

# THERAPEUTIC USE EXEMPTIONS APPLICATION PROCEDURE (TUE\_AP)

Implementing the *WADA Code* and the *International Standard for Therapeutic Use Exemptions (ISTUE)*

## What is a Therapeutic Use Exemption (TUE)?

Athletes, like all people, may have illnesses or conditions that require them to take particular medications or undergo procedures. If the medication or method an athlete is required to take/use to treat an illness or condition is included in the World Anti-Doping Agency's (WADA) Prohibited List, a Therapeutic Use Exemption (TUE) may give that athlete the authorization to take a substance or use a method that is prohibited.

Applications for TUEs are reviewed by a panel of experts, the TUE Committee (TUEC) who may give such permission.

## What are the criteria for granting a TUE?

All of the four following criteria must be met (for more details, please refer to the WADA ISTUE Article 4.2):

- a) the Prohibited Substance or Prohibited Method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence;
- b) the Therapeutic Use of the Prohibited Substance or Prohibited Method will not, on the balance of probabilities, 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 medical condition;
- c) the Prohibited Substance or Prohibited Method is an indicated treatment for the medical condition, and there is no reasonable permitted Therapeutic alternative;
- 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.

## Who should apply for a TUE to NADO Italia, how and when?

The Athlete must check if the medication or method he/she intends to take or use appears on the Prohibited List (<https://www.wada-ama.org/en/resources/science-medicine/2021-prohibited-list-documents>).

The Athlete has the responsibility to inform his/her physician(s) that he/she is bound to antidoping rules. The Athlete and his/her physician(s) should check the Prohibited List for whenever substance/method prescribed. If the substance/method is prohibited, the Athlete must check with his/her physician(s) if there are any alternative treatments that are not prohibited. If not, the Athlete has to apply for a TUE.

The Athlete must check the competition level to determine to which organization, and when to apply for a TUE.

If he/she is a National-Level Athlete<sup>1</sup>, the Athlete must apply to NADO Italia in advance, as soon as the need arises, unless there are emergency or exceptional circumstances.

If the level is lower than the "National-Level" (*Recreational Level Athlete*)<sup>2</sup>, the Athlete is entitled to apply for a retroactive TUE after being tested by NADO Italia or any other Anti-Doping Organization (ADO).

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<sup>1</sup> NADO Italia's definition of *National-Level Athlete*: "An Athlete included in the national RTP; Athletes included in the Club Olimpico (who receive funding from Sports movement); an Athlete who currently or in the last six (6) months has represented Italy at senior level; an Athlete who has been selected to represent Italy in International Events or Competitions, not classified as International-Level Athlete by the relevant International Federation".

<sup>2</sup> NADO Italia's definition of *Recreational Athlete*: In Italy, *Recreational Athlete* is any Person member of a Sport Promotion Entity, or any Person who takes part in local *Competitions* or competes at lower level *Team Sports*.

In any case, *Recreational Athlete* does not include who, within the five (5) years prior to committing any anti-doping rule violation: (i) has been an *International-Level Athlete* (as defined by each International Federation consistent with the *International TUE\_AP, Version 3.1, in effect as from 5<sup>th</sup> September 2022*

If he/she is a International-Level Athlete, the Athlete must apply to the relevant IF, according to its procedural rules.

For substances prohibited In-competition only, the Athlete should apply for a TUE at least 30 days before the Athlete's next competition. Please refer to the section "How to apply to NADO Italia for a TUE?" below.

## Retroactive TUE

According to Article 4.1 and 4.3 of the ISTUE, an Athlete may apply for a retroactive TUE and in each case the requirements of Article 4.2 of the ISTUE must be met.

Specifically, an application for a retroactive TUE may be submitted in the following cases:

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

4.1 (b) there was insufficient time, opportunity or other exceptional circumstances that prevented the Athlete from submitting (or the TUEC to consider) an application for the TUE prior to Sample collection;

4.1 (c) due to national level prioritization of certain sports conducted by NADO Italia, the Athlete's is not required to apply for a prospective TUE;

4.1 (d) if an Anti-Doping Organization chooses to collect a Sample from an Athlete who is not an International-Level Athlete or National-Level Athlete, and that Athlete is Using a Prohibited Substance or Prohibited Method for Therapeutic reasons;

4.1(e) the Athlete Used Out-of-Competition, for Therapeutic reasons, a Prohibited Substance that is only prohibited In-Competition (e.g. S9, glucocorticoids).

