

# FREQUENTLY ASKED QUESTIONS (FAQ) Therapeutic Use Exemptions (TUEs)

#### **BACKGROUND**

Since 13 September 2016, the cyber espionage group "Fancy Bear" has been releasing batches of confidential athlete data on their website, which they illegally obtained from a Rio 2016 Olympic Games account of the World Anti-Doping Agency (WADA)'s Anti-Doping Administration and Management System (ADAMS). Specifically, they are releasing data related to Therapeutic Use Exemptions (TUEs) delivered by Anti-Doping Organizations (ADOs) – International Federations (IFs), National Anti-Doping Organizations (NADOs), and Major Event Organizers (MEOs).

This was made possible by spear phishing of email accounts through which hackers obtained ADAMS passwords.

WADA has no reason to believe that they have accessed the broader ADAMS system.

The Agency is taking this situation concerning athlete privacy very seriously. The incident response team that we have assembled is actively working with law enforcement agencies in Canada and elsewhere, and acting on the intelligence obtained through our investigations to prevent any further intrusions. We are also consulting with leading cyber security experts to ensure that no further information is accessed from the broader ADAMS.

The situation has led to a lot of media coverage; and unfortunately, a tremendous amount of misinformation. It is very unfortunate that athletes' TUEs are being debated publically on the basis of partial, confidential, medical information. Athletes should not be required to publically justify their TUEs.

The TUE program is a rigorous and necessary part of elite sport; which has overwhelming acceptance from athletes, physicians and all anti-doping stakeholders.

This FAQ has been designed to address the misinformation and uphold the rights of clean athletes as embodied within the <u>World Anti-Doping Code (Code)</u> and the <u>International Standard for Therapeutic Use Exemptions (ISTUE)</u>.

### FREQUENTLY ASKED QUESTIONS

### 1. WHAT IS A TUE AND WHY ARE THEY GRANTED?

Athletes, like all people, may have illnesses or conditions that require them to take a particular medication/substance or undergo certain procedures/methods.



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For athletes, the substance or method may appear on WADA's <u>List of Prohibited Substances</u> and <u>Methods (List)</u>. In such instances, they may be granted a TUE, which gives them permission to take a substance or use a method.

TUEs are only granted by Anti-Doping Organizations (ADOs) -- IFs, NADOs and Major Event Organizers (MEOs) -- following a robust review process that is defined in the <u>ISTUE</u>; and, evaluation by three physicians specialized in sports medicine and/or other relevant specialties.

Granted TUEs are subject to further evaluation by the relevant ADOs and WADA.

#### 2. HOW LONG HAVE TUES EXISTED?

TUEs (originally called Medical Exemptions) have been around since the early 1990s. The International Olympic Committee's (IOC's) medical commission acknowledged that some athletes have medical conditions that require the use of medications/substances and/or treatments/methods that are on the Prohibited List.

The International Standard for Therapeutic Use Exemptions was first adopted in 2004 and came into effect 1 January 2005. Further revisions were made in 2009, 2010, 2011 and 2015.

### 3. WHICH ATHLETES CAN APPLY FOR A TUE?

All athletes that compete in sport at the international level (as defined by each International Federation) or the national level (as defined by each National Anti-Doping Organization) can apply for a TUE.

### 4. WHAT ARE THE CRITERIA FOR GRANTING A TUE?

The criteria for granting a TUE are as follows:

- 1. The athlete would experience significant health problems without taking the prohibited substance or method:
- 2. The therapeutic use of the substance would not produce significant enhancement of performance;
- 3. There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance or method;
- 4. The requirement to use that substance or method is not due to the prior use of the substance or method without a TUE, which was prohibited at the time of use.

For the TUE to be granted, <u>all four</u> criteria must be met.



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#### 5. WHO GRANTS TUES?

All ADOs must have a clear process in place; whereby, athletes with documented medical conditions can request a TUE and have such request appropriately dealt with by a panel of independent physicians called a Therapeutic Use Exemption Committee (TUEC).

ADOs must publish details of that process by posting the information in a conspicuous place on their website. ADOs, through their TUECs, are then responsible for granting or declining such applications.

### 6. WHAT IS THE ROLE OF WADA IN THE REVIEW OF TUES?

WADA's role in the TUE process is two-fold. First, the Agency, through its TUEC, has the right to monitor and review any TUE granted by an ADO; and, following such review, to reverse any decision.

Second, an athlete who submits a TUE application to an ADO and is denied, can ask WADA to review the decision. In certain cases, WADA must review TUE decisions of ADOs and it may review other TUE decisions. If WADA determines that denial of the TUE did not comply with the <a href="ISTUE">ISTUE</a>, the Agency can reverse the decision.

WADA itself does not accept TUE applications from athletes.

