

**To the members of FIFA**

Circular no. 1251

Zurich, December 2010  
SG/jdv/kgr

**2011 Prohibited List, International Standard for Therapeutic Use Exemptions and FIFA TUE policy**

Dear Sir or Madam,

We are pleased to enclose three copies of the FIFA TUE policy that comes into effect on 1 January 2011. This policy includes changes necessary to ensure compliance with both the new International Standard Prohibited List and the new International Standard for Therapeutic Use Exemptions (TUEs) published by WADA, which come into effect on 1 January 2011.

We would like to draw your attention in particular to the following important changes:

**1. 2011 Prohibited List**

Substances and methods prohibited at all times (in- and out-of-competition)

**S0. Non-approved substances**

An introductory paragraph has been added introducing a new category of substances that are not covered by the other sections of the Prohibited List. It refers to drugs with no official approval, either because they are in an experimental phase of development or because they are no longer permitted for human use.

**S2. Peptide hormones, growth factors and related substances**

More examples have been added to this section in order to reflect the growing number of substances developed to stimulate erythropoiesis.

Platelet-derived preparations administered by intra-muscular routes have been removed from the Prohibited List and therefore no longer require a TUE. However, individual growth factors are still prohibited when given separately as purified substances as described in S2.5

**S3. Beta-2 agonists**

Salbutamol (maximum 1,600 micrograms over 24 hours) and salmeterol henceforth no longer require a Declaration of Use (DoU) as DoUs are no longer referred to in the 2011 Prohibited List. It is important to note that the presence of salbutamol in urine in excess of 1,000ng/mL is presumed not to be an intended therapeutic use of the substance and will be considered as an adverse analytical finding unless the player proves, through a controlled pharmacokinetic study,

that this is the consequence of the use of a therapeutic dose (maximum 1,600mcg/24hrs) of inhaled salbutamol.

Recommendation to team physicians: in order to avoid exceeding the urinary limit for salbutamol and salmeterol, it is of the utmost importance that physicians carefully instruct all players taking these substances on how to use them correctly. No prescription "as needed" should be made. Players should be reminded to follow the prescription exactly for the administration route, dosage and frequency of use, and should be explicitly warned of the possibility of an adverse analytical finding.

All other beta-2 agonists are prohibited and therefore require a TUE.

### **S5. Diuretics and other masking agents**

Glycerol, which was added to the Prohibited List as an example last year, can be found in different foods and toiletries. However, WADA has explicitly confirmed that such use will not cause a player to test positive for this substance.

Should an exogenous threshold substance (i.e. salbutamol, morphine, cathine, ephedrine, methylephedrine or pseudoephedrine) be detected at any threshold concentration (including sub-threshold) in conjunction with a diuretic or other masking agent, both substances will be reported as adverse analytical findings (AAF) by the laboratory. Therefore, in such a case, the player is required to apply for a TUE for both the threshold substance and the diuretic or masking agent to avoid a positive result.

### **M2. Chemical and physical manipulation**

A new paragraph M2.3 has been added to prohibit the "sequential withdrawal, manipulation, and reinfusion of whole blood". This new paragraph has been added to reflect the process by which a player's blood is removed, treated or manipulated, and then re-injected. Players undergoing haemodialysis, as part of the treatment of chronic kidney disease, will require a TUE for such procedures, and if applicable, for the other prohibited substances used for the treatment of such a disorder.

### **M3. Gene doping**

Significant changes have been made to the wording for clarification purposes.

### Substances and methods prohibited in-competition

### **S6. Stimulants**

Methylhexaneamine has been moved from the non-specified stimulants to the specified stimulants category as the substance can often be found in nutritional supplements and be referred to as "geranium oil" or "geranium root extract". It is highly recommended not to use any products containing such references.

### **S8. Cannabinoids**

The definition has been reworded to clarify that all cannabimimetics are included in this section.

**S9. Glucocorticosteroids**

Only the prohibited routes of administration (oral, intravenous, intramuscular or rectal) requiring a TUE are now listed and are the same as in the 2010 Prohibited List. All other routes no longer require a DoU as DoUs are no longer referred to in the 2011 Prohibited List.

**2. International Standard for Therapeutic Use Exemptions**

For detailed information about the application requirements for a therapeutic use exemption (TUE), refer to the FIFA TUE policy. The most important points are:

**Declaration of use (DoU)**

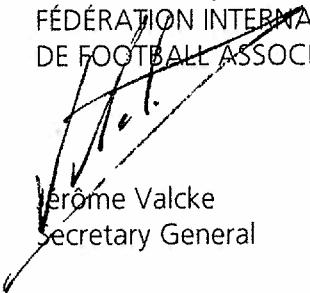
The DoU has been removed from both the 2011 Prohibited List and the ISTUE and is therefore no longer required for any substance (previously required for non-systemic use of glucocorticosteroids, inhaled salbutamol and salmeterol, and platelet-derived preparations not administered by intra-muscular routes).