The classification of sports at the national level did not reveal disciplines for which TUE cannot be submitted in advance.

## How to apply to NADO Italia for a TUE?

Please download the NADO Italia's TUE Application Form ([Modulo di domanda - Nado Italia](#)).

The TUE application must include:

- the TUE application form completed in a legible form and signed by the Athlete and the physician;
- medical certification with a description of the clinical picture, including the results of all examinations performed and laboratory investigations carried out to support the diagnosis;
- any copies of original reports and specialist reports;
- medical records, if any;
- physician's statement supporting the ineffectiveness of treatment with substances or methods not prohibited under the WADA Prohibited List;
- copy of the sport eligibility certificate to participate in competitive sport, or certificate of non-competitive activity where required for the sport practiced.

The TUE application must be sent to TUEC of NADO Italia by registered mail with return receipt to the address "CEFT - NADO Italy, Viale dei Gladiatori, 2 00135 Rome" or by certified e-mail, to [ceft.antidoping@cert.nadoitalia.it](mailto:ceft.antidoping@cert.nadoitalia.it). In case of impossibility, it may be transmitted by e-mail, to the address: [ceft.antidoping@nadoitalia.it](mailto:ceft.antidoping@nadoitalia.it).

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*Standard for Testing and Investigations*) or *National-Level Athlete* (as defined by NADO Italia or other *National Anti-Doping Organization* consistent with the *International Standard for Testing and Investigations*); (i) has represented Italy or any other country in an *International Event* in an open category; (iii) or has been included within any *Registered Testing Pool* or other whereabouts information pool maintained by any International Federation, NADO Italia or other *National Anti-Doping Organization*.

A TUE application will only be considered by the TUEC following the receipt of a properly completed application form, accompanied by all relevant documents. Incomplete or illegible applications will be considered not evaluable and returned to the Athlete for completion and re-submission.

The TUEC may request from the Athlete or his/her physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the Athlete's application.

To assist the Athlete and his/her doctor in providing the correct medical documentation, NADO Italia suggests consulting the WADA's Checklists for TUE applications for guidance and support during the TUE application process ([resource - Therapeutic Use Exemption | World Anti Doping Agency \(wada-ama.org\)](https://wada-ama.org)).

The Athlete should keep a complete copy of the TUE application form and all medical information submitted in support of the application, and proof that it has been sent.

NADO Italia is available to offer support to the Athlete or anyone who expresses such a need. The Athlete may contact NADO Italia at the e-mail address:

[ceft.antidoping@nadoitalia.it](mailto:ceft.antidoping@nadoitalia.it).

### **TUE decision**

NADO Italia's TUEC's must render a decision as soon as possible, and usually within 21 days from the date of receipt of the complete TUE application, including the required medical information by NADO Italia.

### **What if the Athlete need to renew his/her TUE?**

Each TUE has a specific duration, at the end of which it expires automatically. Should the Athlete need to continue to use the prohibited substance or method, it is his/her responsibility to submit a new application for a TUE with updated medical information ahead of the expiry date, so that there is sufficient time for a decision to be made prior to the expiry of the current TUE.

### **Important note:**

The presence (following sample collection), use, possession or administration of the prohibited substance or method shall be consistent with the terms of your TUE. Therefore, in the event that, after the TUE is granted, the Athlete requires a materially different dosage, frequency, route or duration of administration, he/she must apply for a new TUE.

### **What if my NADO Italia's TUE application is denied?**

A decision to deny a TUE application includes an explanation of the reason(s) for the denial. If it is not clear to the Athlete, please contact NADO Italia ([ceft.antidoping@nadoitalia.it](mailto:ceft.antidoping@nadoitalia.it)) to understand exactly why the TUE was denied.

The Athlete shall have the right to file an appeal with the National Antidoping Appeal Body (NADAB) against any decision of rejection of a TUE by the TUEC of NADO Italia, according to the procedure sets out in the NADAB Procedural Rules.

