

CONCEPT

Therapeutic Use Exemption (TUE)

PROCEDURE 2009

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Art. 1: Introduction and Scope

One of the principles of anti-doping policies in sport is to keep the sport healthy. However, anti-doping policies are not meant to exclude people from sport because they are ill or have certain medical conditions.

Therefore the world anti-Doping Code and the IDSF anti-Doping Code includes a system of Therapeutic Use exemptions (TUE's).

The Anti-Doping Code permits athlete's and their physicians to apply for a TUE, i.e. permission to use, for medical therapeutic purposes, substances or methods contained in the List of Prohibited Substances or Methods who's use is otherwise prohibited.

This IDSF TUE Procedure includes criteria for granting a TUE by the IDSF Anti-Doping Commission, confidentiality of information and the TUE application process. The WADA International Standard for Therapeutic Use Exemptions has been taken in consideration as mandatory.

Art. 2: Terms and Definitions

1. The Definitions as per art. 2, IDSF Anti-Doping Code, are reiterated and included.
2. "Therapeutic": of or relating to the treatment of a medical condition by remedial agents or methods; or providing or assisting in a cure.
3. "TUE": Therapeutic Use Exemption.
4. "TUEC": Therapeutic Use Exemption Committee is the Panel established by the IDSF as part of the IDSF Anti-Doping Commission.
5. "WADA TUEC": WADA Therapeutic Use exemption Committee is the Panel established by WADA.

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Art. 3: TUE Application Process

1. An Athlete may request for a TUE only by means of submitting a completed and duly signed TUE Application Form to the Chair of the IDSF Anti-Doping Commission in accordance with this procedure. The Chair of the IDSF Anti-Doping Commission may grant a TUE strictly in accordance with this procedure and the IDSF Anti-Doping Code.

1. A TUE will only be considered following the receipt of a fully completed application form that must include all relevant documents as requested by the TUE Application Form. The application process must be dealt with in accordance with the principles of strict medical confidentiality.

3. The "Therapeutic Use Exemptions Application Form", and the "Certificate of Approval for Therapeutic Use" as attached to this Procedure form an integral part of this procedure. The Forms can be modified by the IDSF Anti-Doping Commission to include additional requests for information providing that no sections or items shall be removed. The former used "Application form Therapeutic Use Exemptions Abbreviated Process" will not be used any longer after January 1st 2009.

4. The TUE Application Forms may be translated into other languages by the IDSF Members providing that the English text will remain and unchanged. Forms used by National Anti-Doping Organizations (NADO's) must also have an English text for acceptance by IDSF. The English text will always prevail.

5. An Athlete may not reply to more than one Anti-Doping Organization for a TUE. A DanceSport Athlete included in IDSF's international list and in the IDSF international testing pool should apply to the IDSF Anti-Doping Commission; he/she cannot apply for a TUE to a NADO. DanceSport athletes included in the national testing pools should apply for a TUE to their NADO. Only when the latter is not possible a national athlete should apply to the IDSF Anti-Doping Commission.

6. The Application must list any previous and/or current requests for permission to use an otherwise Prohibited Substance or Prohibited Method, the body to whom the request was made and the decision of that body.

7. The Application must include a comprehensive medical history and the results of all medical examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnoses and treatment, as well as duration of validity, should follow the WADA "Medical Information to support the decision of TUEC's". For asthma the specific requirements(s) set out in Annex 1 of this Procedure must be fulfilled.

8. The IDSF Anti-Doping Commission has the right to request additional relevant investigations, examinations or imaging studies she deems necessary at the expense of the applicant or his/her national sport organization, the representing IDSF member.

9. The application must include a statement by an appropriate qualified physician attesting to the necessity of the otherwise Prohibited Substance or Prohibited Method

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in the treatment of the athlete and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of his/her condition.

10. The dose, frequency, route and duration of administration of the otherwise Prohibited Substance or Prohibited Method in question must be specified. In case of a change, a new application must be submitted.

11. An application for a TUE will be reviewed by at least three physicians, member of the IDSF Anti-Doping Commission. The majority of their advice is binding.

