# THERAPEUTIC USE EXEMPTION PROCESS

## **GLOSSARY**

**ADAMS:** The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their anti-doping operations in conjunction with data protection legislation.

**Adverse Analytical Finding:** A report from a WADA-accredited laboratory or other WADA-approved laboratory that, consistent with the International Standard for Laboratories, establishes in a Sample the presence of a Prohibited Substance or its Metabolites or Markers or evidence of the Use of a Prohibited Method

**Anti-Doping Organization:** WADA or a Signatory that is responsible for adopting rules for initiating, implementing or enforcing any part of the Doping Control process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other Major Event Organizations that conduct Testing at their Events, International Federations, and National Anti-Doping Organizations.

Athlete: Any Person who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each National Anti-Doping Organization). An Anti-Doping Organization has discretion to apply anti-doping rules to an Athlete who is neither an International-Level Athlete nor a National-Level Athlete, and thus to bring them within the definition of "Athlete." In relation to Athletes who are neither International-Level nor National-Level Athletes, an Anti-Doping Organization may elect to: conduct limited Testing or no Testing at all; analyze Samples for less than the full menu of Prohibited Substances; require limited or no whereabouts information; or not require advance TUEs. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any Athlete whom an Anti-Doping Organization has elected to exercise its authority to test and who competes below the international or national level, then the Consequences set forth in the Code must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and Education, any Person who participates in sport under the authority of any Signatory, government, or other sports organization accepting the Code is an Athlete.

Comment to Athlete: Individuals who participate in sport may fall in one of five categories: 1) International-Level Athlete, 2) National-Level Athlete, 3) individuals who are not Internationalor National-Level Athletes but over whom the International Federation or National Anti-Doping Organization has chosen to exercise authority, 4) Recreational Athlete, and 5) individuals over whom no International Federation or National Anti-Doping Organization has, or has chosen to, exercise authority. All International- or National-Level Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international and national level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations.]

CAS: The Court of Arbitration for Sport

Competition: A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a Competition and an Event will be as provided in the rules of the applicable International Federation.

**In-Competition:** The period commencing at 11:59 p.m. on the day before a Competition in which the Athlete is scheduled to participate through the end of such Competition and the Sample collection process related to such Competition. Provided, however, WADA may approve, for a particular sport, an alternative definition if an International Federation provides a compelling justification that a different definition is necessary for its sport; upon such approval by WADA, the alternative definition shall be followed by all Major Event Organizations for that particular sport.

**Major Event Organizations:** The continental associations of National Olympic Committees and other international multisport organizations that function as the ruling body for any continental, regional or other International Event.

**National Anti-Doping Organization:** The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of Samples, manage test results and conduct Results Management at the national level. If this designation has not been made by the competent public authority(ies), the entity shall be the country's National Olympic Committee or its designee

Prohibited List: The list identifying the Prohibited Substances and Prohibited Methods

**Recreational Athlete:** A natural Person who is so defined by the relevant National Anti-Doping Organization; provided, however, the term shall not include any Person who, within the five years (5) prior to committing any anti-doping rule violation, has been an International-Level Athlete (as defined by each International Federation consistent with the International Standard for Testing and Investigations) or National-Level Athlete (as defined by each National Anti-Doping Organization consistent with the International Standard for Testing and Investigations), has represented any country in an International Event in an open category or has been included within any Registered Testing Pool or other whereabouts information pool maintained by any International Federation or National Anti-Doping Organization.

Comment to Recreational Athlete: The term "open category" is meant to exclude competition that is limited to junior or age group categories.

# 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) Prohibited List 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 <u>WADA International Standard</u> for Therapeutic Use Exemptions (ISTUE) Article 4.2):

- 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 Masters Games Association (IMGA)** 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 IMGA** jurisdiction, ie participating in IMGA events.

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 (<a href="https://globaldro.com">https://globaldro.com</a>) 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 IMGA 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, IMGA 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 international federation 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 an 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 IMGA, 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 IMGA, 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 IMGA 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 **IMGA** 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 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 IMGA 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 IMGA not to recognize or not to grant a TUE may be appealed by the Athlete exclusively to the independent TUE Appeal Committee established by IMGA 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 IMGA?

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: <a href="mailto:medical@wada-ama.org">medical@wada-ama.org</a>. 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 <a href="https://example.com/here">here</a>. 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 IMGA, **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 IMGA.

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: <u>tue@ita.sport</u>.

## **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)