

The World Anti-Doping Program

THERAPEUTIC USE EXEMPTIONS GUIDELINES

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Introduction and scope

These Therapeutic Use Exemption (TUE) Guidelines are a model of best practice developed as part of the World Anti-Doping Program. They are based on the World Anti-Doping Code (Code, or WADC) and on the International Standard for TUE set out in the Code. These Guidelines should, in particular, be read in conjunction with the principles set out in Article 4.4 of the WADC. They were drafted in order to guide and assist the Anti-Doping Organizations (ADOs) concerned throughout the TUE process.

As a model of best practice, these Guidelines are not mandatory and have no legal value. Only the TUE Standard is mandatory and in case of any discrepancy or ambiguity between these Guidelines and the International Standard for TUE, the International Standard for TUE shall be the authoritative document.

ADOs are free to decide how to incorporate them into their current rules and procedures. The Guidelines can be incorporated in whole or in part and can be amended, reworded or modified to best fit the ADO's needs.

Definitions

Defined terms from the Code

Adverse Analytical Finding: A report from a laboratory or other approved *Testing* entity that identifies in a *Specimen* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use* of a *Prohibited Method*.

Anti-Doping Organization (ADO): a *Signatory* that is responsible for antidoping 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*, WADA, International Federations, and *National Anti-Doping Organizations*.

Athlete: For purposes of *Doping Control*, any *Person* who participates in sport at the International-Level (as defined by each International Federation) or National-level (as defined by each *NADO*) and any additional *Person* who participates in sport at a lower level if designated by the *Person's NADO*. 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*.

Code: The World Anti-Doping *Code*.

Event: A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

International Event: An *Event* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization*, or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event*.

International-Level Athlete: *Athletes* designated by one or more International Federations as being within the *Registered Testing Pool* for an International Federation.

International Standard: A standard adopted by WADA in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly.

Major Event Organization: This term refers to the continental associations of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.

National Anti-Doping Organization (NADO): 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*, the management of test results, and the conduct of hearings, all 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.

National Event: A sport *Event* involving International or National-Level *Athletes* that is not an *International Event*.

National Olympic Committee: The organization recognized by the International Olympic Committee. The term *National Olympic Committee* shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical *National Olympic Committee* responsibilities in the anti-doping area.

Person: A natural *Person* or an organization or other entity.

Prohibited List: The List identifying the *Prohibited Substances* and *Prohibited Methods*.

Prohibited Method: Any method so described on the *Prohibited List*.

Prohibited Substance: Any substance so described on the *Prohibited List*.

Registered Testing Pool: The pool of top level *Athletes* established separately by each International Federation and *National Anti-Doping Organization* who are subject to both *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or Organization's test distribution plan.

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, including the International Olympic Committee, International Federations, International Paralympic Committee, *National Olympic Committees*, National Paralympic Committees, *Major Event Organizations*, *National Anti-Doping Organizations*, and WADA.

Team Sport: A sport in which the substitution of players is permitted during a *Competition*.

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

Use: *The application, ingestion, injection or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method.*

WADA: *The World Anti-Doping Agency.*

Defined terms from the International Standard for TUE

Therapeutic: *Of or relating to the treatment of a medical condition by remedial agents or methods; or providing or assisting in a cure.*

TUE: *Therapeutic Use Exemption.*

ATUE: *Abbreviated process for Therapeutic Use Exemption described under Section 8 of International Standard for TUE.*

TUEC: *Therapeutic Use Exemption Committee is the Panel established by the relevant ADO.*

WADA TUEC: *WADA Therapeutic Use Exemption Committee is the Panel established by WADA.*

1. TUE procedure

An athlete, like any other person, may have illnesses or conditions that require the use of particular medications as treatment. But, Substances an athlete is required to take as a treatment may fall under the Prohibited List. In such a case, a Therapeutic Use Exemption (TUE) may, under strict conditions, provide an athlete with the authorization to take the needed medicine, all the while competing in sport, with no resulting doping offence.

1.1. What is a TUE

A Therapeutic Use Exemption (TUE) is an authorization to take a Prohibited Substance under well defined and restricted conditions. An application for a TUE shall be made in accordance with the International Standard for TUE.

A TUE must be obtained for the use of any Substance on the Prohibited List. Depending on the Substance itself and the route of administration (see section 1.1.1 and 1.1.2), either a standard TUE or an Abbreviated TUE (ATUE) can be granted. All athletes who need a medical treatment including a Prohibited Substance or Method and are subject to Testing must obtain a TUE from their relevant ADO. In order to obtain an approval for a TUE, athletes must have a well documented medical condition supported by reliable and relevant medical data.

