

## **FIFA TUE Policy**

This document outlines the procedures governing the application, approval, mutual recognition and administrative management of therapeutic use exemptions (TUEs) within FIFA's jurisdiction as per 1 January 2009.

The FIFA TUE Policy is based on the following documents:

- FIFA Anti-Doping Regulations (ADR) 2009, effective from 1 January 2009;
- World-Anti Doping Code (WADC), effective from 1 January 2009;
- International Standard for Therapeutic Use Exemptions (ISTUE), effective from 1 January 2009.

### **I. Scope**

The purpose of the FIFA TUE Policy is to ensure that the process of granting TUEs is the same for all players participating in FIFA competitions and is harmonised across member associations and confederations.

The WADC permits players and their physicians to apply for TUEs, i.e. for permission to use, for therapeutic purposes, substances or methods contained in the 2009 Prohibited List whose use is otherwise prohibited.

The FIFA TUE Policy defines the criteria for granting a TUE, the confidentiality of information, the TUE application and approval process, and the mutual recognition of TUE approvals.

This FIFA TUE Policy applies to all players participating in FIFA competitions as well as those in the FIFA testing pools (FIFA's international Registered Testing Pool (high-risk international players), FIFA Testing Pool (UEFA Champions League teams), FIFA Pre-Competition Testing Pool (FIFA Confederations Cup 2009 teams)). To facilitate participation in international competitions, all confederations also have to agree in a declaration to adopt this TUE policy.

### **II. Granting body**

The FIFA Medical Committee has overall responsibility for approving applications for therapeutic use exemptions (TUE). It delegates the evaluation and the approval of TUEs to the TUE advisory group. The TUE advisory group includes three physicians with experience in the care and treatment of players and a sound knowledge of clinical, sports and exercise medicine. The members are free of conflicts of interest. The TUE advisory group seeks whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.

The FIFA TUE advisory group grants TUE approvals for:

- FIFA competitions (FIFA competitions 2009, see Annex 1);
- FIFA's international Registered Testing Pool players, testing pool players, pre-competition testing pool players.

Accordingly, TUE applications for players participating in FIFA competitions or included in the FIFA testing pools must be sent to the FIFA Anti-Doping Unit unless there is an agreement of mutual recognition with other granting bodies (see Table 1, and section VII).

<b>Level of play</b>	<b>TUE application send to</b>	<b>Application submitted by</b>
National players participating in domestic competitions only	National Anti-Doping Agency (NADO), or other authorised national body, e.g. National Olympic Committee	Player and / or club physician
International players called up to compete in international team competitions and friendly matches at confederation level; FIFA Testing Pool	Confederation	Player and / or national team physician
International players participating in international club competitions, or who are part of FIFA Testing Pool	Confederation	Player and / or club physician
International players participating in FIFA competitions (incl. FIFA World Cup™ qualifying matches) or who are part of FIFA Pre-Competition Testing Pool	FIFA TUE granted by confederation automatically recognised	Player and / or national team physician
Players in FIFA's international Registered Testing Pool	FIFA	Player and / or national team/ club physician

Table 1: Granting bodies for TUEs

### **III. Criteria for granting TUEs**

TUEs submitted to FIFA shall be evaluated according to the criteria for granting a TUE defined in art. 4 of the ISTUE and Appendix C of the FIFA ADR 2009.

### **IV. Confidentiality of information**

In their applications, players must provide written consent for the transmission of all information pertaining to their application to members of the TUE advisory group and, as required, other independent medical or scientific experts, or to all necessary staff of the FIFA Anti-Doping Unit involved in the management, review or appeal of TUEs. Should the assistance of external, independent experts be required, all details of the application shall be circulated without identifying the player concerned. The player must also provide written consent for the decisions of the TUE advisory group to be distributed to other relevant Anti-Doping Organisations under the provisions of the WADC.

The members of the TUE advisory group and the administration of the FIFA Anti-Doping Unit shall conduct all of their activities in strict confidence. In particular, they shall keep the following information confidential:

- a. All medical information and data provided by the player and physician(s) involved in the player's care.
- b. All details of the application including the name of the physician(s) involved in the process.

Should a player wish to revoke the right of the TUE advisory group or the WADA Therapeutic Use Exemption Committee (WADA TUEC) to obtain any health information on their behalf, the player must notify his (team) physician in writing of the fact. The player has to be aware, however, that as a consequence of such a decision, he cannot receive approval for a TUE or renewal of an existing TUE.

### **V. Application process**

A TUE shall only be considered following the receipt of a completed application form that must include all relevant documents (see Annex 2 – TUE form) and follow the principles laid out in the FIFA Anti-Doping Regulations, Appendix C. The application process must be dealt with in accordance with the principles of strict medical confidentiality.

The TUE application form according to the ISTUE has been modified by FIFA to include additional requests for information, as set out in Annex 2.

- The TUE application form has been translated into French, Spanish and German by FIFA, but the English version is authoritative in the case of any issues arising from different interpretations of the form requirements.
- A player may not apply to more than one anti-doping organisation for a TUE. The application must identify the player's affiliation, and the specific competition, if applicable, for which the application is made.
- 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 that request was made, and the decision of that body.

