THERAPEUTIC USE EXEMPTION PROCESS

WHAT IS A THERAPEUTIC USE EXEMPTION (TUE)?

Athletes may have illnesses or conditions that require them to take medications or undergo procedures. If the medication or method an athlete is required to use to treat an illness or condition is prohibited as per the World Anti-Doping Agency's (WADA) <u>Prohibited List</u> a TUE may give that athlete the authorization to use that substance or method while competing without invoking an anti-doping rule violation (ADRV) and applicable sanction. Applications for TUEs are evaluated by a panel of physicians, the TUE Committee (TUEC).

WHAT ARE THE CRITERIA FOR GRANTING A TUE?

All of the four following criteria must be met (for more details, please refer to the article 4.2: <u>WADA</u> International Standard for Therapeutic Use Exemptions (ISTUE):

- The athlete has a clear diagnosed medical condition which requires treatment using a prohibited substance or method;
- The therapeutic use of the substance will not, on the balance of probabilities produce significant enhancement of performance beyond the athlete's normal state of health;
- The prohibited substance or method is an indicated treatment for the medical condition, and there is no reasonable permitted therapeutic alternative;
- The necessity to use that substance or method is not a consequence of the prior use (without a TUE), of a substance or method which was prohibited at the time of use.

WHO SHOULD APPLY FOR A TUE? WHERE AND WHEN TO APPLY?

The International Committee of the Mediterranean Games (ICMG) has delegated responsibility for all TUE applications to the International Testing Agency (ITA). This means that the ITA is now fully responsible for the TUE application process for all athletes that fall under the ICMG jurisdiction, ie participating in the the Mediterranean Beach Games.

Athletes who are subject to anti-doping rules would need a TUE to take a prohibited substance or use a prohibited method. You should verify with the ITA to know to whom you need to apply and if you can apply retroactively.

First, check if the required medication or method you intend to take, or use is prohibited as per the <u>WADA</u> <u>Prohibited List</u>.

You may also use a 'check your medication' online like globalDRO (https://globaldro.com) or ask your NADO if it has one.

You have a responsibility to inform your physician(s) that you are an Athlete bound to anti-doping rules. You and your physician(s) should check the <u>Prohibited List</u> for the substance/method you are prescribed. If the substance/method is prohibited, discuss non-prohibited alternatives, if there are none, apply for a TUE. Remember Athletes have the ultimate responsibility. Contact your NADO or the ITA if you are having difficulties in assessing the status of a substance.

Then, verify below your status, to determine your competition level and TUE application requirements:

If the ICMG chooses to collect a Sample from an Athlete who is not an International Level Athlete or a National-Level Athlete, and that Athlete is Using a Prohibited Substance or Prohibited Method for therapeutic reasons, the ICMG must permit that Athlete to apply for a retroactive TUE.

International Level Definition

This level is defined by your IF. Outside the period of the Games, you should contact your international federation to apply for a TUE.

National Level Definition

This level is defined by your NADO. Outside the period of the Games, you should contact your NADO to apply for a TUE.

- If it is determined that you are an International-Level Athlete you must apply to your IF in advance, as soon as the need arises, unless there are emergency or exceptional circumstances.
- → If it is determined that you are a national-Level Athlete you must apply to your NADO in advance, as soon as the need arises, unless there are emergency or exceptional circumstances.

For substances prohibited in-competition only, you should apply for a TUE at least 30 days before your next competition, unless one of the exceptions on retroactive TUEs (see below) apply.

Please refer to the section "How to apply to the ITA for a TUE?" below.

If you already have a TUE granted by your IF or National Anti-Doping Organization (NADO):

ITA's TUEC will automatically recognise it for purposes of the Event, if it satisfies the ISTUE criteria for granting a TUE

→ If you are NOT an International-Level Athlete and you have been tested by the ICMG, ITA's TUEC recognizes a valid TUE granted by your NADO (i.e., it satisfies the ISTUE criteria for granting a TUE).

If your level is lower than the "National-Level" as defined by your NADO and you have been tested by the ICMG, you must apply for a retroactive TUE to the ITA.

CAN I GET A RETROACTIVE TUE?

You may only apply retroactively for a TUE to the ITA's TUEC if:

- You required emergency or urgent treatment of a medical condition.
- There was insufficient time, opportunity or other exceptional circumstances that prevented you from submitting the TUE application, or having it evaluated, before getting tested.
- You are a lower level athlete who is not under the jurisdiction of the ICMG or a NADO and were tested.
- You tested positive after using a substance Out-of-Competition that is only prohibited In-Competition (for example glucocorticoids).
- As per our anti-doping rules, you are neither international or national level and therefore were not permitted or required to apply in advance for a TUE

In rare and exceptional circumstances and notwithstanding any other provision in the ISTUE, you may apply for and be granted retroactive approval for a therapeutic use of a prohibited substance or method, if considering the purpose of the Code, it would be manifestly unfair not to grant a retroactive TUE. An Anti-Doping Organization may grant an Athlete's application for a retroactive TUE pursuant to this Article only with the prior approval of WADA (and WADA may in its absolute discretion agree with or reject the Anti-Doping Organization's decision)."

This unique retroactive TUE will only be granted with the prior approval of WADA (and WADA may in its absolute discretion agree with or reject the ITA's TUEC decision).

Important note:

Using a prohibited substance or method without a TUE could result in an Anti-Doping Rule Violation.