1.1.1. What is an Abbreviated TUE (ATUE)?

Based on the same principle, an Abbreviated TUE is an easier administrative means of obtaining an authorization to take a Prohibited Substance. This process only applies for particular Substances and specific routes of administration as mentioned in the Prohibited List.

Forms

Applications for Abbreviated TUEs need to be submitted to the ADO on the appropriate ATUE form. The ATUE form must be obtained from the ADO.

Approval procedure

A notification is sent to the athlete by the relevant organization on receipt of a duly completed request. Please note that a review by the relevant ADO or by the WADA TUE Committee (TUEC, see section 7.1) may be initiated at any time during the validity of the ATUE for International-Level athletes.

Start of medical treatment

The athlete can begin treatment as soon as the duly filled form has been received by the relevant organization and the athlete given notice thereof by the same ADO. As mentioned above, a review may be initiated but the ATUE is habitually granted upon reception of the duly filled out ATUE by the ADO.

1.1.2. What is a standard TUE?

Concerned Substances and route of application

A standard TUE is required for any treatment involving a Substance or Method on the Prohibited List for which an Abbreviated TUE cannot be obtained.

Forms

Applications for standard TUEs need to be submitted to the ADO on the appropriate standard TUE form. The standard TUE form may be obtained from the ADO.

Approval procedure

Standard TUE applications will be reviewed by the TUEC of the relevant ADO. The athlete will be notified of the decision taken by the TUEC. Decisions of the TUEC, should be completed within 30 days of receipt of all relevant documentation, and will be conveyed in writing to the Athlete by the relevant ADO (see section 4.2).

Start of medical treatment

If the TUE is approved, the athlete can only begin treatment and-or sports practice after the reception of the authorization notice from the relevant organization. (In rare emergency or exceptional cases, a retroactive approval may be considered, see section 1.3.)

Athletes should not start using the substance before receiving the authorization notice. The athlete would then be using a prohibited method or substance without authorization and this could constitute an anti-doping rule violation in the event that the TUE is denied by the TUEC.

1.2. What are the criteria for granting a TUE

The four criteria that need to be fulfilled to grant a TUE are stated in the International Standard for TUE:

1. "The athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld in the course of treating an acute or chronic medical condition." (Article 4.2 International Standard for TUE)
2. "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. The use of any Prohibited Substance or Prohibited Method to increase "low normal" levels of any endogenous hormone is not

considered an acceptable therapeutic intervention.” (Article 4.3. International Standard for TUE)

By enhancement of performance should be understood: the return by the athlete to the level of performance possessed before the treated medical condition occurred. It means that a certain enhancement of individual performance, due to the efficacy of the treatment, can occur, but that it cannot go beyond the level of performance of the athlete prior to his/her medical condition.

3. “There is no reasonable therapeutic alternative to the use of the otherwise Prohibited Substance or Prohibited Method.” (Article 4.4. International Standard for TUE.)

Two points on reasonable therapeutic alternatives must be retained:

- Only valid and referenced medications are considered alternative.
 - The definition of what is valid and referenced can vary in different countries. These differences should be taken into account. E.g. A medicine could be registered in a country and not in another, or still be under testing, etc.
4. “The necessity for the use of the otherwise Prohibited Substance or Prohibited Method cannot be a consequence, wholly or in part, of prior non-therapeutic use of any substance from the Prohibited List.” (Article 4.5. International Standard for TUE.)

A TUE can only be granted if all four criteria are fulfilled.

1.3. Deadline for TUE submission and retroactive approvals

According to Article 4.1. of the International Standard for TUEs, a TUE for any Substances and Methods that are prohibited in competition has to be submitted by the athlete no less than 21 days before participating in an Event.

In order to make sure that the Athlete has the TUE before participating in a competition all Athletes are strongly advised to send in their applications at least 30 days before participating in an event as the TUECs have 30 days to render their decision. (This discrepancy will be changed in the next revision of the International Standard for TUE.)

For substances which are prohibited in and out of competition, the TUE application has to be submitted as soon as a pathology requesting the use of prohibited Substances and/or Methods has been diagnosed.

There are some situations when retroactive approval can be accepted. Even if a potential retroactive case is given consideration, this in no way guarantees that the TUE will be accepted. The evaluation procedure is the same as for a normal TUE request. The request will be considered by the relevant TUEC who will then render its decision. According to Article 4.7 of the International Standard for TUE, the following two situations may lead to a retroactive approval:

1. Emergency treatment or treatment of an acute medical condition.
2. Exceptional circumstances. If there was not enough time or opportunity for an applicant to submit, or if a TUEC did not have sufficient time to consider an application prior to Doping Control.

