

Q&A: 2009 International Standard for Therapeutic Use Exemption

What are International Standards?

International Standards are aimed at bringing harmonization among anti-doping organizations (ADOs) responsible for specific technical and operational parts of anti-doping programs. Adherence to the International Standards is mandatory for signatories to the World Anti-Doping Code (Code).

What is a Therapeutic Use Exemption (TUE)?

Athletes, like all others, may have illnesses or conditions that require them to take particular medications. If the medication an athlete is required to take to treat an illness or condition happens to fall under the WADA Prohibited List, a TUE may give that athlete the authorization to take the needed medicine.

What is the purpose of the International Standard for Therapeutic Use Exemption (ISTUE)?

The main purpose of the ISTUE is to ensure that the process of granting TUEs is harmonized across sports and countries.

What are the criteria for granting a TUE?

The criteria are:

- The athlete would experience significant health problems without taking the prohibited substance or method;
- The therapeutic use of the substance 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; and
- There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance or method.

Who grants TUEs?

The ISTUE and the Code state that all International Federations (IFs) and National Anti-Doping Organizations (NADOs) must have a 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). IFs and NADOs, through their TUECs, are then responsible for granting or declining such applications.

More information on procedures and protocols for TUEs can be found in the TUE section of WADA's Web site. (<http://www.wada-ama.org/en/exemptions.ch2>.)

Why was it decided to revise the ISTUE?

Concurrent to the revision of the Code, WADA launched in 2006 a process for updating the International Standards (including testing, laboratory activities and accreditation, and therapeutic use exemptions), to build on the experience gained by WADA and its stakeholders in the application of the Standards since their coming into force and to improve all anti-doping protocols and processes. Revisions to the ISTUE were approved by WADA's Executive Committee at its May 10 and September 20, 2008, meetings.

What major changes does the 2009 ISTUE include?

Generally speaking, the feedback received indicated that the principles and the philosophy of TUEs are well accepted and considered as useful. The only revisions requested concerned the Abbreviated TUE process (as opposed to Standard TUEs), due to the administrative workload it generates for ADOs. This concerns a limited number of identified substances. The 2009 ISTUE addresses these concerns by eliminating the concept of the Abbreviated TUE.

Asthma treated by inhaled Beta-2 agonists

The 2009 ISTUE, which takes into consideration stakeholder feedback and current medical perspectives such as the International Olympic Committee Consensus on Asthma issued in February 2008 (calling for strict control of use of controls of these drugs by athletes), is based on the premise that for the process to be manageable while at the same time deterrent enough for elite athletes, different requirements can be requested of athletes depending on their level (international or national level). All athletes needing to use inhaled Beta-2 agonists for medical reason must have a justifying medical file

and must declare these substances on the doping control form and in ADAMS where reasonably feasible.

Specific provisions depending on the level of the athlete:

For international-level athletes:

- Athletes part of an international registered testing pool (IRTP) need an approved TUE for asthma prior to using the substance.
- For athletes who are no part of an IRTP but are taking part in an international event, it is at the discretion of the IF either to deliver a TUE prior to the event or to provide a retroactive TUE in case of an adverse analytical finding (AAF). The granting of a retroactive TUE has to comply with the criteria set forth in the 2009 ISTUE.

For national-level athletes:

- It is at the discretion of the NADO either to approve the TUE or to provide a retroactive TUE in case of an AAF.

In any case, all athletes may request a TUE if they wish to do so.

Glucocorticosteroids (GCS) used by non-systemic routes including inhaled route

In the case of GCS used by non-systemic routes including inhaled route, the athlete must provide a minimum declaration that includes the diagnosis, the substance taken, and contact information of the medical doctor who administered the treatment. It is at the discretion of the ADO to ask for more than this minimum declaration. For topical use of GCS, neither a TUE nor a declaration is requested.

When did the 2009 ISTUE go into effect?

The 2009 ISTUE went into effect on January 1, 2009, at the same time as the 2009 Code.