In case an application for a retroactive TUE is necessary following sample collection, you are strongly advised to have a medical file prepared and ready to submit for evaluation.

HOW TO APPLY TO THE ITA FOR A TUE?

The **ICMG** encourages submissions of TUE applications via ADAMS, together with the required medical information. If you do not have an ADAMS account yet, please visit this page to contact ITA's TUE support. This support service is only active during the Games period.

Otherwise, please download the <u>TUE Application Form</u> (found on https://ita.sport/TUE), and once duly completed and signed, gather the required medical file and contact <u>tue@ita.sport</u>.

Your TUE application must be submitted in legible capital letters or typing.

The medical file must include:

- A comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible);
- The results of all examinations, laboratory investigations and imaging studies relevant to the application.

Any costs incurred by the Athlete in making the TUE application and in supplementing it as required by the TUEC are the responsibility of the Athlete.

Any TUE application that is not complete or legible will not be dealt with and will be returned for completion and re-submission.

To assist you and your doctor in providing the correct medical documentation, we suggest consulting the WADA's <u>Checklists for TUE applications</u> for guidance and support, and <u>Medical Information to Support the Decisions of TUECs</u> for guidance on specific common medical conditions, treatments, substances, etc.

Keep a complete copy of the TUE application form and all medical information submitted in support of your application, and proof that it has been sent.

HOW TO SUBMIT A REQUEST FOR RECOGNITION OF MY IF OR NADO TUE TO THE ITA?

ITA's TUEC will automatically recognise your TUE for purposes of the Event without the need to review the relevant clinical information. If the TUE is correctly entered in ADAMS, there is no need to contact us. Nevertheless, should you require a confirmation, you can submit your request to the ITA in writing quoting your ADAMS TUE reference number.

You can download your TUE certificate directly from ADAMS.

WHAT HAPPENS DURING THE EVENTS?

Before the Period of the Games

You should follow the normal process and submit new requests to your IF or NADO. Pre-existing TUEs will be recognised provided they are entered in ADAMS.

During the Period of the Games

See the chapter above on "How to apply to the ITA for a TUE"

WHEN WILL I RECEIVE A DECISION ON MY TUE APPLICATION [OR REQUEST FOR RECOGNITION]?

The **ITA**'s TUEC must render a decision as soon as possible, and usually within 21 days from the date of receipt of the complete TUE application, or request for recognition, unless in exceptional circumstances.

WHAT IF I NEED TO RENEW MY TUE?

It advised that you contact the organization that granted the original TUE.

Each TUE has a specific duration, at the end of which it expires automatically. Should you need to continue to use the prohibited substance or method, it is your 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 must be consistent with the terms of your TUE. Therefore, if you require a materially different dosage, frequency, route or duration of administration, you should contact the **ITA**, as you may be required to apply for a new TUE. Some substances and dosages, e.g. insulin, are often modified during treatment and these possible fluctuations should be mentioned by the treating physician in the TUE application and would usually be accepted by the ITA's TUEC.

WHAT IF MY ICMG TUE APPLICATION IS DENIED?

A decision to deny a TUE application will include a written explanation of the reason(s) for the denial. If it is not clear to you, please contact the **ITA** to understand exactly why the TUE was denied. Sometimes, there may be a critical piece of information, diagnostic test, laboratory results missing, etc. In which case, you should reapply to us.

A decision by ICMG not to recognize or not to grant a TUE may be appealed by the Athlete exclusively to the independent TUE Appeal Committee established by ICMG for that purpose. If the Athlete does not appeal (or the appeal is unsuccessful), the Athlete may not Use the Prohibited Substance or Prohibited Method in question in connection with the Event.

However, any TUE granted by the Athlete's National Anti-Doping Organization or International Federation for that substance or method remains valid outside of that Event.

It should be noted that WADA may review TUE decisions at any time but is not obliged to proceed with a request for a review.

WHAT IF MY NADO'S TUE IS NOT RECOGNIZED BY THE ICMG?

You and/or your NADO 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. 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 your NADO should be submitted to WADA. Please use a secure on-line method unless sending by registered mail.

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

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

WILL MY 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 your TUE request is kept strictly confidential and treated in accordance with the Athlete's Declaration contained in the ADAMS TUE and in the TUE Application Form which can be found here. All members of the TUEC and any other authorized recipients of your TUE request and related information (as described in the Athlete's Declaration) are subject to a professional or contractual confidentiality obligation.

Please review the terms of the Athlete's Declaration carefully. In particular, note that should you wish to revoke the right of the ITA's TUEC to obtain the information related to your TUE in accordance with the Athlete's Declaration, your TUE application will be deemed withdrawn without approval [or recognition] being granted.

Your TUE request-related information will be retained by the ICMG, **ITA's TUEC** and any other authorized recipients for no longer than necessary for the purposes stated in the Athlete's Declaration, in accordance with the International Standard for the Protection of Privacy and Personal Information.

CONTACT INFORMATION

For any further information and questions in relation to personal information practices, please contact the ITA at <u>privacy@ita.sport</u> or the ICMG.

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 about TUEs, please contact: tue@ita.sport.

OTHER USEFUL LINKS:

WADA International Standard for Therapeutic Use Exemptions (ISTUE)

WADA Q&A on the Prohibited List

WADA Checklists for TUE Applications

WADA Guidelines for the International Standard for Therapeutic Use Exemptions (ISTUE)

WADA Anti-Doping Education and Learning (ADEL)