Some clarification on these two points:

- An emergency situation is when the vital prognosis of the athlete is endangered. E.g. when the medical condition justifies the treatment applied and requires immediate application.
- An example of an exceptional circumstance is when a TUE could not be delivered on time by no fault of the athlete. E.g.: An athlete who has a chronic disease must apply for a TUE 21 days before an event. However, the case of an athlete who is normally healthy and who suddenly encounters a significant health problem a few days before an event and was unable to get a TUE on time for TUEC approval could be considered an "exceptional circumstance."

2. Documentation/information

2.1. What is sufficient?

A TUE application should be considered as sufficient if it allows the ADO to render a reasoned decision in accordance with the criteria set in the International Standard for TUE.

As mentioned on the TUE application form and in accordance with the International Standard for TUE the following documents must be attached to the duly filled-in application form in support of a standard TUE request:

- Evidence confirming the diagnosis must be included.
- Copies of the original reports or letters.
- A comprehensive medical history and the results of all relevant examinations, laboratory investigations and imaging studies relevant to the application (Article 7.6 of the International Standard for TUE).

Note: Any additional relevant investigations, examinations or imaging studies requested by TUEC of the ADO will be undertaken

at the expense of the applicant or his/her national sport governing body (Article 7.7 of the International Standard for TUE).

- A statement by a qualified physician attesting to 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 to treat this condition (Article 7.8 of the International Standard for TUE).

Note: Evidence should be as objective as possible under the clinical circumstances.

- In the case of non-demonstrable conditions, independent supporting medical opinion will assist the application.

The data provided should be up-to-date and accurate in form and substance.

2.2. Who decides what is sufficient?

The ADO in charge of the decision (see section 3) and more specifically its TUEC decides what is sufficient. The TUEC holds the right to require more information at any time if it is needed to render a decision.

WADA can ask for more information to the granting body in the frame of its reviewing activity should the evidence supporting the diagnosis be insufficient. While WADA is examining such cases the initial decision remains valid (see section 7.1).

2.3. Incomplete TUE applications

As mentioned in section 2.1, applications for standard TUE have to be documented with all medical evidence supporting the diagnosis. It is the ADO's responsibility to request the missing documentation to allow the TUEC to render a decision.

2.4. TUE application forms

According to Article 7.2 of the International TUE Standard, application forms can be modified by the ADOs. Additional information can be added but it is very important that all information requested by WADA remains on the forms, no section or items can be removed.

It is further advised that ADOs do not impose additional requests on the forms that could create disharmony, confusion or discredit to the process. Accordingly, any modification to the forms should be limited to the ADOs customization of the forms, by adding their logo or contact details for instance.

2.5. TUE application received by e-mail or fax by ADO

Usually, on reception of a TUE application by e-mail or fax by IFs and NADOs, the evaluation part of the process starts, even if the hard copies have not yet been received. The e-mail or fax application must however

be followed by the reception of the hard copy of the complete application containing all requested relevant medical information/documentation.

2.6. Renewing a TUE

2.6.1. Full application or not?

TUEs cannot be renewed without a new medical consultation and confirmation thereof. This means the athlete must fill in a new request signed by his or her Physician upon expiration. Even in the case of chronic use, a TUE can only be granted for a limited period of time. The Physician should give a recommendation to the TUEC on the duration of the validity of the TUE based on the date of the next scheduled appointment with his/her patient for follow-up on the specific medical condition.

2.6.2. Renewal option in ADAMS

There is a renewal option available in ADAMS (see section 7.2). This option simplifies the process by providing a computerized form with all fields already filled-in. The athlete must nevertheless obtain and submit Physician documentation on a regular basis and the TUE shall be renewed accordingly. All application forms must be duly filled-in, signed and dated by the Physician and the athlete, whether it is a first application or a renewal request.

2.6.3. Automatic continuation?

Automatic continuation is not acceptable in any case. The Physician must see the athlete on a regular basis and evaluate if the medical condition has changed and if the treatment is still appropriate for the stated medical condition.

2.7. Duration

As mentioned earlier, a TUE should always be granted for a limited period of time even if the use of the Substance is chronic. The use of the Substance shall be followed-up by a Physician on a regular basis. The TUE will be renewed consequently.

For specific guidance regarding duration of TUEs, please refer to the Medical Information to support TUEC decisions.

