



World Anti-Doping Programme

THERAPEUTIC USE EXEMPTION GUIDELINES

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Introduction and scope

These Therapeutic Use Exemption (TUE) Guidelines are a model for best practice developed as part of the World Anti-Doping Programme. They are based on the World Anti-Doping Code (Code or WADC) and the International Standard for TUEs established through the Code. These guidelines should, in particular, be read in conjunction with the principles set out in Article 4.4 of the WADC. They have been developed in order to guide and assist competent Anti-Doping Organisations (ADOs) throughout the entire TUE procedure.

As a model for best practice, these guidelines are not mandatory and have no legal status. Only the International Standard for TUEs is mandatory and, in the event of any differences or ambiguities between the present guidelines and the International Standard for TUEs, the latter shall prevail.

ADOs are free to decide how to incorporate these guidelines into their own rules and procedures. They may be incorporated in full or in part, and may be amended or reworded to best fit the requirements of the ADO.

Definitions

Terms defined in the Code

Adverse Analytical Finding: A report from a laboratory or other WADA-approved entity that, consistent with the *International Standard* for Laboratories and related Technical Documents, identifies in a *Sample* 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 Organisation (ADO): A *Signatory* that is responsible for adopting 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 Organisations* that conduct *Testing* at their *Events*, WADA, International Federations and *National Anti-Doping Organisations*.

Athlete: Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organisation*, including but not limited to those *Persons* in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organisation accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and therapeutic use exemptions, must be applied to international- and national-level competitors. Some *National Anti-Doping Organisations* may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national-calibre competitors. *National Anti-Doping Organisations* are not required, however, to apply all aspects of the *Code* to such *Persons*. Specific national rules may be established for *Doping Control* for non-international-level or non-national-level competitors without being in conflict with the *Code*. Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organisation* holding an *Event* only for masters-level competitors could elect to test the competitors but not require therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempted Administration*) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government or other sports organisation accepting the *Code* is an *Athlete*.

[Comment to athlete: This definition makes it clear that all international- and national-calibre athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations

and National Anti-Doping Organisations respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. That does not mean, however, that all such athletes must be included in a National Anti-Doping Organisation's Registered Testing Pool. The definition also allows each National Anti-Doping Organisation, if it chooses to do so, to expand its anti-doping programme beyond national-calibre athletes to competitors at lower levels of competition. Competitors at all levels of competition should receive the benefit of anti-doping information and education.]

Code: The World Anti-Doping Code.

Doping Control: All steps and processes from test distribution planning through to ultimate disposition of any appeal, including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, therapeutic use exemptions, results management and hearings.

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 Organisation*, or another international sport organisation 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. *International Standards* shall include any Technical documents issued pursuant to the *International Standard*.

Major Event Organisations: The continental associations of *National Olympic Committees* and other international multi-sport organisations that function as the ruling body for any continental, regional or other *International Event*.

National Anti-Doping Organisation (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. This includes an entity which may be

designated by multiple countries to serve as regional *Anti-Doping Organisation* for such countries. 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 organisation recognised 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 organisation 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 Organisation* who are subject to both *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or *National Anti-Doping Organisation's* test distribution plan. Each International Federation shall publish a list which identifies those *Athletes* included in its *Registered Testing Pool* either by name or by clearly defined, specific criteria.

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 Organisations*, *National Anti-Doping Organisations*, 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 utilisation, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

WADA: The World Anti-Doping Agency.

Terms defined in the International Standard for TUEs

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 approved by a Therapeutic Use Exemption Committee based on a documented medical file before the *Use* of the substance in sports.

TUEC: Therapeutic Use Exemption Committee is the panel established by the relevant *Anti-Doping Organisation*.

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

1. TUE and declaration of use procedure

Athletes, like all people, may be taken ill or find themselves in a situation that requires the use of particular medications or treatments. However, the substances or methods that athletes could be required to use for treatment may feature on the Prohibited List. In this case, a Therapeutic Use Exemption (TUE) may, under certain well-defined and restricted conditions, enable athletes to take the necessary medication whilst competing in sporting events without resulting in a doping offence. A TUE application must be made by an athlete to the relevant ADO in accordance with the International Standard for TUEs. Depending on the substance itself and the route of administration (see sections 1.1.1 and 1.1.2), a TUE may be granted. In order to obtain a TUE, athletes must have a well-documented medical condition backed up by reliable, relevant and sufficient medical data.

1.1. TUE procedure

1.1.1. General procedure for prohibited substances and methods

Substances and routes of administration concerned

A TUE is required for all treatments involving the use of a prohibited substance or method detailed as such on the Prohibited List.