### **Validity and recognition of a TUE**

A TUE granted by NADO Italia is only valid at the national level. This validity is extended to other NADOs for national level competitions only. If the Athlete is, or become an International-Level Athlete, or compete at Major Games, that TUE will not be valid unless it is recognized by the relevant International Federation (IF) or Major Event Organization (MEO). It is Athlete's responsibility to check if NADO Italia's TUE is recognized by such IF or MEO without submitting a request for recognition.

NADO Italia can assist the Athlete in the determination of his/her level and TUE application requirements, and, should the need occur, assists in presenting NADO Italia's TUE to an IF or MEO for recognition.

## **What if NADO Italia's TUE is not recognized by the relevant IF?**

Pending WADA's decision, NADO Italia's TUE remains valid for national-level competition and out-of-competition testing only. If the matter is not referred to WADA for review, NADO Italia must determine whether the original TUE granted should nevertheless remain valid for national-level Competition and Out-of-Competition Testing.

The Athlete/NADO Italia have 21 days from the date of decision to refer the matter to WADA for review. The email address to enquire and/or send the request for review is: [medical@wada-ama.org](mailto:medical@wada-ama.org). Alternatively, you may send to:

WADA Medical Department  
World Anti-Doping Agency  
Stock Exchange Tower  
800 Place Victoria (Suite 1700)  
P.O. Box 120  
Montreal (Quebec) H4Z 1B7  
Canada

The same information that was provided to NADO Italia should be submitted to WADA. Please use a secure on-line method unless sending by registered mail.

Pending WADA's decision, NADO Italia's TUE remains valid for national-level competition and out-of-competition testing only.

If the matter is not referred to WADA for review, NADO Italia must determine whether the original TUE that was granted should remain valid for national-level Competition and Out-of-Competition Testing.

## **Will the Athlete medical information be treated in a confidential manner?**

All the information contained in a TUE application including the supporting medical information, and any other information related to the evaluation of the TUE request is kept strictly confidential and treated in accordance with the relevant data protection regulation. All members of the TUEC and any other authorized recipients of the TUE request and related information (as described in the Athlete's Declaration) are subject to a professional or contractual confidentiality obligation.

The TUE request-related information will be retained by NADO Italia and any other authorized recipients in accordance with the all relevant data protection regulations, including the International Standard for the Protection of Privacy and Personal Information and the ADSC Article 19.5.

For any further information and questions in relation to NADO Italia's personal information practices, please contact the Privacy Lead at [privacylead@nadoitalia.it](mailto:privacylead@nadoitalia.it).

## **Contact information**

If you have a doubt as regards to which organization you should apply for a TUE, or as to the recognition process, or any other question with regard to TUEs, please contact [ceft.antidoping@nadoitalia.it](mailto:ceft.antidoping@nadoitalia.it)

## **Other useful links:**

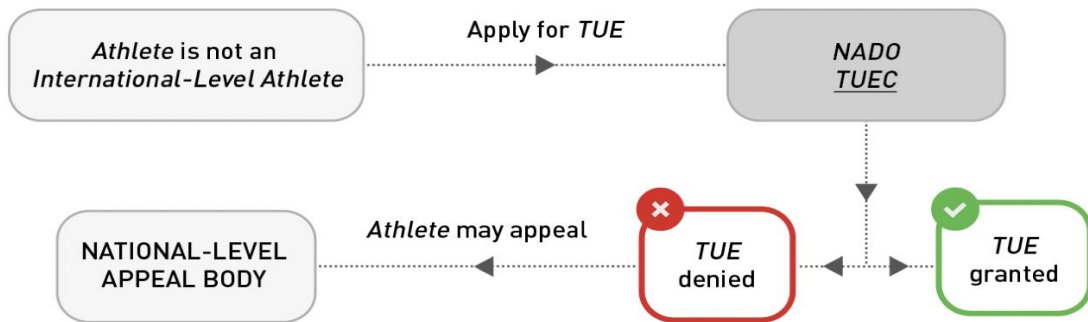
[WADA International Standard for Therapeutic Use Exemptions \(ISTUE\)](#)

[WADA Guidelines for Therapeutic Use Exemptions](#)

[WADA Q&A on Therapeutic Use Exemptions](#)

[WADA Checklists for TUE applications](#)

*TUE* procedure if *Athlete* is not an *International-Level Athlete* when need for *TUE* arises



*TUE* procedure if *Athlete* is an *International-Level Athlete* (and so subject to the International Federation's *TUE* requirements) when need for *TUE* arises