3. Who grants TUE?

Under the World Anti-Doping Code (WADC), WADA has issued an International Standard for granting of TUEs. The Standard states 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 a request appropriately evaluated 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 denying such requests.

IFs and NADOs grant TUEs depending on the level of the athlete. A TUE request can only be submitted to one body at a time. Please refer to section 3.4. for the procedure to follow for an athlete who changed his level of competition. In certain circumstances, National Federations can also grant TUEs for National-Level athletes.

Major Events

Special protocols for TUE applications may be in effect during Major Events. Major Events include those organized by international multi-sports organizations that function as the ruling body for any continental, regional or other international event (e.g. IOC, IPC, FISU, etc.). For instance during the Olympic Games, the IOC is considered as an ADO possessing the capacity to deliver ATUEs or TUEs to athletes who need them.

3.1. Deadline to request a TUE

According to criteria 4.1. of the International Standard for TUE, the deadline to request a TUE is 21 days before the athlete's participation in a Competition. Please refer to the recommendation in 1.3 regarding the deadline to request a TUE.

3.2. International Federations (IFs) for International-Level athletes

Athletes included by an IF in its Registered Testing Pool and other athletes prior to their participation in any International Event must obtain a TUE from their relevant IF (regardless of whether the athlete previously has received a TUE at the national level). An IF can recognize a TUE delivered by a NADO under its own authority (see section 5).

Athletes who already have a TUE at the national level but are participating in an International Event and do not already have a TUE registered with their IF must request a TUE from the IF no later than 21 days before the athlete's participation at an International Event (see section 3.4).

3.3. National Anti-Doping Organizations (NADOs) and National Federations (NF) for National-Level athletes

National-Level athletes and athletes participating in National Events shall obtain a TUE from their NADO, unless the athlete has previously received a TUE from an International Federation (IF) and such TUE is still valid and its granting has been reported to the NADO (see WADC Article 15.4 on mutual recognition).

National Federations (NF)

Where a National Sporting Federation TUEC has been set up for a given sport in accordance with the International Standard for TUE; this body may also be competent to deliver TUEs.

Status of Continental Federations

WADA does not recognize TUEs granted by Continental Federations, which are currently not signatories of the WADC (unlike IFs).

3.4. What does a National-Level athlete need to do if she/he becomes an International-Level athlete?

A TUE request can only be submitted to and granted by one body at the time. If the level of the athlete changes, the athlete must submit a new application to the relevant body. For instance, a National-Level athlete has a TUE registered with his NADO, if the athlete becomes an International-Level athlete he will have to submit a TUE request to his IF 21 days before the athlete's participation in an International Event.

4. IF and NADO duties

4.1. TUEC constitution

This section refers to Articles 6.1 to 6.3 of the International Standard for TUE.

The ADO should build up a network of Physicians to evaluate TUE applications. TUE Committees (TUECs) should include at least three Physicians with experience in the care and treatment of Athletes and a sound knowledge of clinical, sports and exercise medicine (see Article 6.1 International Standard for TUE). The TUEC will be chaired by one of its member Physicians.

ADOs can have a permanent TUEC or may form a TUEC for each individual case, depending on the specialization and availability of the experts in their network.

In practice, at least one expert should have a sound knowledge in the specific medical area of the request. For applications involving Athletes with disabilities, at least one TUEC member must possess specific experience with the care and treatment of Athletes with disabilities (see Article 6.1 International Standard for TUE).

The TUEC so designated shall promptly evaluate TUE requests in accordance with the International Standard for Therapeutic Use Exemptions and render a decision on such requests. This shall be the final decision of the ADO. TUECs may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.

4.1.1. Non-conflict of interest and confidentiality issues

In order to ensure the impartiality of decisions, a majority of the members of the TUEC should not have any official responsibility in the Anti-Doping Organization (see Article 6.1 International Standard for TUE).

Ideally, to avoid potential conflicts of interest, all members of TUECs should be independent from the ADO. Where members of the TUEC have an interest in an individual NADO, IF, or NF, they must be excluded from considering applications for TUEs from athletes who are members of the same individual NADO, IF or NF.

The members of TUECs will sign a non-conflict of interest form as well as confidentiality form prepared by the ADO. (Please refer to appendix 1 for a model of a non-conflict of interest and confidentiality form.)

4.2. 30-day deadline

According to the provisions of the 2005 International Standard for Therapeutic Use Exemptions (see Article 7.10 International Standard for TUE), decisions of the TUEC should be completed within 30 days of receipt of all relevant documentation and will be conveyed in writing to the Athlete by the relevant ADO.

