website. The application forms are standard as more and more anti-doping organizations submit TUEs in ADAMS in order to encourage mutual recognition and a sharing of information between entities on a need-to-know basis who are allowed to access the confidential information.

Once a duly filled-out TUE application is submitted, a TUE Committee (TUEC), which should include at least three physicians with experience in the care and treatment of athletes and a sound knowledge of clinical, sports

and exercise medicine, will consider the merits of the application and render a decision granting or denying the same. In normal circumstances a TUEC should render a decision as soon as possible, and never more than 30 days after having received the TUE application.

THE APPLICABLE RULES

The Code and the ISSF Anti-Doping Rules' respective provisions on TUEs outline the application process and assist athletes in determining to whom, and when, an athlete must submit his or her TUE application and to which extent the TUE, if granted, may or may not be valid for national and or international competition.

Article 4.4.3 of the Code and of the 2015 ISSF Anti-Doping Rules states as follows:

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

4.4.3.1 Where the Athlete already has a TUE granted by his or her National Anti-Doping Organization for the substance or method in question, if that TUE meets the criteria set out in the International Standard for Therapeutic Use Exemptions, then the International Federation must recognize it. If the International Federation considers that the TUE does not meet those criteria and so refuses to recognize it, it must notify the Athlete and his or her National Anti-Doping Organization promptly, with reasons. The Athlete or the National Anti-Doping Organization shall have 21 days from such notification to refer the matter to WADA for review. If the matter is referred to WADA for review, the TUE granted

by the National Anti-Doping Organization remains valid for national-level Competition and Out-of-Competition Testing (but is not valid for international-level Competition) pending WADA's decision. If the matter is not referred to WADA for review, the TUE becomes invalid for any purpose when the 21-day review deadline expires.

4.4.3.2 If the Athlete does not already have a TUE granted by his or her National Anti-Doping Organization for the substance or method in question, the Athlete must apply directly to his or her International Federation for a TUE as soon as the need arises. If the International Federation (or the National Anti-Doping Organization, where it has agreed to consider the application on behalf of the International Federation) denies the Athlete's application, it must notify the Athlete promptly, with reasons. If the International Federation grants the Athlete's application, it must notify not only the Athlete but also his or her National Anti-Doping Organization, and if the National Anti-Doping Organization considers that the TUE does not meet the criteria set out in the International Standard for Therapeutic Use Exemptions, it has 21 days from such notification to refer the matter to WADA for review. If the National Anti-Doping Organization refers the matter to WADA for review, the TUE granted by the International Federation remains valid for international-level Competition and Out-of-Competition Testing (but is not valid for national-level Competition) pending WADA's decision. If the National Anti-Doping Organization does not refer the matter to WADA for review, the TUE granted by the International Federation becomes valid for national-level Competition as well when the 21-day review deadline expires.

With regards to the validity of a TUE, Article 5.7 of the ISTUE clearly states that:

5.7 Any TUE that an Athlete has obtained from a National Anti-Doping Organization shall not be valid if the Athlete becomes an International-Level Athlete or competes in an International Event unless and until the relevant International Federation recognizes that TUE in accordance with Article 7.0. Any TUE that an Athlete has obtained from an International Federation shall not be valid if the Athlete competes in an International Event organized by a Major Event Organization, unless and until the relevant Major Event Organization recognizes that TUE in accordance with Article 7.0. As a result, if the International Federation or Major Event Organization (as applicable) declines to recognize that TUE, then (subject to the Athlete's rights of review and appeal) that TUE may not be relied upon to excuse the presence, Use, Possession or Administration of the Prohibited Substance or Prohibited Method mentioned in the TUE vis-à-vis that International Federation or Major Event Organization.

HOW THIS WORKS IN PRACTICE

When the TUE application is submitted at the national level:

Under the ISSF Anti-Doping Rules, where the TUE has been granted by a national-level

TUEC to an athlete at the national-level, the ISSF must be promptly informed of the TUE by the relevant NADO and then the ISSF is given 21 days to decide whether or not to recognize that TUE.

Upon receipt of the TUE, the ISSF TUE Committee (ISSF TUEC) would assess whether or not, in its expert opinion and based on the information submitted by the athlete with the application, the granted TUE meets the four well-established ISTUE criteria.

Should the ISSF TUEC determine that the TUE does satisfy the four criteria, it shall so inform the athlete and the NADO that ISSF recognizes the TUE as granted. In such a case the athlete will be able to compete at the international level with no problem.

