

THERAPEUTIC USE EXEMPTION PROCESS

1. WHAT IS A THERAPEUTIC USE EXEMPTION (TUE)?

Riders may have illnesses or conditions that require them to take medications or undergo procedures. If the medication or method a Rider 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 Rider 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).

2.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 for</u> Therapeutic Use Exemptions (ISTUE) Article 4.2):

- The Rider 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 Rider'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.

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

The Fédération International de Motocyclime (FIM) 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 international-level Riders that fall under the FIM's jurisdiction.

Riders 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 Prohibited</u> <u>List</u>.

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

You have a responsibility to inform your physician(s) that you are a rider bound to anti-doping rules. You and your physician(s) should check the Prohibited List 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 Riders 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:

International Level Definition

- (a) Riders who participate in the FIM World Championship or a FIM Cup/Prize Event (the list of FIM World Cup/Prize Events can be found at the following link: https://www.fim-moto.com/en/
- (b) Riders who are part of the FIM Registered Testing Pool, Testing Pool or other Pool established by FIM
- → If it is determined that you are an International-Level Rider you must apply to the ITA 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 National Anti-Doping Organization (NADO):

Your NADO's TUE is only valid at the national level, and you must submit a request for recognition to the ITA. Please refer to the section "How to submit a request for recognition of your NADO's TUE to the ITA?" below.

→ If you are NOT an International-Level Rider and you have been tested by the FIM, ITA's TUEC recognizes a valid TUE granted by your NADO (i.e., it satisfies the ISTUE criteria for granting a TUE); unless you are required to apply for recognition of the TUE because you are competing in an international event.

If you are NOT a National-Level Rider as defined by your NADO and you have been tested by **the FIM**, you must apply for a retroactive TUE to the **ITA**.

4.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 rider who is not under the jurisdiction of FIM or NADO and were tested.
- You tested positive after using a substance Out-of-Competition that is only prohibited In-Competition (for example glucocorticoids).

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 a Rider'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)."

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.

5.HOW TO APPLY TO THE ITA FOR A TUE?

The **FIM** encourages to submit TUE applications via ADAMS, together with the required medical information. If you do not have an ADAMS account, you can use the online submission form found here: <u>Therapeutic Use Exemption Submission (microsoft.com)</u>

Please download the <u>TUE Application Form</u> (found on https://ita.sport/TUE), duly complete it and sign it.

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

In addition to your TUE form, 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 Rider in making the TUE application and in supplementing it as required by the TUEC are the responsibility of the Rider.

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

To assist you and your doctor in providing the correct medical documentation, we suggest consulting the WADA's Checklists for TUE applications for guidance and support, and Medical Information to Support the Decisions of TUECs 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.

6.HOW TO SUBMIT A REQUEST FOR RECOGNITION OF MY NADO'S TUE TO THE ITA?

Your request for recognition should be submitted to the ITA in writing quoting your ADAMS TUE reference number.

Keep a complete copy of the proof that your request for recognition has been sent to the ITA.



7.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.

8.WHAT IF I NEED TO RENEW MY 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.

9.WHAT IF MY FIM 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 re-apply to us.

You and/or your NADO may refer the matter to WADA for review no later than 21 days after notification of the ITA's TUEC decision. You should send the same information that you submitted to us, and on which the decision to deny the TUE was based on, via a secure on-line method or by registered mail at:

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 email address to enquire and/or send the request for review is: medical@wada-ama.org

It should be noted that WADA is not obliged to proceed with a request for a review. In that case, you and/or your NADO may appeal to the Court of Arbitration for Sport (CAS).



10.WHAT IF MY NADO'S TUE IS NOT RECOGNIZED BY THE ITA'S TUEC?

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.

11.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 FIM, 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.

12.CONTACT INFORMATION

For any further information and questions in relation to personal information practices, please contact the ITA at privacy@ita.sport or the FIM at privacy.anti-doping@fim.ch.

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*.



13.OTHER USEFUL LINKS:

WADA International Standard for Therapeutic Use Exemptions (ISTUE)

WADA Q&A on Therapeutic Use Exemptions

WADA Checklists for TUE Applications

WADA Guidelines for the 2021 International Standard for Therapeutic Use Exemptions (ISTUE)

WADA Anti-Doping Education and Learning (ADEL)