4.3. Notification to athlete

For standard TUEs, the decision of the TUEC will be sent to the athlete within the 30-day deadline.

For ATUE applications, the ADO must send a notification of approval to the athlete upon receipt of a duly completed request. This approval notification can be carried by the athlete to facilitate the doping control process.

4.4. Non-compliance with the International Standard for TUE

An athlete who has not received an answer for a TUE application after the 30-day deadline for the decision has elapsed, is encouraged to contact the ADO to determine the status of the TUE application.

In case there is a problem, the athlete should inform WADA about this non-compliance and WADA will decide on the appropriate action.

4.5. Testing pool

4.5.1. Communication of Testing Pools

The list of athletes included in Testing Pools shall be shared between various ADOs and should be regularly updated as necessary.

e.g.: IFs should communicate their Registered Testing Pools to NADOS and/or NFs by posting them on their Web sites and clearly designating, by

name, all International-Level athletes that are included on this list at a given time.

Such cooperation between ADO's will serve to prevent duplication of tasks and will also clarify both the ADO's and Athlete's respective responsibilities.

4.5.2. Team Sports

The name of every team member shall be communicated to the IFs by NADOs or NFs because only the NADOs or NFs know which athletes are part of these teams. IFs may only determine which teams are in the IF Testing Pool.

5. Validity of TUEs and Mutual recognition

5.1. Mutual recognition and WADC

"Subject to the right to appeal provided in Article 13, the Testing, Therapeutic Use Exemptions and hearing results or other final adjudications of any Signatory which are consistent with the Code and are within that Signatory's authority, shall be recognized and respected by all other Signatories. Signatories may recognize the same actions of other bodies which have not accepted the Code if the rules of those bodies are otherwise consistent with the Code." (Article 15.4 WADC.)

It is important to underline the notion of "within that Signatory's authority" in this provision. As explained below, IFs have international competence and authority over International-Level athletes, while NADOs have national competence and authority over National-Level athletes.

5.2. TUEs granted by IFs vs. TUEs granted by NADOs and NFs

TUEs delivered by a NADO or NF are not necessarily recognized at the International-Level while TUEs delivered by an IF are valid at the national level.

On the one hand, TUEs delivered by an IF are valid at the national level. As such, an athlete participating in National Events who has previously received a TUE from an IF, and whose TUE is still valid and has been reported to the NADO, does not need to obtain a TUE from the NADO. (see WADA, Models of Best Practice for NADOs Article 4.6).

On the other hand, in order to ensure equal treatment for athletes competing in a same international event, IFs will not automatically recognize TUEs granted at the national level since international competitions are not within NADOs authority. IFs can decide to recognize TUEs from certain NADOs (or NFs), see 5.1.4. In that case the IF endorses the decision and the TUE. A prerequisite for this recognition is that the procedure and decision of the National TUEC strictly complied with the IF's procedure. In all other cases, a National-Level athlete who becomes an

International-Level athlete must submit a new TUE application to the IF (see section 3.4).

5.3. Recognition by IFs of TUEs granted by NADOs

As stated above, mutual recognition of National-Level TUEs by an IF is not automatic.

In some circumstances, a mutual recognition process between the NADO and the IF exists. In such a case the NADO shall inform the athlete of this existing process.

In case an IF decides to recognize a TUE from a NADO, the IF has to issue a new notification of approval for the application under the aegis of the IF. The IF becomes the authorization body and will be registered as such at WADA.

The IF must then notify the athlete that it has recognized the NADO's TUE by sending an official confirmation of the newly recognized and registered TUE to the athlete.

6. Reporting system

This section is meant to clarify what information needs to be reported to which body.

6.1. NADO duties

The NADO shall promptly report any TUE granted to an athlete in its Registered Testing Pool to the applicable IF and to the athlete's National Sports Federation.

In accordance with the modifications brought to the International Standard for TUE on January 1st 2005, the following procedure applies:

- For National-Level athletes, **only standard TUEs need to be reported to WADA.**
- **Abbreviated TUEs** need to be sent to WADA for **International-Level athletes only.**

In practice, this means that unless a mutual recognition agreement exists, NADOs or NFs should be sending only standard TUE applications for their national athletes to WADA. IFs on the other hand must submit both TUEs and ATUEs for their International-Level athletes to WADA as stated in Article 6.2 of the International Standard for TUE.

With regard to reporting obligations to WADA, NADOs should follow the instructions given in Article 6.2 of the International Standard for TUE.

