

## **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 and in accordance with article 7 of the International Standard for Therapeutic Use Exemptions as per 1 January 2010.

The FIFA TUE policy is based on the following documents:

- FIFA Anti-Doping Regulations (ADR) 2010;
- World-Anti Doping Code (WADC), effective from 1 January 2009;
- International Standard for Therapeutic Use Exemptions (ISTUE), effective from 1 January 2010.

### **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 2010 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 registered testing pool (which comprises the FIFA international registered testing pool (high-risk international players), the elite testing pool (elite clubs/associations participating at a confederation level) and the FIFA pre-competition testing pool (representative teams participating in the competition(s) selected by FIFA during the two-month preparation phase prior to that (those) competition(s))). 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 approval of TUEs to the FIFA TUE advisory group. The FIFA 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 FIFA 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 aims to render its decision within 21 days of receipt of all of the requested information.

In compliance with art. 8.1 of the ISTUE, the FIFA TUE advisory group grants TUE approvals for:

- FIFA competitions (FIFA competitions 2010, see annexe 1);
- FIFA's international registered 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 for the attention of the FIFA TUE advisory group unless there is an agreement of mutual recognition with other granting bodies (see table 1, and section VI).

<b>Level of play</b>	<b>TUE application to be sent to:</b>	<b>Application to be submitted by:</b>
National players participating in domestic competitions only	National anti-doping organisation (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 elite testing pool	Confederation	Player and/or representative team physician
International players participating in international club competitions, or who are part of FIFA elite 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 The TUE granted by the confederation is automatically recognised	Player and/or representative team physician
Players in FIFA international registered testing pool	FIFA	Player and/or representative team/club physician

Table 1: Granting bodies for TUEs in football

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

TUE applications 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.

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

The collection, storage, processing, disclosure and retention of personal information by FIFA in the TUE process complies with the International Standard for the Protection of Privacy and Personal Information.

A player applying for a TUE shall provide written consent for the transmission of all information pertaining to the application to all therapeutic use exemption committees (TUECs) with authority under the WADC to review the file and, as required, other independent medical or scientific experts, and to all necessary staff involved in the management, review or appeal of TUEs and WADA. The applicant shall also provide written consent for the decision of the FIFA TUE advisory group to be distributed to other relevant anti-doping organisations and FIFA member associations under the provisions of the WADC.

Should the assistance of external, independent experts be required, all details of the application shall be circulated without identifying the player concerned.

The members of the FIFA TUE advisory group, all independent experts and the staff of the FIFA Medical Office and 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 the player wish to revoke the right of the FIFA TUE advisory group or any TUEC to obtain any health information on his behalf, the player must notify his medical practitioner in writing of the fact. As a consequence of such a decision, the player will not receive approval for a TUE or renewal of an existing TUE.

FIFA shall retain personal information obtained in the TUE process for a period of ten years.

### **V. TUE application process**

A TUE shall only be considered following the receipt of a completed application form that must include all relevant documents (see annexe 3 – TUE application form) and follow the principles laid out in the FIFA Anti-Doping Regulations, appendix C.

- The player should submit an application for TUE no less than twenty-one days before he needs the approval (e.g., for a FIFA competition).

- The TUE application form which appears as an annexe in the ISTUE has been modified by FIFA to include additional requests for information, as set out in annexe 3.
- 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.
- The following players must obtain a TUE from FIFA (see also section II) unless they are in possession of a TUE which has been granted by a confederation and is automatically recognised by FIFA:
  - Players in the FIFA international registered testing pool
  - Players in the FIFA pre-competition testing pool
  - Players participating in any FIFA competition
- The application must identify the player's affiliation and the specific competition, if applicable, for which the application is being made.
- The application must be submitted in fully legible writing in one of the four official FIFA languages.
- The application must list any previous and/or current TUE requests, the body to whom that request was made, and the decision of any other body on review or appeal.
- The application must include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The medical information provided to support the diagnosis and treatment, as well as the duration of validity, should follow WADA's "Medical Information to Support the Decisions of TUECs".
- Applications for beta-2-agonists other than salbutamol and salmeterol in the case of asthma must comply with the specific requirement(s) set out in annexe 2.
- 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/club.
- 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 substance in question must be given its generic name. Brand names will not be accepted and will lead to the application being returned. 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, the decisions of the FIFA TUE advisory group should be completed within twenty-one (21) 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, 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 elite 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 WADC, 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 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. Mutual recognition of TUE approvals**

- The FIFA TUE advisory group recognises TUE approvals granted by confederations for players within FIFA's international registered testing pool and players participating at FIFA competitions.
- NADOs do not have authority and therefore shall not grant TUEs for players known to be in FIFA's 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 TUE advisory group (if the original application is not in one of the four official FIFA languages, it needs to be translated to English); and
  - the FIFA TUE advisory group establishes the conformity of the application with the FIFA TUE policy.