### 7. WHAT HAPPENS WHEN AN ATHLETE IS GRANTED A TUE?

TUEs are granted for a specific method or a substance with a defined dosage and route of administration. They are also granted for a specific period of time and do expire. The athlete must comply with all the treatment conditions outlined in the TUE application. Material changes to the treatment require a new application and TUEC review.

Once a TUE has been granted by an ADO, it will inform WADA, which then has the opportunity to review the decision. If the decision does not conform to the ISTUE, WADA may reverse it and deny the TUE.

WADA's decision is not retroactive. Therefore, a reversal shall not apply retroactively and athletes' results prior to such notification shall not be disqualified. Where the TUE reversed was a retroactive TUE, however, the reversal shall also be retroactive.

### 8. ARE TUES NECESSARY? SHOULD PEOPLE NEEDING PROHIBITED SUBSTANCES OR METHODS BE PRECLUDED FROM SPORT?

Yes, TUEs have been overwhelming deemed necessary by athletes, physicians and all antidoping stakeholders.



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The notion of precluding athletes that suffer from illnesses and conditions such as diabetes, asthma, inflammatory bowel disease, rheumatological conditions, etc. from sport cannot be given serious consideration. It would undermine a fundamental value of sport that is the right of access and participation to sport and play, which has long been recognized by numerous international conventions.

### 9. COULD TUES BE USED BY ATHLETES, ENTOURAGE, ETC. TO CHEAT?

The granting of a TUE follows a rigorous review process as defined in the Code and the (ISTUE). This process includes the evaluation of all TUEs by three physicians specialized in sports medicine and/or other relevant specialities.

A TUE provides a limited exemption to use a particular prohibited substance or method at a prescribed dosage, frequency, route of administration and duration. The TUECs, which evaluate the applications, are comprised of medical experts with experience in sport medicine and/or other relevant specialties.

TUEs granted by NADOs must be recognized (accepted) by IFs for international athletes. WADA has the right to monitor, review and overturn any granted TUE application.

### 10. IS A TUE UNFAIR TO ATHLETES WITHOUT MEDICAL CONDITIONS WHO CAN'T USE PROHIBITED SUBSTANCES OR METHODS?

As stated in the (ISTUE), an athlete can only be granted a TUE if he/she proves:

- that there is a legitimate medical condition requiring treatment;
- there is no reasonable non-prohibited alternative; and
- that there is no performance enhancement beyond a return to normal.

The majority of athletes needing TUEs often remain at a disadvantage because of their illness/condition despite the ability to use medications.

### 11. WHY IS INFORMATION ON ATHLETES' USE OF TUES NOT PUBLICLY DISCLOSED?

It is a fundamental human right that personal medical information be kept confidential. Nobody would want such information disclosed, let alone for it to be debated publically.

Athletes should not be required to publish their TUE information, which may de facto disclose their disease or condition, nor should they be required to publically defend their legitimate use of a TUE.



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It is very unfortunate that, with the cyber-hacking situation, athletes' TUEs are being debated publically on the basis of partial, confidential, medical information and misinformation as it relates to the TUE program.

The TUE program is a rigorous and necessary part of elite sport; which has overwhelming acceptance from athletes, physicians and all anti-doping stakeholders.

## 12. GIVEN THE CURRENT CYBER HACKING ACTIVITY, WOULD AN ATHLETE BE FOUND IN BREACH OF ANTI-DOPING RULES IF THEY DID NOT ENTER THEIR TUES IN ADAMS?

Athletes are encouraged to continue entering their data in ADAMS.

WADA believes that the cyber espionage group operator by the name of Fancy Bear illegally gained access to ADAMS via an account created for the Rio 2016 Games. This was made possible by spear phishing of email accounts through which hackers obtained ADAMS passwords. We have no reason to believe that they have accessed the broader ADAMS system.

### 13. IS THE BROADER ADAMS SECURE?

The cyber-attack was made possible by spear phishing of email accounts through which hackers gained access to ADAMS via an account created for the Rio 2016 Games.

WADA has no reason to believe that they have accessed the broader ADAMS system.

### 14.WHY HAS THERE BEEN A 48% INCREASE IN TUE'S BETWEEN 2014 AND 2016?

This increase is a result of an increase of TUEs being entered into ADAMS and not an increase in TUE applications. This is partly a function of WADA's Foundation Board decision of May 2016 to reinforce the mandatory requirement for ADOs to enter all TUEs in ADAMS, combined with the increased use of ADAMS due to the Rio 2016 Olympics and Paralympics.

### 15. IS IT TRUE THAT MANY ATHLETES ARE BEING GRANTED TUES FOR ANALGESICS, BETA-2 AGONISTS (ASTHMA MEDICATION) AND THYROID HORMONES?

A TUE can only be granted for a substance or method that is prohibited. Thyroid hormones, most analgesics and many inhaled beta-2 agonists (when taken in therapeutic doses) are not prohibited.