6.2. IF duties

IFs must report all granted TUEs (Abbreviated and Standard) to the athlete's NADO and NF (see Article 8.4 sub b of TUE Standard). This eliminates a duplication of work as TUEs granted by IFs should be recognized and respected by the NADO.

IFs must report ATUEs and TUEs to WADA. The following instructions apply to all relevant communications:

TUEs and ATUEs have to be sent to WADA **separately** (e.g. group all the TUEs in a separate folder). All TUEs have to be sent by postal mail to:

World Anti-Doping Agency
Maison du Sport International
Av. De Rhodanie 54
1007 Lausanne

ATUEs can be sent by postal mail, e-mail or fax:

E-mail: tue@wada-ama.org
Confidential fax: 001 514 904 1400

7. WADA's role

WADA has three main roles in the TUE process as explained hereafter: a monitoring role, a reviewing role upon request of an athlete and a role in the management of data through ADAMS.

7.1 TUE monitoring role

Firstly, according to Article 4.4 of the WADC, WADA's TUEC, on its own initiative, may review the granting of a TUE to any International-Level athlete or National-Level athlete that is included in the NADO's Registered Testing Pool.

If WADA determines that the granting or denial of a TUE did not comply with the International Standard for TUE in force at the time, then WADA may reverse that decision and the TUE shall be cancelled. In the event of a reversal, WADA will advise all concerned parties (the athlete, IF, NADO, NF).

7.2 Review by WADA TUEC upon a request of an athlete

Secondly, according to Article 4.4 of the WADC, an International-Level athlete or a National-Level athlete who has been denied a TUE can ask for a review of the decision to the WADA TUEC. Refer to section 11 for the procedure for an athlete to request WADA for a review.

Decisions on TUEs are also subject to further appeal (see section 12) and pursuant to the rules of CAS (Cf. Article 13.3 WADC).

7.3. ADAMS

7.3.1. What is ADAMS?

The Anti-Doping Administration and Management System (ADAMS) is an internet-based database management tool. It is a centralized system that allows data entry and storage, as well as data-sharing and reporting to take place in a highly secure environment that restricts access to all but relevant and authorized parties. It is designed exclusively to assist stakeholders and WADA in their anti-doping operations with full compliance with the WADC.

7.3.2. ADAMS and TUEs

The TUE management module on ADAMS allows:

- Online submission of TUE requests;
- Online management of TUE requests;
- Notification of receipt to athlete;
- Notification of TUE denial to athlete;
- Provision of TUE certificate to athlete;
- Online notification to relevant parties of TUE expiry/change of status;
- Sharing of TUE information with all relevant parties;
- Linking of TUE to Adverse Analytical Finding (AAF);
- Conduct searches and print reports.

7.3.3. ADAMS and athletes

ADAMS will allow athletes to fill in the forms online, submit their TUEs online, receive an online notification form from the ADO and consult changes in the status of approval of their application.

7.3.4. ADAMS and ADOs

ADAMS allows online management of TUE requests for ADOs. ADOs are able to grant or deny TUEs online and send notifications to athletes. ADOs can also verify whether a TUE is under revision by WADA.

8. Language issues

8.1. Application forms

English or French must figure on all forms that have been customized by ADOs in addition to the national language(s). Moreover, all copies of applications sent to WADA must be in English or French.

8.2. Medical information

All relevant medical information needed for the decision also has to be provided in English or French. If the file received by the ADO is not in English or French it has to be translated before it is sent to WADA.

9. Data protection

9.1. Agreement with athlete

The athlete shall provide written consent for the transmission of all information pertaining to the application to members of the TUEC and, as required, to other independent medical or scientific experts, as well as to all necessary staff involved in the management, review or appeals of TUEs. The athlete shall also provide written consent for the decisions of the TUEC to be distributed to other relevant ADOs under the provisions of the Code and for data to be stored in and transferred to the WADA Clearinghouse (ADAMS).

9.2. Confidentiality clause for people working with the data

The ADOs and all TUECs shall conduct the management and determination of TUE applications in strict confidence.

A confidentiality agreement established by each ADO has to be signed by people handling the data (see the appendix for an example of this agreement).

9.3. How long is the information kept?

The information will be kept by the concerned ADO for eight years. According to Article 17 of the WADC, no action may be commenced against an athlete or other person for an anti-doping rule violation unless such action is commenced within eight years from the date the violation occurred.

9.4. Amendment of information

As stated above in section 9.2, information regarding TUEs has to be handled in strict confidence. Information can only be amended by the body which granted the TUE. As a consequence, designated staff members of the ADO delivering the authorization are the only persons who can access the file.