Forms

TUE applications must be submitted to the ADO via ADAMS or in paper format using the appropriate TUE form. The paper form can be obtained from the ADO.

Submission deadline

In order to ensure that the TUE is granted to the athlete prior to participation in a competition, all athletes are strongly advised to submit their applications at least **30 days** prior to participating in an event. For substances prohibited in and out of competition, the TUE application must be submitted as soon as the medical condition requiring the use of prohibited substances or methods is diagnosed.

Approval procedure

TUE applications will be examined by the TUEC of the relevant ADO. The athlete will be notified of the decision taken by the TUEC. TUEC decisions will be taken during the 30 days following receipt of all of the necessary documentation and will be communicated in writing to the athlete by the relevant ADO (see section 2.2). Checks may be carried out at any time during the period of validity of the TUE by the relevant ADO or the WADA TUE Committee (see section 3.2).

Commencement of medical treatment

If the TUE is approved, the athlete may commence treatment and/or sporting practice only after receipt of notification of authorisation from the relevant organisation. (A retroactive TUE may be envisaged in the uncommon event of an exceptional case or emergency; see section 1.1.4.)

In relation to sporting practice, athletes should consider not using the substance prior to receiving notification of authorisation, otherwise they would be using a prohibited substance or method without authorisation. This would constitute an anti-doping rule violation in the event of denial of the TUE by the TUEC.

1.1.2. Specific procedure for asthma treated with inhaled beta-2 agonists

Starting in January 01, 2010, salbutamol and salmeterol when taken by inhalation at therapeutic doses are no longer on the prohibited list. It should be noted that suprathreshold dosages may result in urinary levels of >1000 ng/ml which would be considered an AAF. In such cases, the athlete will have the burden to demonstrate, through a controlled pharmacokinetic study, that the high levels in the urine were a result of therapeutic inhaled use. The use of these products nevertheless will still require a declaration of use via ADAMS and/or the doping control form at the time of testing.

Alternate beta 2 agonists such as terbutaline and formoterol are prohibited and need a TUE from the relevant ADO. The request for a TUE should include a complete medical file with a clear explanation of why an alternate medication is being prescribed. It should be noted that, at least for 2010, the intent is not to deny the use of alternate beta 2-agonists because there is now a permitted substitute salbutamol/salmeterol particularly where a treatment regimen has already been established. However, for athletes newly diagnosed with asthma, permitted beta2 agonists, shall be considered as primary treatments unless otherwise justified.

All athletes who need to use inhaled beta-2 agonists (other than salbutamol and salmeterol) for medical purposes must:

- Have a justifying medical file.
- Declare these substances in ADAMS where reasonably possible.
- Declare these substances on the DCF.

An athlete's failure to declare Use on a Doping Control Form and through ADAMS when available shall not be an anti-doping rule violation. The rules of ADOs with jurisdiction over an athlete may impose consequences other than an anti-doping rule violation for a failure to declare.

1.1.3. Criteria for granting a TUE

The four criteria that must be fulfilled before a TUE is granted are set forth in the International Standard for TUEs:

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 4.1 a. of the International Standard for TUEs.)
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 4.1b of the International Standard for TUEs.)

Enhancement of performance should be taken to mean the return by the athlete to his/her level of performance prior to the onset of the medical condition requiring treatment. This means that there may be some enhancement of individual performance as a result of the efficacy of the treatment. Nevertheless, such enhancement must not exceed the level of performance of the athlete prior to the onset of his/her medical condition.

3. "There is no reasonable therapeutic alternative to the Use of the otherwise *Prohibited Substance* or *Prohibited Method*." (Article 4.1 c of the International Standard for TUEs.)

Two points should be noted in relation to reasonable therapeutic alternatives:

- Only valid and referenced medications are considered as alternatives.
 - The definition of what is valid and referenced may vary from one country to another. These differences should be taken into account. For example, a medication may be registered in one country and not in another, or approval may be pending, 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 4.1 d. of the International Standard for TUEs.)

A TUE may be granted only if these four criteria are fulfilled.

1.1.4. Retroactive TUEs

There are situations for which TUEs may be granted retroactively. Nevertheless, even if a potential retroactive TUE case is examined, under no circumstances does this provide any guarantee that the TUE will be granted. The evaluation procedure is the same as that for the standard TUE application. The application will be studied by the relevant TUEC, which will issue its decision. In accordance with Article 4.3 of the International Standard for TUEs, the following two situations may result in a retroactive TUE:

1. Emergency treatment or treatment of an acute medical condition.
2. If, due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a TUEC to consider, an application prior to doping control.