- 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's "Medical Information to Support the Decisions of TUECs". For asthma, the specific requirement(s) set out in section VI below must be fulfilled.
- Any additional relevant investigations, examinations or imaging studies requested by the FIFA TUE advisory group before approval shall be undertaken at the expense of the applicant or his national governing body.
- 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 player and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.
- The dose, frequency, route and duration of administration of the otherwise Prohibited Substance or Prohibited Method in question must be specified. If any of these change, a new application should be submitted.
- In normal circumstances, decisions of the FIFA TUE advisory group should be completed within thirty (30) days of receipt of all relevant documentation and shall be conveyed in writing by the FIFA Anti-Doping Unit to the contact details indicated by the player on the TUE application. In the case of TUE applications not made within the required time limit of twenty-one (21) days (s. Appendix C, FIFA ADR 2009), but made within a reasonable time limit prior to a competition, the FIFA TUE advisory group shall make every effort to complete the TUE process before the start of the competition. Where a TUE has been granted to a player in FIFA's international Registered Testing Pool, the FIFA Testing Pool, the FIFA Pre-Competition Testing Pool or a player participating in a FIFA competition, the player and WADA shall promptly be provided with an approval that includes information pertaining to the duration of the TUE and any conditions associated with the TUE.
- A player may request a review by the WADA TUEC, which shall, as specified in art. 4.4 of the WADA Code, be able to reverse a decision by the FIFA TUE advisory group to deny a TUE. The player must provide the WADA TUEC with all of the information on the TUE that was initially submitted to the FIFA TUE advisory group, accompanied by an application fee. Until the review process has been completed, the original decision of the FIFA TUE advisory group shall remain in effect.
- If a decision regarding the granting of a TUE is reversed by WADA upon review, the reversal shall not apply retroactively and shall not disqualify the player's results during the period that the TUE had been granted and shall take effect no later than fourteen (14) days after the player has been notified of the decision.
- The WADA TUEC is required to explain in detail all medical aspects which led to the reversal of a decision by the FIFA TUE advisory group in language comprehensible to lay people (e.g. the player).

## **VI. Application for asthma treatment**

### **General comment by the FIFA Medical Committee**

The diagnosis of asthma demands the synthesis of medical history with respiratory symptoms, physical examination and appropriate laboratory and/or field tests. The FIFA TUE advisory group emphasises that the mainstay of treatment for asthma is inhaled glucocorticosteroids (GCS) with the use of beta-2-agonists for emergency, breakthrough symptoms or pre-exercise only. Exclusive use of beta-2-agonists is only rarely indicated. The overuse of short- and long-acting beta-2-agonists has detrimental health effects.

Since, as per 1 January 2009, only beta-2-agonists of those substances used in treatment of asthma are on the WADA 2009 Prohibited List, the following applies:

1. The use of inhaled formoterol, salbutamol, salmeterol and terbutaline reflects current clinical practice.
2. For all players included in any of the FIFA testing pools and for players participating in a FIFA competition but who are not included in any of the FIFA testing pools, the use of these substances requires a TUE approved by FIFA.
3. The use of these substances must also be declared on FIFA Doping Control Form 0-1, which is to be completed by the team physician at the time of testing. Failure to declare shall be taken into account in the results management process, particularly if there is no regular TUE.
4. The use of these substances may be declared in the Anti-Doping Administration & Management System (ADAMS) in accordance with the WADA Code. As this system is not yet generally used by FIFA, and therefore players in the FIFA testing pools or participating in FIFA competitions are not generally registered, a player must have undergone preliminary registration before he or his physician can declare any use. The player has to apply to FIFA beforehand in order to register and receive a user ID and password granting access to ADAMS.
5. Players using the substances listed above by inhalation must have a medical file justifying this use and meeting the requirements outlined below.
6. Any player who has applied for a TUE and who was denied such TUE may not use the substance without the prior granting of a TUE (no retroactive TUE shall be permitted).
7. The TUE application for the use of the substances listed above needs to clearly establish whether the diagnosis is:
  - exercise-induced asthma (EIA; some patients require only pre-exercise treatment);
  - mild or more severe chronic, persistent asthma with an exercise-induced component (daily anti-inflammatory therapy plus pre-exercise treatment required);
  - bronchial hyper-reactivity during exercise following an upper respiratory tract infection (therapy of shorter duration up to three months).
8. Players must declare (through their physician) the use of inhaled glucocorticosteroids on the TUE application form (s. Annex 2) and on FIFA Doping Control Form 0-1, which is to be completed by the team physician at the time of testing. For the declaration of use of glucocorticosteroids, see also section VIII.

