

ADVISORY NOTE

INTRODUCTION

In accordance with IAAF Rule 34.9, a Therapeutic Use Exemption (TUE) is required whenever an athlete with a documented medical condition requires the use of a prohibited substance or a prohibited method which is listed on the WADA Prohibited List.

This implies that athletes and their doctors are fully aware of the list of prohibited substances contained in the WADA Prohibited List (reviewed annually) and that they pay particular attention to the contents of all pharmaceutical products purchased over the counter or prescribed to them by a doctor.

☞ It is important to remember that athletes are personally responsible for the presence of a prohibited substance in their body.

If an athlete does not file a TUE application and subsequently tests positive for the prohibited substance, he or she may be found guilty of an anti-doping rule violation and face sanctions under IAAF Rules.

These Explanatory Notes provide practical information regarding the TUE process under the new IAAF Anti-Doping Rules and Regulations through questions and answers.

QUESTIONS & ANSWERS

What has changed since the last version of the IAAF Anti-Doping Rules and Regulations?

TUE applications must be submitted to the IAAF no less than 30 days before the athlete needs the approval (for instance, a competition).

Salbutamol¹ and salmeterol by inhalation are not prohibited anymore and therefore no longer require a TUE. However, athletes are required to declare the use of either of these substances to the IAAF.

A Declaration of use is also required for the use of glucocorticosteroids administered by intraarticular, periarticular, peritendinous, epidural, intradermal, inhalation routes and for the use of platelet-derived preparations (e.g. Platelet Rich Plasma, "blood spinning") - or similar substances - administered by other than intramuscular route (e.g. peritendinous). Platelet-derived preparations by intra-muscular route require a TUE.

How can such declaration be made?

The Declaration of use can be made through the IAAF Declaration of use Form which can be downloaded from the IAAF website or through ADAMS. In any event, athletes are required to declare the use of the substances described above on the relevant section of the doping control form in case of a doping test.

¹ The presence of salbutamol in urine in excess of 1000 ng/ml is presumed not to be an intended therapeutic use of the substance and will be considered as an adverse analytical finding unless it is proven, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of a therapeutic dose of inhaled salbutamol (max. 1600 micrograms).

What happens if an athlete fails to make such declaration of use?

Unlike TUEs, the failure to declare cannot result in an anti-doping rule violation.

Who must apply to the IAAF for a TUE?

All athletes requiring the use of a prohibited substance contained in the WADA Prohibited List must have a TUE on file. However, **only International-level athletes** are required to apply to the IAAF for a TUE.

For the purpose of the IAAF Anti-Doping Rules and Regulations, an International-level athlete is defined as:

1. an athlete who is in the IAAF Registered Testing Pool of athletes subject to out-of-competition testing at the time of the application; or
2. an athlete competing in one of the major International competitions contained in the List of International competitions established for the purpose of the IAAF Anti-Doping Rules.

Note: each athlete is personally notified of his/her inclusion in the Registered Testing Pool. The List of athletes in the IAAF Registered Testing Pool is available on the IAAF website. You must never assume that you are an International-level athlete or that you are competing in an International competition until after checking either the List of athletes in the Registered Testing Pool or the List of International competitions available on the IAAF website.

The applicant will be asked to confirm on the IAAF TUE application form whether they fulfill one of the above criteria. **Applications sent by athletes who are not International-level athletes under IAAF Rules will be automatically rejected.**

Athletes who are not International-level athletes must apply for TUEs to their relevant national TUE body. All Member Federations should contact their athletes to notify them of the relevant national TUE body to which applications should be made (with a copy to the IAAF). The relevant national TUE body may be:

- the National Federation itself; or
- such other body as may be designated by the National Federation to review TUE applications on its behalf; or
- such other independent body which has competent authority to grant TUE applications in the country or territory of the National Federation.

You must be aware that TUEs granted on a national level shall have no application internationally. If an athlete who has been granted a TUE at national level subsequently becomes an International-level athlete or wishes to compete in an International competition, he/she must at that point submit a separate international application for a TUE to the IAAF. If an athlete tests positive at an International competition for a prohibited substance without a TUE on file that has been granted by the IAAF, he/she shall be subject to investigation by the IAAF for an anti-doping rule violation.

When should I apply to the IAAF?

A TUE application for the use of a substance prohibited in-competition must be submitted to the IAAF at least **30 days** before the competition in question. For the prohibited substances out-of-competition, the TUE application must in any event be submitted before the use of the prohibited substance.

A TUE application by an International-level athlete will not be considered for retroactive approval except in cases where:

- (i) emergency treatment or treatment of an acute medical condition was necessary ; or
- (ii) due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit an application, or for an application to be reviewed, prior to the doping control.

How do I make my application?

A TUE application to the IAAF must be submitted on the IAAF TUE Application Form which can be downloaded from the IAAF website.