By way of explanation in relation to the aforementioned points:

- An emergency situation occurs when the life of an athlete could be at risk if he/she is unable to use the prohibited substance or method; in other words, if the medical condition justifies the treatment and warrants immediate administration.
- Circumstances are considered to be exceptional when, for example, a TUE cannot be granted in time through no fault of the athlete. Thus, an athlete with a chronic illness must request a TUE 30 days prior to an event. Nevertheless, the case of a normally healthy athlete suddenly affected by a significant medical condition some days prior to an event, and unable to request a TUE within the allotted time to enable the TUEC to grant the TUE, may be considered as an "exceptional circumstance".
- Medical emergencies or acute medical situations requiring administration of an otherwise prohibited substance before an application for a TUE can be made are uncommon. Similarly, circumstances requiring expedited consideration of an application for a TUE due to imminent competition are infrequent. Anti-Doping Organisations granting TUEs should have internal procedures that permit such situations to be addressed.

1.2. Declaration of use procedure

Substances and route of administration concerned

A declaration of use is required for glucocorticosteroids administered by non-systemic and non-topical routes, namely, by intraarticular,

periarticular, peritendinous, epidural and intradermal injection, and by inhalation. A declaration of use is also required for those taking inhaled salbutamol or salmeterol.

Forms

Declarations of use may be submitted via ADAMS and/or completed on the doping control form at the time of testing.

Approval procedure

There is no approval procedure for declarations of use. Failure to file a declaration of use will not be considered an anti-doping rule violation. Nevertheless a specific ADO with jurisdiction over an athlete may choose to impose consequences other than an anti-doping rule violation.

1.3. Documentation/information

1.3.1. What is sufficient?

A TUE application is deemed sufficient if it enables the ADO to issue a decision based on the fulfilment of the criteria set forth in the International Standard for TUEs.

As mentioned in the TUE application form, and in accordance with the International Standard for TUEs, the following documents must be attached to the completed application form in support of the application for a TUE:

- Evidence of the diagnosis must be attached.
- Copies of the original reports or letters.
The application must include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis and treatment, as well as duration of validity, should follow the WADA "Medical Information to Support the Decisions of TUECs". NB: Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organisation* before approval will be undertaken at the expense of the applicant or his/her national sport governing body (Article 6.2 of the International Standard for TUEs).
- The application must include a statement by an appropriately 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 in the treatment of this condition (Article 4.1 c. of the International Standard for TUEs).
NB: the evidence must be as objective as possible, given the clinical circumstances.
- For conditions that cannot be demonstrated, independent medical justification must be attached to the application.

The information provided must be up to date and exact, in terms of both content and form.

1.3.2. Who decides what is sufficient?

The ADO responsible for the decision (see section 2.2) and, more specifically, its TUEC, decides what is sufficient. The TUEC has the right to request further information at any time if it deems such information necessary in order to issue its decision.

WADA can request further information from the body granting the TUE in the context of its review activity, if the evidence in support of the diagnosis is insufficient. The initial decision continues to apply during the examination of such cases by WADA (see section 3.3.1).

1.3.3. Incomplete TUE applications

As mentioned in section 2.1, TUE applications must be accompanied by all of the medical evidence justifying the diagnosis. It is the responsibility of the ADO to request any missing documentation to enable the TUEC to issue its decision.

1.3.4. TUE application forms

In accordance with Article 8.5 of the International Standard for TUEs, application forms may be modified by ADOs. Additional requests for information may be added, but it is extremely important that all of the requests for information stipulated by WADA remain on the forms. No sections or articles may be removed.

Furthermore, ADOs are advised not to add further requirements to the forms that may thwart efforts to harmonise, result in confusion or discredit the procedure. Consequently, any changes must be limited to the adaptation of the forms by ADOs through the inclusion of their logo and contact details, for example.

1.3.5. TUE applications received via ADAMS

Generally speaking, the evaluation part of the procedure commences upon receipt of the TUE application sent through ADAMS to the IFs or NADO. All accompanying documents should be sent as soon as possible, preferably by scanning and attaching documents to ADAMS file. However, accompanying documents will also be accepted via other means (e.g. fax).

1.3.6. Renewal of TUEs

Complete application or not?

TUEs cannot be renewed without a new medical consultation and confirmation thereof. This means that the athlete has to complete a new application signed by his/her physician when the previous TUE expires. Even for chronic use of medication, a TUE can be granted only for a

limited period. The physician should attach a recommendation for the TUEC concerning the duration of validity of the TUE based on the next appointment scheduled with his/her patient in order to monitor the specific medical condition.