In accordance with the International TUE Standard valid from 1 January 2009, and the medical information on asthma provided by WADA, the medical file to be used for a TUE application to the FIFA TUE Advisory Group in the case of asthma and its clinical variants has to include the following to reflect current best medical practice:

- 1) a complete medical history incl. the presence of symptoms typically related to asthma (e.g. chest tightness, shortness of breath, coughing, wheezing) during and after exercise, including fatigue, prolonged recovery and poor performance, as well as the onset and severity of symptoms related to exercise, including resolving of the symptoms after cessation of exercise; and any influencing factors (e.g. environmental conditions, infections of the respiratory tract);
- 2) a comprehensive report of the clinical examination with a specific focus on the respiratory system;
- 3) a spirometry report containing the reading of the Forced Expiratory Volume in one second (FEV1) at rest (peak expiratory flow measurements are not accepted);
- 4) if airway obstruction is present at rest, spirometry needs to be repeated after inhalation of a short acting beta-2-agonist to demonstrate the reversibility of bronchoconstriction (however, absence of response to bronchodilators does not exclude diagnosis of asthma);
- 5) in the absence of reversible airway obstruction at rest, a bronchial provocation test is required to establish the presence of airway hyper-responsiveness; this may either be by an exercise test or metacholine challenge;
- 6) exact name, speciality, address (including telephone, e-mail, fax) of examining physician.

If applicable, a peak flow diary listing, for example, the peak flow values, the time they were measured, the symptoms, the possible allergen exposure etc. to support the application is recommended, but not mandatory.

(s. also Annex 1 of the International Standard for Therapeutic Use Exemptions, January 2009)

TUEs for asthma shall be granted for four years in the case of chronic asthma and exercise-induced asthma. For a TUE to be renewed, the results of at least annual follow-ups by a respiratory physician or a physician experienced in treating asthma in the players during the time granted, recent lung function test results no older than three months, and ideally the peak flow diary shall be submitted to the FIFA Anti-Doping Unit.

## **VII. Mutual recognition of TUE approvals**

- The FIFA TUE Advisory group recognises TUE approvals granted by FIFA-recognised confederations for players within FIFA's international Registered Testing Pool and players participating at FIFA competitions.
- National Anti-Doping Organisations (NADOs) do not have authority and therefore shall not grant TUEs for players known to be in FIFA's international Registered Testing Pool or players participating at FIFA competitions in the first place.
- A TUE granted by a NADO will not automatically be valid at international level.
- However, in the case of players moving into one of these categories at short notice, the FIFA TUE Advisory Group recognises TUEs granted by NADOs, provided that:

- the respective NADO follows the FIFA criteria for granting a TUE, in particular with regard to asthma treatment;
- the original application form, including all medical information submitted to the granting body, is provided to the FIFA Anti-Doping Unit; and
- the FIFA TUE Advisory Group establishes the conformity of the application with the FIFA TUE Policy.

## **VIII. Declaration of use process**

- Glucocorticosteroids administered by non-systemic and non-inhaled routes, namely intraarticular, periarticular, peritendinous, epidural, and intradermal injections, are frequently used to treat medical conditions encountered in football players. These substances, for which the route of administration is not prohibited, shall require a declaration of use.
- A player must declare (through his physician) the use of the substance in question on FIFA Doping Control Form 0-1 at the time of testing.
- The use of these substances may be declared in ADAMS in accordance with the WADA Code. As this system is not yet generally used by FIFA, and therefore players in the FIFA testing pools or participating in FIFA competitions are not generally registered, a player must have undergone preliminary registration before he or his physician can declare any use. The player has to apply to FIFA beforehand to register and receive a user ID and password granting access to ADAMS.
- Players (through their physicians) are free to submit a declaration of use to the FIFA Anti-Doping Unit either by fax (to the confidential number +41 43 222 7503) or by secure e-mail (to [medical@fifa.org](mailto:medical@fifa.org)) at the time of use. Please note that the confidentiality of information sent by unsecured e-mail cannot be guaranteed. The declaration should mention the diagnosis, the name of the substance, the dose undertaken, and the name and contact details of the physician (s. Annex 3).

## **IX. TUE approvals**

- FIFA is required to provide WADA with all TUEs approved for players who are part of its testing pools or who participate in FIFA competitions, as well as all supporting documentation.

## **X. Transitional provision**

Abbreviated Therapeutic Use Exemptions (ATUEs) delivered prior to 31 December 2008 shall remain governed by the 2005 ISTUE.

These ATUEs shall remain valid after 1 January 2009 until the earliest of the following dates:

- the date on which they are cancelled by the competent TUEC following review in accordance with art. 8.6 of the 2005 ISTUE;
- their expiry date as mentioned on the ATUE;
- 31 December 2009.

## **Annex 1**

The following FIFA competitions 2009 require a TUE granted by FIFA or by an anti-doping organisation approved for mutual recognition by FIFA:

Qualification matches for the 2010 FIFA World Cup South Africa™

FIFA Confederations Cup South Africa 2009

FIFA U-20 World Cup Egypt 2009

FIFA U-17 World Cup Nigeria 2009

FIFA Beach Soccer World Cup 2009

FIFA Club World Cup 2009

## **Annex 2**

FIFA TUE application form

## **Annex 3**

FIFA Declaration of Use form governing the use of glucocorticosteroids