12. In normal circumstances, decisions of the IDSF TUEC should be completed within thirty (30) days of receipt of all relevant documentation, i.e. a fully completed and documented TUE Application Form.

13. The Chair of the IDSF Anti-Doping Commission/IDSF Anti-Doping Director will convey all decisions of the IDSF TUEC in writing to the Athlete. Where a TUE has been granted to an Athlete, the athlete, WADA and the particular NADO will be promptly provided with a Certificate of Approval that include all relevant information pertaining to the duration of the exemption and any conditions associated with the TUE.

14. The WADA TUEC will be able to reverse a decision on a TUE, granted or not, by the IDSF TUEC. When an Athlete has been denied a TUE by the IDSF TUEC, the Athlete may request the WADA TUEC to review such denial. The Athlete shall provide to the WADA TUEC all information for a TUE as submitted initially to the IDSF anti-Doping Commission accompanied by an application fee as requested by WADA. Until the review process has been completed, the original decision remains in effect. Any process of review by the WADA TUEC shall not take longer than thirty (30) days following the receipt of all the Athlete's information by WADA.

15. WADA can, on its own initiative, undertake a review at any time.

16. If the decision regarding the granting of a TUE is reversed on review by the WADA TUEC, the reversal shall not apply retroactively and shall not disqualify the Athlete's results during the period that the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the Athlete.

Art. 4: Asthma

Procedure handling the treatment of asthma and its clinical variants; the use of inhaled only GCS and Beta2 agonists:

1. The use of inhaled glucocorticosteroids and/or inhaled formoterol, salbutamol, salmeterol, terbutaline reflects current clinical practice. The use of these substances must be declared on ADAMS where reasonably feasible and in accordance with the IDSF Anti-Doping Code as soon as the product is used and must as well be declared on the Doping Control form at the time of testing. Failure to declare will be taken into consideration in the result management process in particular in case of application for a retroactive TUE.

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2. Athletes using the substances listed above by inhalation must have a medical file justifying this use and meeting the minimum requirements outlined below. This file must reflect current best medical practice to include:

- a) A complete medical history
- b) A comprehensive report of the clinical examination with specific focus on the respiratory system
- c) A report of the spirometry with the measure of the forced expiratory volume in 1 second (FEV1)
- d) If airway obstruction is present, the spirometry will be repeated after inhalation of a short acting Beta2 agonist to demonstrate the reversibility of bronchoconstriction
- e) In the absence of reversible airway obstruction, a bronchial provocation test is required to establish the presence of airway hyper responsiveness
- f) Exact name, specialty, address (including telephone, email, fax) of examining physician.

The complete file must be presented to the IDSF Anti-Doping Commission when asked for.

3. Depending upon the category of the athlete, the medical file will be evaluated as follows:

- a) For all Athletes included in the International IDSF Testing Pool a regular TUE must be approved before the use of the substance is allowed
- b) For all Athletes participating in an International Event and IDSF Championships, but who are not included in the International IDSF Testing Pool, either a TUE or a retroactive TUE in the case of an Adverse Analytical Finding is required
- c) For national level Athletes who are not included in the International IDSF Testing Pool, whether or not they included in a National Testing Pool, either a TUE or a retroactive TUE in the case of an Adverse Analytical Finding, in accordance with the rules of the National Organization, is required
- d) No retroactive TUE will be granted if the requirements of paragraph 2 above of this article are not met meaning that if any Adverse Analytical Finding reported by the laboratory in these circumstances will result in an anti-doping rule violation
- e) Any Athlete may apply for a TUE at any time if they wish
- f) Any Athlete who has applied for a TUE or a retroactive TUE and who was denied such TUE may not use the substance without the prior granting of a TUE (no retroactive TUE will be permitted).

Art. 5: Criteria for granting a TUE

A Therapeutic Use Exemption (TUE) may be granted to an Athlete permitting the Use of a Prohibited Substance or Prohibited Method contained in the Prohibited List.

A TUE will be granted only in strict accordance with the following criteria.