However, should the ISSF TUEC determine that the national-level TUEC incorrectly concluded that the four mandatory ISTUE criteria had been met when deciding to grant the national-level TUE, ISSF will not recognize the TUE and so inform the athlete and his or her NADO. In such a case, as stated in Article 5.7 of the ISTUE cited above, the athlete would not be able to compete at the international-level while using the substance for which the national-level TUE was granted and would risk an anti-doping rule violation with all its consequences should the athlete continue to use the substance for which the TUE was denied. The existence of a national-level TUE would then not be an adequate defence to an anti-doping rule violation.

Upon receiving notice of the ISSF's refusal to recognize the national-level TUE, the athlete and/or NADO may then request that the WADA TUEC review the TUE application in order to decide whether or not the ISSF was correct in its decision to not recognize the TUE for international-level competition.

Further to its receipt by the relevant parties, the WADA TUEC decision may then be appealed by ISSF or the athlete to the Court of Arbitration for Sport.

When the TUE is submitted at the international-level:

All TUE applications submitted to the ISSF TUEC are carefully scrutinized. The contents of the applications are given conscientious consideration by the expert medical panel. This includes an assessment of the athlete's condition, the prescribed dosage, the amount of the time for which the TUE has been requested etc. Of course each ISTUE criteria is considered alongside the documented application form.

Where, in the opinion of the ISSF TUEC, the athlete fulfills the four ISTUE criteria, the ISSF TUEC grants the TUE for the requested dosage and a specific amount of time and the ISSF so informs the athlete and all relevant ADOs.

Where the ISSF TUEC decides that the athlete does not fulfill the ISTUE criteria, the TUE is denied with reasons and the ISSF so informs the athlete and all other relevant ADOs. The athlete, his national federation and his or her NADO can then apply to WADA for a review of the ISSF TUEC decision.

If the WADA TUEC agrees with the ISSF TUEC decision, the TUE denial would be upheld. The athlete could then have the right to appeal that decision to CAS.

But if the WADA TUEC renders a decision in which it overturns the ISSF TUEC decision to deny the TUE and instead grants the athlete a TUE, and should the ISSF not agree with the WADA TUEC's reasons for doing so, the ISSF then has a right to appeal the WADA TUEC decision to CAS.

For the benefit of clean sport and in order to protect the integrity of shooting sport and its athletes, ISSF has not wavered from appealing to CAS when such a situation has presented itself and shall certainly be vigilant in doing so in the future should the situation re-occur.

In sum, whether the application is made at the national-level or international-level, the TUE process may therefore present and involve various legal obstacles. Most would agree that although they may be necessary to safeguard the transparency, legitimacy and fairness of the process, burdensome reviews to WADA and costly appeals to CAS should seek to be avoided. This is why being properly informed on the TUE process and properly applying the ISTUE criteria is so important.

THE FOUR ISTUE CRITERIA

National Federations, NADOs and IFs must cooperate with each other to ensure that all national athletes and NADO TUECs and all international athletes and IF TUECs are equally made aware of the ISTUE criteria. Conversely, TUECs hold the important responsibility of judiciously applying the criteria to each TUE application in order to make certain that the applicant athlete does in fact fulfil the burden of showing that he or she has satisfied the ISTUE criteria and that he or she should be allowed to compete while using a prohibited substance.

Article 4.1 of the ISTUE clearly outlines the criteria that an athlete must fulfill in order to be granted a TUE. It reads as follows:

4.1 An Athlete may be granted a TUE if (and only if) he/she can show that each of the following conditions is met:

- a.** The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.
- b.** The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition.
- c.** There is no reasonable Therapeutic alternative to the Use of the Prohibited Substance or Prohibited Method.
- d.** The necessity for the Use of the Prohibited Substance or Prohibited Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method

which was prohibited at the time of such Use.

So, put in simple terms, in order to satisfy the four ISTUE criteria the athlete must show that:

- His or her medical condition is so very serious or chronic that it must be treated by the said medication, failing which the athlete's health would suffer significantly.

The athlete must also show that:

- The use of the substance will not or does not have the potential of enhancing the athlete's performance over and above what is needed to return to a normal state of health.

The athlete must also show that:

- There are no other alternatives, whether medical, surgical or other, open to him or her other than the use of the substance in question to treat his or her specific medical condition.

And finally, the athlete must also show that:

- The need for the substance does not stem from the effects of the use of another prohibited substance.
- The athlete bears the burden of proving that he or she fulfills each and every one of this criterion.

If there is no severe medical condition and/or if the use of a substance is or has the potential to be performance enhancing and /or if there exist any reasonable alternative treatments, the athlete should not be granted a TUE.