Renewal option in ADAMS

ADAMS provides a renewal option (see section 3.1.2). This option simplifies the procedure with a computerised form in which all of the fields are already completed. Nevertheless, the athlete must obtain and submit the medical documentation in the usual manner, and the TUE will be renewed in accordance with the procedure. All application forms must be duly completed, signed and dated by the physician and the athlete, whether this is the first application or an application for renewal.

No Automatic extensions

An automatic extension cannot be accepted under any circumstances. The physician must examine the athlete again and determine whether the medical condition has changed and the treatment is still appropriate in relation to the declared or new medical condition.

1.3.7. Duration of validity

As mentioned previously, a TUE will always be granted for a limited period of time, even if use of the substance is chronic. The use of the substance will be regularly monitored by a physician, and the TUE will be renewed accordingly.

The substance, dose, frequency, route and duration of administration of the otherwise *Prohibited Substance* or *Prohibited Method* in question must be specified. In case of change, a new application must be submitted. (Article 8.12 of the International Standard for TUEs.)

For advice concerning the duration of TUEs, please read the medical information to support the decisions of TUECs available on the WADA website.

1.4. Languages used

1.4.1. Application forms

English or French must feature on all of the forms personalised by ADOs, as well as their national language(s). In addition, all copies of applications sent to WADA must be written in English or French.

1.4.2. Medical information

All of the appropriate medical information necessary for the decision must also be submitted in English or French. If the file received by the ADO is not in English or French, it must be translated prior to being sent to WADA.

1.5. Data protection

1.5.1. Athlete consent

The athlete should provide written consent for the transmission of all information pertaining to the application to members of the TUEC and, if necessary, to other independent medical or scientific experts, as well as all of the members of staff responsible for the management and review of TUEs and consequent appeals. The athlete should also provide written consent for TUEC decisions to be distributed to other ADOs concerned, in accordance with the provisions of the Code, and for the storage of such data and its transfer to the WADA information centre (ADAMS).

1.5.2. Confidentiality clause for people working with data

The ADOs and all TUECs will manage TUE applications in the strictest of confidence.

A confidentiality declaration drawn up by each ADO must be signed by those people responsible for the data (see Annex for a declaration template).

1.5.3. For how long is this information stored?

Information will be stored for eight years by the relevant ADO. In accordance with 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 upon which the violation is asserted to have occurred.

1.5.4. Modification of information

As set forth above in section 1.5.2, information concerning TUEs must be treated in the strictest of confidence. Information may be modified only by the body that granted the TUE. Consequently, the members of staff appointed by the ADO granting the TUE are the only people who are allowed to access the file.

2. Role of ADOs

2.1. ADO functions

2.1.1. Setting up a TUEC

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

The ADO must set up a network of physicians responsible for evaluating 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 of the International Standard for TUEs). The TUEC will be chaired by one of the member physicians.

ADOs may have a permanent TUEC or may set up TUECs for each individual case, depending on the expertise and availability of the experts in their network.

In practice, at least one expert should have in-depth knowledge of the specific medical sector pertaining to the application. In 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 of the International Standard for TUEs).

Thus established, the TUEC will evaluate TUE applications without delay in accordance with the International Standard for TUEs and will issue a decision on these applications. Such decision will constitute the final decision of the ADO. The TUEC may seek whatever medical or scientific expertise it deems appropriate in reviewing the circumstances of any application for a TUE.

Conflict of interest and confidentiality

In order to ensure a level of independence of decisions, the majority of the members of any TUEC should be free of conflicts of interest or political responsibility in the Anti-Doping Organisation (see Article 6.1 of the International Standard for TUEs).

Ideally, in order to avoid possible conflicts of interest, all members of TUECs should be independent of the ADO. Should members of a TUEC find themselves caught in a conflict of interest in relation to their NADO, IF, or NF, they must be excluded from the examination of TUE applications made by athletes who are members of their NADO, IF or NF.

Members of the TUEC must sign a conflict of interest and confidentiality declaration drawn up by the ADO (please see Annex 1 for a conflict of interest and confidentiality declaration template).

2.1.2. 30-day deadline

In accordance with the provisions of the International Standard for TUEs, which entered into force on 1 January 2010, decisions of the TUEC should be completed within thirty (30) days of receipt of all relevant documentation and will be conveyed in writing to the athlete by the relevant Anti-Doping Organisation (see Article 8.13 of the International Standard for TUEs). In the case of a TUE application made in a reasonable time limit prior to an event, the TUEC of the appropriate ADO should use its best endeavours to complete the TUE process before the start of the event.