10. Result management

In case of an Adverse Analytical Finding (AAF), the following procedure applies.

10.1. Results Management for Tests initiated by an ADO

“Upon receipt of an A Sample Adverse Analytical Finding (AAF), the ADO shall conduct a review to determine whether: (a) an applicable

Therapeutic Use Exemption has been granted, or (b) there is any apparent departure from the International Standards for Testing or Laboratory Analysis that undermines the validity of the Adverse Analytical Finding.” (Article 7.1 WADC)

10.2. Consultation process between ADOs

In case of an AAF, ADOs should consult each other in order to determine if a TUE has been granted. If the reporting has been done properly (see section 6), the different ADOs should already be in possession of all the relevant information.

The consultation process will be facilitated by the implementation of ADAMS which allows online management and consultation for result management.

10.3. Existing TUE and consistent level of Prohibited Substance

When the certificate of analysis reveals the presence of a Prohibited Substance or Method for which a TUE has been granted in accordance with the International Standards for TUEs, no further action is required so long as the level reported is consistent with the prescribed therapeutic scheme and authorized dose.

10.4. Existing TUE but level of Prohibited Substance is not consistent with TUE

If the athlete has been granted a TUE in accordance with the International Standard for TUE, but the level of the Prohibited Substance in the Sample is not consistent with the authorized dose, the ADO shall continue to follow its results management regulations with respect to the Adverse Analytical Finding.

10.5. No TUE

If the athlete has not been granted a TUE in accordance with the International Standard for TUE, then the ADO shall follow its results management regulations with respect to the Adverse Analytical Finding.

If the athlete has no TUE or it is not valid the following procedure applies:

“If the initial review does not reveal an applicable Therapeutic Use Exemption of departure from the International Standard for Testing or the International Standard for laboratory analysis in force at the time of Testing or analysis that undermines the validity of the Adverse Analytical Finding, the ADO shall promptly notify the athlete of: (a) the Adverse Analytical Finding; (b) the anti-doping rule violated , or, in a case under Articles 7.1.8 or 7.1.9 of the IF Models of Best Practice, a description of the additional investigation that will be conducted as to whether there is an anti-doping rule violation; (c) the athlete’s right to promptly request

the analysis may be deemed waived; (d) the right of the athlete and/or the athlete's representative to attend the B Sample opening and analysis if such analysis is requested; and (e) the athlete's right to request copies of the A and B Sample laboratory documentation package which includes information as required by the International Standard for Laboratory Analysis." (Article 7.2 WADC.)

11. TUE Review procedure

What can an athlete do if her/his TUE is denied by the relevant ADO?

As mentioned in section 7.2, an athlete can submit a review request to WADA. Depending on the outcome, an appeal may then be brought before the Court of Arbitration for Sport (CAS). The athlete can appeal to CAS if WADA confirms the TUE denial. The ADO can also appeal to CAS if its decision is amended by WADA (see section 12). In any event, WADA must have reviewed any TUE before a TUE granting-denial case may be appealed to CAS.

11.1. Requesting WADA to review

The review request to WADA is the first possible phase in a TUE review.

As provided in Article 4.4 of the WADC, WADA may review a TUE denial upon the request of an International-Level athlete or a National-Level athlete included in a Registered Testing Pool (see section 11.2. for the procedure).

WADA will review the decision taken by the IF or NADO on basis of the identical file that had been submitted to the same IF or NADO. No additional data/medical information shall be taken into account.

Currently the International Standard for TUE is silent on a time limitation in which an athlete may seek a TUE review. Time limitations established in the IF or NADO Regulations shall apply where relevant.

11.2. Procedure for requesting a WADA review

The athlete must send a registered letter to WADA asking for a review of his/her case. The athlete needs to provide all information given during the first submission (complete file) as well as the initial decision taken and the reasoning by the ADO of why the TUE has not been granted.

The proof of payment of the requisite fee (US\$500) must be included with the request. This fee is non-refundable, regardless of the outcome of the review procedure. Upon request, WADA will provide all relevant banking information for payment of the fee.

The review process will start upon receipt by WADA of the payment and the full documentation.

On reception of a complete review request, WADA will establish and coordinate the WADA TUEC which will review the case and render a decision in no later than 30 days. WADA shall inform all relevant parties of its decision.

11.3. Status of TUE during review procedure by WADA

The review procedure does not suspend the first decision. As such, the initial decision remains valid throughout the whole procedure until the decision is taken. Therefore, the athlete is not allowed to use the Substance and/or Method while awaiting WADA's decision.