Why?

The reasoning is simple: An athlete who is granted a TUE when he or she does not fulfill all four ISTUE criteria is essentially being authorized to compete against clean athletes while using a prohibited and potentially performance enhancing substance. The very thought of this occurring defeats the purpose of the fight against doping in sport as it would create an uneven playing field.

And yet – it happens regularly. Athletes who apply for a TUE but do not satisfy all four ISTUE criteria are often granted TUEs.

Why?

The answer is simple: Because the TUE process is not always being respected or properly implemented.

THE PROPER IMPLEMENTATION OF THE ISTUE CRITERIA

Although the process is clearly outlined in the ISTUE and in the TUE application form, far too many athletes and medical experts who sit on TUECs are not fully aware of the importance of an athlete fulfilling all the ISTUE criteria prior to being granted a TUE.

Further, not all fully appreciate that it is the athlete who must satisfy the burden of showing that his or her TUE application should be granted because all four ISTUE criteria are fulfilled.

It is imperative for all TUECs to carefully and objectively decide whether or not an athlete has shown, through his or her application and submitted medical documents, that he or she does in fact fulfil the four ISTUE criteria prior to being granted a TUE.

An athlete who does not thoroughly satisfy the criteria, irrespective of his or her medical condition or of the empathy a TUEC may feel

towards him or her or of any other subjective factors that may come into play throughout the deliberations, must not be granted a TUE. The following provides a helpful reminder of some of the responsibilities both athletes and TUE Committees hold with regards to the TUE process:

REMINDER TO ALL IPOD READERS:

There is a certain perverse mentality among some athletes, coaches and officials in all sports that doing anything to produce higher scores or better results is OK.

This thinking is dangerous and wrong.

The ISSF is of the firm opinion that neither the use of performance-enhancing equipment and clothing nor the use performance-enhancing substances (beta blockers especially) can or should substitute valid, honest and concrete efforts to improve training and performance.

Let's keep our athletes and our sport clean.

Let's all shoot straight and play by the rules.

Some athlete responsibilities when applying for a TUE:

Athletes must be aware of their responsibility to satisfy the four ISTUE criteria and make certain that their application fulfills each individual criterion.

- Athletes must be exhaustive and thorough when submitting a TUE application.
- The application should have a statement by an appropriately qualified physician, attesting to the athlete's mandatory need to use the prohibited substance or prohibited method in question for therapeutic reasons. This statement should also attest that there are no other reasonable treatment alternatives that exist or that are available to the athlete.
- The application should include a comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible) and the results of all examinations, laboratory investigations and imaging studies relevant to the application.
- Athlete must include as much relevant documentation (medical, scientific, statistical etc.) as possible which shows that the criteria is met.
- Where the substance in question is known to be performance enhancing in the athlete's specific sport (like for example beta blockers in shooting sport), the athlete should provide some proof, scientific, medical

or otherwise, that in his or her specific case, the use of the substance does not or may not have the potential of being performance enhancing.

- The athlete should make sure to submit the correct TUE application form to the relevant ADO via ADAMS or as otherwise specified by the ADO.

Some TUEC responsibilities when assessing the merits of a TUE:

- Each TUEC must be aware of not only the four ISTUE criteria, but also, and more importantly of the application athlete's burden of proving that he or she fulfills each individual criterion.
- A decision to grant a TUE must specify the dosage(s), frequency, route and duration of administration of the prohibited substance or prohibited method in question that the TUEC is permitting, reflecting the clinical circumstances, as well as any conditions imposed in connection with the TUE.
- Incomplete requests for recognition of a TUE should be returned to the athlete for completion and re-submission.
- The TUEC should request from the athlete or his/her physician any additional information, examinations or imaging studies, or other information if it deems necessary to adequately consider the athlete's application;
- The TUEC may seek the assistance of such other medical or scientific experts as it deems appropriate.
- A decision to deny a TUE application must include an explanation of the reason(s) for the denial. E.g. Where an applicant does not fulfill all four criteria adequately, a reasoned decision must be drafted explaining why the TUE is denied and provide details on which criterion (or criteria) have not been met and why.
- It is always better for a TUEC to say more than less. Explaining in medical terms why a TUE is denied or granted will minimize reviews to WADA and/or costly appeals to CAS.

The TUE process is perhaps an onerous one, but it needs to be in order to be sure that where an athlete is granted a TUE to use a substance which would otherwise be prohibited (because among others of its potential of enhancing performance), he or she is not gaining an unfair advantage over all the other competitors against whom he or she is competing.