2.1.3. Failure to comply with the International Standard for TUEs

An athlete who has received no response to his/her TUE application after the 30-day period or before the event should contact the ADO in order to find out the status of his/her TUE application.

When an *Anti-Doping Organisation* does not respond within a reasonable period of time to a TUE application submitted in due form, such absence of a decision may be considered a denial for the purposes of rights of appeal provided for in Article 13.4 of the WADC.

2.1.4. Registered testing pool

Communication of registered testing pools

The list of athletes included in registered testing pools will be shared among the various ADOs and regularly updated.

Also, IFs will communicate their registered testing pools to NADOs and NFs by posting them on their websites and clearly indicating the names of all the international-level athletes included on the list at that time.

Furthermore, each IF shall publish the list of *international events* for which a TUE is required by the International Federation.

Such cooperation among ADOs will avoid duplication of tasks and will also specify the respective responsibilities of ADOs and athletes.

Team sports

The name of each member of a team will be communicated to the IFs by the NADOs or NFs insofar as only the NADOs and NFs know which athletes form part of these teams. IFs may determine only which teams will be included in their registered testing pools.

2.2. ADO jurisdiction: who grants TUEs?

In accordance with the World Anti-Doping Code, WADA has published an International Standard for TUEs. This standard stipulates that all IFs and NADOs shall have a procedure according to which athletes with documented medical conditions may make an application for a TUE which will be appropriately evaluated by a group of independent physicians (TUEC). The IFs and NADOs, through their respective TUECs, are therefore responsible for approving or rejecting these applications.

Depending on the level of the athlete, IFs or NADOs grant TUEs. A TUE application may be submitted only to one body at a time. Please see section 2.2.3 for the procedure to be followed by an athlete whose competition level changes. Under certain circumstances, National Federations may also grant TUEs to national-level athletes.

Major events

Special protocols for TUE applications may be established on the occasion of major sporting events. Major events are those organised by international multisport organisations operating as the managing body for any continental, regional or international event (for example, the IOC, IPC, FISU, etc.). Thus, for Olympic Games, the IOC is considered to be an ADO with the capacity to grant TUEs to athletes who submit an application during the Games period.

2.2.1. International Federations (IF) for international-level athletes

Athletes included in a registered testing pool of an IF must obtain a TUE from the IF to which they belong. An IF may recognise, on its own authority, a TUE issued by a NADO (see section 5).

Those athletes not included in a registered testing pool of an IF but who participate in an international event for which the IF requests a TUE from the IF must apply to the IF in question.

2.2.2. National Anti-Doping Organisations (NADOs) and National Federations (NFs) for national-level athletes

National-level athletes and athletes participating in national events will obtain TUEs from their NADOs, with the exception of athletes who have already received TUEs from an IF that are still valid, the granting of which the NADO has been informed (see Article 15.4 of the WADC on mutual recognition).

National Federations (NFs)

When the TUEC of an NF has been set up for a given sport in accordance with the International Standard for TUEs, this body is also competent to grant TUEs.

Status of continental federations

WADA does not recognise TUEs granted by continental federations that are not currently signatories of the WADC (unlike IFs).

2.2.3. What must a national-level athlete do upon becoming an international-level athlete?

A TUE application may be submitted only to one body at a time. If the level of the athlete changes, the athlete must submit an application to the relevant body. Thus, when a national-level athlete with a TUE registered by his/her NADO becomes an international-level athlete, he/she must submit a TUE application to his/her IF within 30 days of requiring such TUE (for example, for an event).

2.3. Mutual recognition: validity of TUEs among ADOs

2.3.1. Mutual recognition and the WADC

"Subject to the right to appeal provided in Article 13, *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 recognised and respected by all other *Signatories*." (Article 15.4.1 of the WADC.)

It is important to highlight the notion of "signatory's authority" in this provision. As explained above, IFs have international competence and international-level athletes are under their authority, whilst NADOs have national competence and national-level athletes are under their authority. Unless the rules of an International Federation or an agreement with an International Federation provide otherwise, National Anti-Doping Organisations do not have the power to grant Therapeutic Use Exemptions to international-level athletes.

"Signatories shall recognise 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 15.4.2 of the WADC.)

Where the decision of a body that has not accepted the Code is in some respects Code-compliant and in other respects not Code-compliant, Signatories should attempt to apply the decision in harmony with the principles of the Code. For example, if in a process consistent with the Code a non-Signatory has found an Athlete to have committed an anti-doping rule violation on account of the presence of a Prohibited Substance in his body but the period of ineligibility applied is shorter than the period provided for in the Code, then all Signatories should recognise the finding of an anti-doping rule violation and the Athlete's National Anti-Doping Organisation should conduct a hearing consistent with Article 8 to determine whether the longer period of ineligibility provided in the Code should be imposed.