If WADA overturns the first decision and grants the TUE, the athlete is then allowed to start using the Substance and/or Method in accordance with the granted TUE. But, the ADO who rendered the first decision will then possess the right to appeal WADA's decision to CAS for a final determination (see section 12 below). WADA's decision remains valid until CAS renders its final decision.

12. Appeals against decisions rendered by WADA

12.1 Appeal procedure

The decision by WADA can be appealed as follows (see Article 13.3 WADC):

If the first decision is reversed by WADA, WADA's decision may be appealed exclusively to CAS by the athlete or by the ADO whose decision was reversed.

If the first decision denying a TUE is not reversed by WADA, WADA's decision may be appealed:

To CAS by International-Level athletes, or

To the National-Level reviewing body by other athletes. In this case, if the National-Level reviewing body reverses the decision to deny a TUE, that decision may be appealed to CAS by WADA.

CAS decisions on TUEs are final.

12.2 Role of CAS and CAS power of examination

CAS has a limited role as it is not a substitute for the TUE Committee.

Unlike TUE Committees (TUECs), CAS Panels are not composed of physicians and as such do not necessarily hold the required medical competences held by TUECs. It is only on the basis of very probative

elements in the TUE application file that CAS could deem that a TUE Committee wrongfully refused a TUE request (CAS 2004/A/769).

In addition, CAS cannot rule on facts and evidence that have not been submitted to the appropriate TUE Committee along with the TUE application. In fact, "...it is in principle inadmissible for an athlete to request CAS to rule on facts and evidence that have not been submitted to the appropriate TUE Committee along with the TUE application" (CAS 2004/A/769). As mentioned in section 11.1, (whether in the case of a review by WADA or in the case of an appeal before CAS), **no additional medical data/information can be provided**. The review/appeal has to be judged on the same documents as the first decision.

12.3 Time limitation

The time limitation depends on the rules of each organization. Special attention should be paid to the following Article of the CAS Rules which deals with the arbitration procedure on appeal:

"In the absence of a time limit set in the statutes or regulations of the federation, association or sports-related body concerned, or of a previous agreement, the time limit for appeal shall be twenty-one days from the receipt of the decision appealed against. After having consulted the parties, the Division President may refuse to entertain an appeal if it is manifestly late." (Section C Article R49, CAS, Statutes of the Bodies Working for the Settlement of Sports-related Disputes.)

References

WADA, 2003, *World Anti-Doping Code*.

WADA, *International Standard for Therapeutic Use Exemptions*, In force January 1st 2005

WADA, 2003, *Models of Best Practice for International Federations*.

WADA, 2004, *Models of Best Practice for NADOs*.

WADA, *TUE Q&As Leaflet*.

CAS, *Statutes of the Bodies Working for the Settlement of Sports-related Disputes*.

APPENDIX

DECLARATION OF CONFIDENTIALITY AND NON-CONFLICT OF INTEREST

As a member of the [name of organization] TUE Committee, I _____, declare and accept that, by executing this Declaration, I am bound by its terms.

I understand that the nature of my involvement as a member of the above Committee is such that I will have knowledge of, or become aware of, sensitive and confidential information.

I do swear or solemnly affirm that as a member of the [name of organization] TUE Committee, I will comply with all the requirements pertaining to the confidentiality of the information received by me or that comes to my knowledge, in any other way, in the course of my duties and tasks during and after the term of my involvement.

Except as required by law, or as authorized in the course of my duties, or as expressly authorized by [person in charge at your organization], I will not disclose or give to any person whatsoever, including in particular members of the media, any confidential information or document that comes to my knowledge or possession either directly or indirectly through my involvement as a member of the [name of the organization] TUE Committee, except for the information which has already been publicly disclosed or in my possession independently from [name of the organization]. I will not use my title of member of the Committee to make any public statement.

I hereby acknowledge that [name of the organization] has all rights to possession of and title to all Materials and any copies, extracts and summaries and other confidential information originating during the course of my involvement as a member of the [name of the organization] TUE Committee.

Furthermore, I understand that breach of my obligation of confidentiality may result in possible legal action against me and in immediate termination of my involvement with the [name of the organization] TUE Committee.

In case of a conflict of interest with a party involved in a Therapeutic Use Exemption application process to be dealt with by the [name of the organization] Therapeutic Use Exemption Committee, I will immediately inform the [person in charge at the organization] and abstain from taking part in the decision process for that specific case.

DATED THIS _____ DAY OF _____ YEAR _____

SWORN OR AFFIRMED BY _____
(SIGNATURE)