The World Anti-Doping Program seeks to ensure that the playing field is always level. While the TUE process allows for exceptions to be made to certain rules, it must also be respected in order to ensure that the playing field does in fact remain level.

If both athletes and TUEC committees understand the ISTUE process and properly respect and apply the ISTUE, TUEC decisions should for the most part be correct and justified- whether the outcome is ultimately to grant or deny the athlete the requested TUE.

THE ROLE OF THE ISSF

The ISTUE is mandatory to all Code Signato-

ries and all athletes subject to the Code, the International Standards and their relevant IF and/or NADO anti-doping rules. Its purpose is to ensure that the process of granting TUEs is harmonized across sports and countries. Its goal is to ensure that athlete's with medical conditions can compete so long as their doing so does not violate the principles of the World Anti-Doping Program.

As a Signatory to the Code, the ISSF must safeguard the application of its ISSF Anti-Doping Rules and must defend the principles inherent to these Rules and the World Anti-Doping Program.

The ISSF's role is therefore to carefully monitor national-level TUEs and for the ISSF TUEC to carefully consider international TUE applications. In both instances, where a TUE is warranted, it will be recognized and granted. But where a TUE does not satisfy the mandatory criteria it certainly shall not be recognized or will be denied. And as previously stated, where the WADA TUEC overturns an ISSF TUEC decision to deny a TUE, should the ISSF not agree with the WADA TUEC's reasons, it will not hesitate to appeal the matter to the Court of Arbitration for Sport.

If the ISSF TUEC was to recognize or grant a TUE to an athlete where the ISTUE criteria is not convincingly fulfilled it would be ut-

terly unfair to all the other athletes against whom he or she is competing. Such a decision would essentially condone an athlete's use of a prohibited and potentially performance enhancing substance while competing against athletes who are competing clean.

All athletes competing in shooting sport must have the certainty that they are competing against an even playing field. This is why the proper application and respect of the ISTUE criteria by all TUE Committees, including the ISSF's, is imperative.

CONCLUSION

The fight against doping in sport is not an easy fight, just as the monitoring of TUEs is not an easy task. But, they both seek fairness. They both seek to protect the spirit of sport. They both seek to provide every athlete a chance to compete against an even playing field.

That is why each individual case and TUE application must be carefully and objectively considered on its merits:

- Where a TUE application shows that the use of substance is necessary and justified in accordance with the ISTUE criteria, then it should be granted. In such a case an athlete who would not otherwise be able to compete at all should be given the rightful opportunity to do so.

- But where a TUE application does not show that the medical use of a substance, whether or not for valid medical reasons does not or may not have the potential to be performance enhancing, or can not be replaced by an alternative treatment, irrespective of the athlete's condition, it must not be granted.

This may be a harsh reality for the athlete whose TUE application is denied. However, the TUE process simply cannot be subjective; it certainly is not meant to be. ISSF and every one involved in shooting sport must be steadfast in respecting this reality. It is not sport specific. It is not individualized. This reality is shared by every athlete competing in every sport.

Indeed, we are all bound by the same rules even if it is not always easy to implement them and to accept them. This is the process that WADA has established and that must be respected and applied by all for the benefit of clean sport.

Certainly, the TUE process is tedious and can be seemingly iniquitous at times. But in the end, few will argue that the TUE process under which we all operate is reasonable and fair and that its proper application is crucial to maintaining a level playing field for all athletes.

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Sauer Shooting Sportswear congratulates "their" world champions



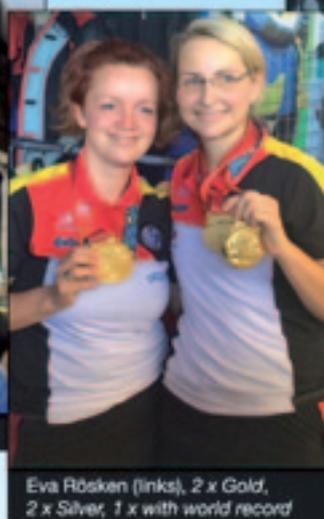
Beate Gauß, 4 x Gold,
2 x with world record



André Link, 2 x Gold, 1 x Silver,
1 x with final world record



Daniel Brodmeier, 1 x Silver



Eva Röskén (links), 2 x Gold,
2 x Silver, 1 x with world record



Snjezana Pejčić, 1 x Silver



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The Sauer team is delighted for all of "its" sports shooters who were successful in so many individual and team competitions at the World Championships in Granada. And of course, that includes all those whom we could not show here.