2.3.2. TUEs granted by IFs compared to TUEs granted by NADOs and NFs

TUEs granted by a NADO or an NF are not necessarily recognised on an international level, whereas TUEs granted by an IF are valid on a national level.

TUEs granted by an IF are valid on a national level. An athlete participating in national events who has already received a TUE from an IF which is still valid and the granting of which has been declared to the NADO is therefore not required to obtain a TUE from the NADO (see Article 15.4 of the WADC).

However, in order to ensure that athletes participating in the same international event are treated fairly, IFs will not automatically recognise

TUEs granted on a national level, given that international competitions do not fall under the authority of NADOs. IFs may decide to recognise TUEs granted by certain NADOs (or NFs), in which case the IF recognises the TUE decision. Such recognition occurs provided that the procedure and the decision of the national TUEC are strictly in accordance with the IF 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 2.2.3).

2.3.3. IF recognition of TUEs granted by NADOs

As stated above, the mutual recognition of national-level TUEs by an IF is not automatic.

In some circumstances, a mutual recognition procedure exists between NADOs and IFs. In such cases, the NADO will inform the athlete as to the existence of such procedure.

Should an IF decide to recognise a TUE granted by a NADO, it must issue a new approval notification/recognition. It therefore becomes the TUE body and will be registered as such by WADA.

The IF must notify the athlete that it has recognised the NADO TUE by sending the athlete official confirmation of such newly recognised and registered TUE.

Note that ADAMS has a new functionality that allows IF to recognize TUEs granted by NADOs without having to re-enter data.

2.4. Forwarding information

The aim of this section is to specify the information that must be provided and to which body.

2.4.1. NADO responsibilities

The NADO will immediately send notification of all TUEs granted to athletes in its registered testing pool to the relevant IF and NF.

In accordance with the International Standard for TUEs granted to athletes included in the national or international registered testing pool or to *international-level athletes* where the rules of the *International Federation* authorize NADO to grant TUEs to *International-Level Athletes* **must be reported to WADA through ADAMS.**

In practice, this means that, unless mutual recognition agreements exist, NADOs or NFs must send information on TUEs for their athletes included in national registered testing pools to WADA through ADAMS.

2.4.2. IF responsibilities

IFs must send information on all of the TUEs that they have granted to the respective NADOs and NFs of the athletes. This will avoid duplication of work, since TUEs granted by IFs must be recognised and respected by NADOs.

IFs **must report** the granting of TUEs – including complete medical file - **to WADA through ADAMS.**

2.5. Results management

In the event of an AAF, the following procedure applies:

2.5.1. Results management for controls organised by an ADO

"Upon receipt of an *A Sample Adverse Analytical Finding*, the *Anti-Doping Organisation* responsible for results management shall conduct a review to determine whether: (a) an applicable therapeutic use exemption has been granted or will be granted as provided in the *International Standard for Therapeutic Use Exemptions*, or (b) there is any apparent departure from the *International Standard for Testing* or *International Standard for Laboratories* that caused the *Adverse Analytical Finding*." (Article 7.1 of the WADC.)

2.5.2. Consultation among ADOs

In the event of an AAF, ADOs must consult to determine whether a TUE was granted. If it was correctly reported (see section 2.4), the ADOs should already be in possession of the appropriate information.

The consultation procedure is facilitated by ADAMS, which enables online results management and consultation.

2.5.3. Existing TUEs and corresponding level of prohibited substance

When the laboratory report reveals the presence of a prohibited substance or method for which a TUE has been granted in accordance with the International Standard for TUEs, no action is required as long as the reported level corresponds to the prescribed treatment plan and authorised dose.

2.5.4. Existing TUEs whereby the level of the prohibited substance does not correspond to the TUE

If a TUE has been granted to an athlete in accordance with the International Standard for TUEs but the level of the prohibited substance in the sample does not correspond to the authorised dose, the ADO must

continue to follow the results management procedure applicable to adverse analytical findings.

2.5.5. Absence of a TUE

If the athlete has not received a TUE in accordance with the International Standard for TUEs, the ADO must follow its rules regarding results management applicable to adverse analytical findings.