## **VII. Declaration of use**

- Glucocorticosteroids administered by non-systemic routes, namely intraarticular, periarticular, peritendinous, epidural, and intradermal injections and inhaled, 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 only.

- The therapeutic use of inhaled salbutamol and salmeterol by players suffering from asthma will no longer be prohibited and will require a declaration of use only. Please note that systemically applied salbutamol and salmeterol as well as all other beta-2-agonists taken by all administration routes still require a TUE.

Please also note that, in order to ensure that the urinary limit for salbutamol and salmeterol is not exceeded, it is of the utmost importance that physicians carefully teach all players who are using these substances the correct inhalation mode. The players should be reminded to follow the prescription for the administration route, dosage and frequency of salbutamol and salmeterol exactly, and explicitly warned of the possibility of an adverse analytical finding.

- Platelet-derived preparations (e.g. platelet-rich plasma, blood spinning) administered by any routes other than intramuscular require a declaration of use. Application of such preparations by intramuscular routes is prohibited and requires a TUE.
- Declaration of use is made by a player's physician on the FIFA Doping Control Form 0-1 at the time of testing and is mandatory.
- 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 (not mandatory). Please note that the confidentiality of information sent by unsecured e-mail cannot be guaranteed. It might in fact be advisable for players to submit a declaration of use at the time of use in the case of local glucocorticosteroid injections in players playing at international level, because the physicians of representative teams might not be fully aware of the medications provided by club physicians, and a player might forget about the injection while the substance remains present in his body tissues.
- The declaration of use should mention the diagnosis, the name of the substance, the dose undertaken, and the name and contact details of the physician (see annexe 4).

## VIII. TUE approvals

- FIFA is required to use ADAMS 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.
- In the same way, NADOs and confederations are required to use ADAMS to provide WADA and FIFA 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.

## IX. Previously granted abbreviated therapeutic use exemptions (ATUEs)

- Abbreviated therapeutic use exemptions (ATUEs) granted prior to 31 December 2008 that have not already expired shall expire on 31 December 2009.

## Annexe 1

The following matches and FIFA competitions in 2010 require a TUE granted by FIFA or by an anti-doping organisation recognised by FIFA:

- Friendly matches prior to the 2010 FIFA World Cup South Africa™
- 2010 FIFA World Cup South Africa™
- FIFA U-20 Women's World Cup Germany 2010
- FIFA U-17 Women's World Cup Trinidad & Tobago 2010
- FIFA Club World Cup 2010

## Annexe 2

### 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 leads to tolerance and has detrimental health effects.

As per 1 January 2010, salbutamol and salmeterol, when taken by inhalation and in therapeutic doses, have been removed from the WADA Prohibited List and only require a declaration of use on the FIFA Doping Control Form 0-1 as described in section VII. However, there is no intent to deny the use of alternate beta-2-agonists in players who require this medication.

For all beta-2-agonists other than salbutamol and salmeterol, the following applies:

1. For all players included in any of the FIFA registered 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 beta-2-agonists requires a TUE approved by FIFA.
2. Any player who has applied for a TUE and been denied such TUE may not use the substance without the prior granting of a TUE (no retroactive TUE shall be permitted).
3. As with all medication used by players during the 72 hours prior to a competition, the use of beta-2-agonists must be declared on the FIFA Doping Control Form 0-1, which is to be completed by the team physician at the time of testing.
4. 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).
5. If applicable, players must declare (through their physician) the concomitant use of inhaled glucocorticosteroids on the TUE application form (see annexe 4) to allow for evaluation of the medication applied (the use of inhaled glucocorticosteroids also needs to be declared on FIFA Doping Control Form 0-1 completed by the team physician at the time of testing; see also section VII).
  6. In accordance with the medical information on asthma provided by WADA, players using alternate beta-2-agonists by inhalation must have a medical file justifying this use and meeting the requirements outlined below to reflect current best medical practice:
    - a) A complete medical history incl. the recurrence of symptoms of bronchial obstruction (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. provocation by hyperventilation or other stimuli such as environmental conditions, allergies, infections of the respiratory tract).
    - b) A comprehensive report of the clinical examination with a specific focus on the respiratory system.
    - c) A spirometry report containing the reading of the forced expiratory volume in one second (FEV1) at rest (peak expiratory flow measurements are not accepted) to demonstrate airway obstruction (reduced FEFV1 / FVC ratio).
    - d) 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 or a response not meeting the requirements of the standard diagnostic test does not exclude diagnosis of asthma).
    - e) 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 methacholine challenge.
    - f) Spirometry and other diagnostic test results should be submitted together with the report by the examining respiratory physician.
    - g) 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.) is recommended to support the application, but is not mandatory.
  7. 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 after that period, 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 shall be submitted to the FIFA TUE advisory group together with repeated lung function tests, and ideally the peak flow diary.



## **Annexe 3**

FIFA TUE application form

## **Annexe 4**

FIFA declaration of use form governing the local use of glucocorticosteroids, salbutamol/salmeterol by inhalation and platelet-derived preparations