The TUE application must be legible and complete. It will be considered to be complete if all boxes on the TUE Application Form have been properly filled in and if it is accompanied by all supporting medical documents including:

- (a) a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application;
- (b) a statement by an appropriately qualified physician demonstrating the necessity of the otherwise Prohibited Substance or Prohibited Method in the treatment of the athlete and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of such a condition;
- (c) the dose, frequency, route and duration of administration of the otherwise Prohibited Substance or Prohibited Method in question must be specified in the application and, in case of change, a new application must be submitted.

Incomplete and illegible applications will be systematically returned to the applicant.

In response to a generally recognised increase in the use of beta-2 Agonists by athletes, the IAAF Council has endorsed a recommendation from the IAAF Medical and Anti-Doping Commission to require more detailed information and documents from International-level athletes and athletes competing in International competitions who seek a TUE for the use of beta-2 Agonists by inhalation for asthma and/or exercise-induced bronchoconstriction (to the exception of salbutamol and salmeterol which only require a declaration of use).

According to the IAAF beta-2 Agonists Protocol, an IAAF authorisation to use beta-2 agonists is subject to the following requirements:

- Synthesis of medical history with respiratory symptoms
- Physical examination
- A report of spirometry with the measure of the Forced Expiratory Volume in 1 second (FEV1)

If an airway obstruction is present, the spirometry will be repeated after inhalation of a short acting beta-2 agonist to demonstrate the reversibility of bronchoconstriction. In the absence of reversible airway obstruction, a bronchial provocation test is required to establish the presence of airway hyperresponsiveness (Bronchial provocation test). Provocation may be obtained by inhalation of cold, dry air, inhalation of aerosols or exercise. Specific parameters/tests results have to be reached in order to obtain the authorisation.

Who will review my application?

Your application will be reviewed by the IAAF TUE sub-commission which is composed of at least three independent and experienced physicians with sound knowledge of clinical, sports and exercise medicine. The chairman of the IAAF TUESC may decide in appropriate circumstances to delegate responsibility for reviewing TUE applications to a single experienced physician.

All members of the IAAF TUESC are required to maintain strict confidentiality concerning the information contained in the TUE applications referred to them.

How long will it take?

In normal circumstances, a decision of the IAAF TUESC should be completed within 30 days of receipt of a complete application.

Which are the criteria for granting a TUE?

TUE applications will be granted by the IAAF TUESC only in cases of a clear and compelling need in strict accordance with the following criteria:

- that the athlete would experience a significant impairment to his health if the Prohibited Substance or Prohibited Method was to be withheld in the course of treating an acute or chronic medical condition.
- that the therapeutic use of the Prohibited Substance or Prohibited Method would produce no additional enhancement of performance other than that which might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition. . .
- that it is possible without undue difficulty to monitor or control the dose, frequency, method of administration or other aspect of the use of a Prohibited Substance or Prohibited Method that may otherwise permit an enhancement of performance other than a return to a state of normal health;
- that there is no reasonable therapeutic alternative to the use of the otherwise Prohibited Substance or Prohibited Method.
- that the necessity for the use of the otherwise Prohibited Substance or Prohibited Method is not a consequence, either wholly or in part, of the prior use, without a TUE, of a Prohibited Substance or Method which was prohibited at the time of the use.

In no circumstances, shall a TUE be granted to an athlete if the IAAF considers that he would thereby gain a competitive advantage over another athlete.

How do I know if my TUE application was granted or rejected?

The decision of the TUESC will be notified to you in writing at the e-mail or postal address indicated on your TUE application form. A TUE certificate will be attached to the notification if the TUE you applied for is granted. The IAAF Certificate will specify the substance you are allowed to use (its dosage, frequency, route of administration) and the duration of the TUE. You will be required to strictly comply with the specifications contained in the IAAF TUE Certificate.

Who else is informed on the decision of the IAAF TUESC?

Your Federation, your National Anti-Doping Organisation (if appropriate) and the World Anti-Doping Agency (WADA).

What happens if my application is rejected?

You will be informed on the reason(s) for rejecting your application. Your application may simply not be legible, or incomplete. In such cases, you can resend another application immediately.

If your application is rejected because the IAAF TUESC considered that you did not fulfill all criteria for granting a TUE (see above), you can submit your TUE application to the WADA TUESC which can reverse the IAAF TUESC's decision to deny you a TUE. A decision to deny a TUE can also be appealed to the Court of Arbitration for Sport in accordance with IAAF Rule 42.11.

Further questions/assistance

If there are any questions arising from these Explanatory Notes or if there are any other questions regarding the relevant procedures to be followed for TUE applications under IAAF Rules, please do not hesitate to contact the IAAF Medical and Anti-Doping Department for further information at: tue-application@iaaf.org.

List of relevant IAAF documents and location on the IAAF website

(All documents are available in English and French)

NAME	LOCATION
IAAF Beta-2-Agonist Protocol	Anti-Doping>Athlete's Area>Therapeutic Use Exemptions
IAAF TUE Application Form	Anti-Doping>Athlete's Area>Therapeutic Use Exemptions
IAAF Advisory note on TUE's	Anti-Doping>Athlete's Area>Therapeutic Use Exemptions
IAAF List of International Competitions	Anti-Doping>Athlete's Area>Therapeutic Use Exemptions