If the athlete does not have a TUE or if the TUE is not valid, the following procedure applies:

"If the initial review of an Adverse Analytical Finding under Article 7.1 does not reveal an applicable therapeutic use exemption or entitlement to a therapeutic use exemption as provided in the International Standard for Therapeutic Use Exemptions, or departure that caused the Adverse Analytical Finding, the Anti-Doping Organisation shall promptly notify the Athlete, in the manner set out in its rules, of: (a) the Adverse Analytical Finding; (b) the anti-doping rule violated; (c) the Athlete's right to promptly request the analysis of the B Sample or, failing such request, that the B Sample analysis may be deemed waived; (d) the scheduled date, time and place for the B Sample analysis if the Athlete or Anti-Doping Organisation chooses to request an analysis of the B Sample; (e) the opportunity for the Athlete and/or the Athlete's representative to attend the B Sample opening and analysis within the time period specified in the International Standard for Laboratories if such analysis is requested; and (f) 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 Laboratories. The Anti-Doping Organisation shall also notify the other Anti-Doping Organisations described in Article 14.1.2. If the Anti-Doping Organisation decides not to bring forward the Adverse Analytical Finding as an anti-doping rule violation, it shall so notify the Athlete and the Anti-Doping Organisations as described in Article 14.1.2." (Article 7.2 of the WADC.)

3. Role of WADA

WADA has the following three main roles in the TUE procedure: a role of monitoring and review on its own initiative, a role of review at the request of an athlete, and a role of data management through ADAMS.

3.1. Data management role: ADAMS

3.1.1. What is ADAMS?

The Anti-Doping Administration and Management System (ADAMS) is a Web-based database management tool. It is a centralised system that allows for the entry and storage of data, as well as the sharing and reporting of such data in a highly secure environment, which restricts access only to relevant authorised parties. It was designed exclusively to

assist stakeholders and WADA in their anti-doping operations, in strict compliance with the WADC.

3.1.2. ADAMS and TUEs/declarations of use

The TUE/declaration of use management module in ADAMS allows for the following operations to be carried out:

- Online submission of TUE applications/declarations of use by athletes;
- Online submission of TUE applications/declarations by athlete physicians;
- Online submission of TUE applications by ADOs to TUEC physicians;
- Online management of TUE applications;
- Notification of receipt to athletes;
- Notification of refusal to grant a TUE to athletes;
- Sending of TUE certificates to athletes;
- Online notification of the expiry/change in status of a TUE/declaration of use to relevant parties;
- Sharing of information relating to the TUE/declaration of use with all relevant parties;
- Recognition by IF of TUE granted by NADOs;
- Link between TUEs and AAFs;
- Search function and printing of reports.

3.1.3. ADAMS and athletes

ADAMS will enable athletes to complete forms and submit their TUE applications and declarations of use online, receive online notification from ADOs and consult changes in the approval status of their applications.

3.1.4. ADAMS and physicians

Athletes' physicians may complete TUE application forms for their patients online after identifying themselves to their patients' ADO.

3.1.5. ADAMS and ADOs

ADAMS enables ADOs to manage TUE applications online. ADOs may grant or deny TUEs online and send notification to athletes. ADOs may confirm whether a TUE is being reviewed by WADA.

3.2. Role of monitoring and reviewing TUEs on its own initiative

In accordance with Article 4.4 of the WADC, the WADA TUEC may review, on its own initiative, the granting of a TUE to an international-level athlete or a national-level athlete in a NADO registered testing pool.

If WADA determines that the granting or denial of a TUE does not comply with the International Standard for TUEs in force at the time, it may overturn the decision and the TUE will be invalidated. Should a decision be overturned, WADA will advise all of the relevant parties (the athlete, the IF, the NADO and the NF).

3.3. Role of reviewing TUEs at the request of an athlete

In accordance with Article 4.4 of the WADC, an international-level athlete or a national-level athlete who has been denied a TUE may request that this decision be reviewed by the WADA TUEC.

3.3.1. TUE review procedure

WADA review request procedure

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

As set forth in Article 4.4 of the WADC, WADA may review a TUE denial at the request of an international-level athlete or a national-level athlete in a registered testing pool.

The athlete must send the request for a review of his/her case by registered letter to WADA. The athlete must provide all of the information sent during the initial submission (complete file), along with the initial decision issued and the explanation provided by the ADO as to why the TUE was not granted.

The certificate of payment of the required application fee (USD 500) must be included in the request. Such fee is non-refundable, regardless of the result of the review procedure. WADA will provide all of the bank information concerning the payment of such fee upon request.

The review procedure will commence upon receipt of payment and all of the necessary documentation by WADA.

Upon receipt of the complete request for review, WADA will set up and coordinate the WADA TUEC, which will review the case and issue its decision within a maximum of thirty (30) days. WADA will inform all of the relevant parties as to the decision issued.