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1. The Athlete must submit an Application for a TUE not less than twenty-one (21) days before he/she needs the approval (for instance participating in an Event or competition).
2. 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.
3. 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.
4. There is no reasonable therapeutic alternative to the use of the otherwise Prohibited Substance or Prohibited Method.
5. 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.
6. The TUE will be cancelled by the IDSF TUEC, if:
 - a) The Athlete does not promptly comply with any requirement or condition imposed by the IDSF Anti-Doping Commission;
 - b) The term for which the TUE was granted has expired;
 - c) The Athlete is advised that the TUE has been withdrawn by the IDSF TUEC.
7. An Application for a TUE will not be considered for retroactive approval except in cases where:
 - a) Emergency treatment or treatment of an acute medical condition was necessary, or
 - b) Due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or the IDSF TUEC to consider, an application prior to an Anti-Doping Control, or
 - c) the conditions as set forth under art. 4. Asthma, apply.

Art. 6: the IDSF TUE Committee (TUEC)

1. The physicians of the IDSF Anti-Doping Commission will act as the IDSF Therapeutic Use Exemption Committee (TUEC). For this reason the IDSF Anti-Doping Commission should include at least three physicians with experience in the treatment and care of Athletes and a sound knowledge of clinical, sports and exercise medicine. In order to ensure a level of independence of decisions, the physicians of the IDSF Anti-Doping Commission should not have any other official responsibility in the IDSF organization. Said physicians should sign a conflict of interest agreement. In Applications involving Athletes with disabilities, an outside specialist with special experience in care and treatment of athletes with disabilities should be consulted.

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2. The physicians of the IDSF TUEC may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.
3. The WADA TUEC may review on its own initiative TUE decisions granted by the IDSF TUEC or upon request by Athletes who have been denied a TUE by the IDSF TUEC, review such a negative decision, with the power to reverse said decisions.

Art. 7: Confidentiality of Information

1. The applicant must provide written consent for the transmission of all information pertaining to the application to members of the IDSF TUEC and, as required, other independent medical or scientific experts, or to all necessary staff involved in the management, review or appeal of TUE's. Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the physician involved in the Athlete's care. The applicant must also provide written consent for the decisions of the TUEC to be distributed to other relevant Anti-Doping Organizations under the provisions of the IDSF Anti-Doping Code and the World Anti-Doping Code.
2. The members of the TUEC's and the administration of the Anti-Doping Organization involved will conduct all of their activities in strict confidence. All members of TUEC and all staff involved will sign confidentiality agreements. In particular they will keep the following information confidential:
 - a) All medical information and data provided by the Athlete and physicians involved in the Athlete's care.
 - b) All details of the application including the name of the physicians involved in the process.

Should the Athlete wish to revoke the right of the TUEC or the WADA TUEC to obtain any health information on/his behalf, the athlete must notify his/her medical practitioner in writing of the fact. As a consequence of such a decision, the Athlete will not receive approval for a TUE or renewal of an existing TUE.

Art. 8: Declaration of Use Process

1. It is acknowledged that some substances included on the List of Prohibited Substances are used to treat medical conditions frequently encountered in the athlete population. For monitoring purposes, these substances, for which the route of administration is not prohibited, will require a simple declaration of use. These are strictly limited to the following:
Glucocorticosteroids used by non systemic and non inhaled routes, namely intraarticular, periarticular, peritendinous, epidural, intrathecal and intradermal injection.
2. For the mentioned substances, the declaration of Use should be done through ADAMS, where reasonably feasible and in accordance with the IDSF Anti-Doping Code,

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by the Athlete at the same time as the Use starts. This declaration should mention the diagnosis, the generic name of the substance, the dose undertaken, the name and the contact details of the physician.

3. In addition the Athlete must declare the use of the substance in question on the Doping Control Form when tested.

Art. 9: Clearinghouse

1. The IDSF Anti-Doping Commission is required to provide WADA with all TUE's approved for Athletes who are part of a National or International Registered Testing Pool, and all supporting documentation, issued under this procedure.
2. The declarations of use should be available to WADA (ADAMS).
3. The WADA Clearinghouse shall guarantee strict confidentiality of all the medical information.

Art. 10: Taking Effect

This IDSF TUE Procedure 2009 is approved by the IDSF Presidium in its Meeting at Barcelona, Spain, on January 17-18, 2009, and will be effective January 1st 2009.

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