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

The International Standard for TUEs currently makes no mention of the period during which an athlete may request a review of the TUE. If necessary, the time set forth in the rules of the IF or NADO will apply.

Status of a TUE during the WADA review procedure

The review procedure does not suspend the initial decision. As such, the initial decision remains in effect throughout the duration of the procedure until the decision is issued. Consequently, the athlete is not allowed to use the substance or method whilst awaiting the decision from WADA if he was initially denied the TUE.

If WADA overturns the initial decision and grants the TUE, the athlete may then start to use the substance or method in accordance with the TUE granted. Nevertheless, the ADO that issued the first decision has a right to appeal the decision handed down by WADA before the CAS, which will make a final ruling (see section 3.3.2 below). The WADA decision will remain in effect until the CAS hands down the final decision.

3.3.2. Appeal of decisions handed down by WADA

Appeal procedure

The decision handed down by WADA may be appealed in the following manner (see Article 13.3 of the WADC):

If the initial decision is overturned by WADA, only the athlete or the ADO whose decision was invalidated may appeal this decision before the CAS.

If the initial decision denying a TUE is not invalidated by WADA, the WADA decision may be appealed:

- Before the CAS by international-level athletes, or
- Before the national-level review body by other athletes. In this case, if the national-level review body invalidates the decision to deny the TUE, WADA may appeal such decision before the CAS.

CAS decisions on TUEs are final.

The role and scope of review of the CAS

The CAS has a limited role, as it does not act as a substitute for TUE Committees.

Unlike TUE Committees (TUECs), CAS panels are not made up of physicians. As such, they do not have the medical expertise of TUECs. The CAS may consider that a TUE Committee has unduly rejected a TUE application only on the basis of particularly convincing elements contained in the TUE application file (CAS 2004/A/769).

Furthermore, the CAS cannot hand down a decision based on facts and other evidence that were not submitted to the relevant TUE Committee with the TUE application. Indeed, "In principle, an athlete is not allowed to ask the CAS to hand down a decision based on facts and other evidence that have not been submitted to the relevant TUE committee with the TUE application" (CAS 2004/A/769). **No additional medical**

information/data may be submitted. The review or appeal must be considered based on documents identical to those resulting in the initial decision.

Time limit

The time limit depends on the rules of each organisation. Particular attention will be paid to the following article in the CAS rules, which deals with the arbitration procedure for appeals:

“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, *World Anti-Doping Code, 2009*.

WADA, *International Standard for Therapeutic Use Exemptions*, which entered into force on 1 January 2010.

WADA, *Model Rules for International Federations*.

WADA, *Model Rules for National Anti-Doping Organisations*.

WADA, *Q&A: International Standard for Therapeutic Use Exemptions, 2009*.

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

ANNEX

CONFLICT OF INTEREST AND CONFIDENTIALITY DECLARATION

As a member of the TUE Committee of [name of the organisation], I, the undersigned, _____, affirm and acknowledge that, by signing this declaration, I am bound by the terms of such declaration.

I understand that the nature of my participation as a member of the aforementioned committee is such that I shall come into contact with or be made aware of sensitive and confidential information.

I swear or solemnly state that, as a member of the TUE Committee of [name of the organisation], I shall respect all of the requirements relating to the confidentiality of the information that I receive or that is brought to my attention in any way whatsoever during the course of my duties and functions throughout and beyond the duration of my participation.

With the exception of legal obligations, authorisation by virtue of my office, or the express authorisation of [person in charge of your organisation], I shall not reveal or hand over to anybody, particularly to representatives of the media, any confidential information or document that is brought to my attention or is in my possession, either directly or indirectly through my participation as a member of the TUE Committee of [name of the organisation], excluding information that has already been made public or is in my possession independently of [name of the organisation]. I shall not use my title as member of the committee for any public declaration.

I, the undersigned, acknowledge that [name of the organisation] holds all of the property rights and titles to all of the material, copies, extracts, summaries and other confidential information drawn up during my participation as a member of the TUE Committee of [name of the organisation].

Furthermore, I understand that the violation of my confidentiality obligation may result in possible legal proceedings against me and the immediate termination of my participation as a member of the TUE Committee of [name of the organisation].

In the event of any conflict of interest with a party to the application for a Therapeutic Use Exemption that the TUE Committee of [name of the organisation] may have to handle, I shall immediately inform [person in charge of the organisation] and abstain from taking part in the decision procedure for the specific case in question.

DATED THE _____ DAY OF _____, 20_____

BY _____
(SIGNATURE)