Regardless of the above, please note art. 1.3 of appendix E of the FIFA Anti-Doping Regulations: *"The team doctor shall enter in legible handwriting on Doping Control Form 0-1 any medicaments taken by players or administered to them in the 72 hours preceding the match, indicating the name of the substance, the dose, when and for how long prescribed and the method of administration."*

Please note that the above summary of the most important points is in no way sufficient for a full understanding of the new regulations. The FIFA Medical Committee advises all member associations to read the FIFA TUE policy carefully and acquaint themselves with the stipulations in order to avoid any misunderstanding. We particularly recommend that you distribute the FIFA TUE policy to all medical staff working for your association and inform players accordingly.

We thank you for your support in the fight against substance abuse in football.

Yours faithfully,  
FÉDÉRATION INTERNATIONALE  
DE FOOTBALL ASSOCIATION



Jérôme Valcke  
Secretary General

Encl: FIFA TUE policy

cc:

- Executive Committee
- Medical Committee
- Confederations
- WADA

## 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 2011.

The FIFA TUE Policy is based on the following documents:

- FIFA Anti-Doping Regulations (ADR), effective from 1 April 2010;
- World-Anti Doping Code (WADC), effective from 1 January 2009;
- International Standard for Therapeutic Use Exemptions (ISTUE), effective from 1 January 2011.

### 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 2011 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 (selected by the FIFA Anti-Doping Unit; player informed by the respective member association), the elite testing pool (as defined by the respective confederation), the FIFA pre-competition testing pool (FIFA Women's World Cup 2011™ teams)). To facilitate participation in international competitions, all confederations have agreed 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 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 their decision within 21 days of receipt of all requested information.

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

- FIFA competitions (FIFA competitions 2011, see annexe 1);
- FIFA 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 TUEs granted by confederations are automatically recognised	Player and/or representative team physician
Players in FIFA international registered testing pool	FIFA TUEs granted by confederations are automatically recognised	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 in the TUE process by FIFA comply 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 ADR, appendix C.

- The following players must obtain a TUE from FIFA (see also 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 player should submit an application for a TUE no less than twenty-one (21) 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 is available in English, French, Spanish and German by FIFA, and has to be completed in fully legible writing in one of the four FIFA languages. The medical file, including all documents and reports, also has to be provided in one of the FIFA languages.
- The application must identify the player's affiliation, and the specific competition, if applicable, for which the application is being made.
- 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 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 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).
- WADA, at the request of a player or on its own initiation, may review the granting or denial of any TUE by FIFA. Decisions by WADA reversing the granting or denial of a TUE may be appealed exclusively to CAS by the player or FIFA.

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

- The FIFA TUE advisory group recognises TUE approvals granted by confederations for players within FIFA's registered testing pool and players participating in 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 in 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 the categories above 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 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. TUE approvals**

FIFA is required to provide WADA with all TUEs approved for players who are part of the FIFA international registered testing pool, the FIFA pre-competition testing pool or who participate in FIFA competitions, as well as all supporting documentation.

## **Important note:**

The former "Declaration of Use" (valid in 2009 and 2010) has been removed from the 2011 Prohibited List and the ISTUE and is therefore no longer required for any substance. Regardless of this, please note article 1.3 of appendix E of the FIFA ADR: "The team doctor shall enter in legible handwriting on Doping Control Form 0-1 any medicaments taken by the players or administered to them in the 72 hours preceding the match, indicating the name of the substance, the dose, when and for how long prescribed and the method of administration."

## **Annexe 1**

The following FIFA competitions in 2011 require a TUE granted by FIFA or a TUE issued by another anti-doping organisation that has been mutually recognised by FIFA:

- FIFA U-17 World Cup Mexico 2011
- FIFA Women's World Cup Germany 2011™
- FIFA U-20 World Cup Colombia 2011
- FIFA Beach Soccer World Cup 2011
- FIFA Club World Cup 2011

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

1. For all players included in the FIFA registered testing pool and for players participating in a FIFA competition, the use of beta-2-agonists requires a TUE approved by FIFA (or a confederation).
2. 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).
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 (see also section VII).
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 3) so that it can be determined whether medical best practice is being applied (the use of inhaled glucocorticosteroids also needs to be declared on the 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 beta-2-agonists other than salbutamol or salmeterol by inhalation must have a medical file justifying this use and meeting the requirements outlined below to reflect current best medical practice:
    - 1) A complete medical history: recurrent symptoms of bronchial obstruction such as chest tightness, wheezing and coughing provoked by hyperventilation, exercise or other stimuli, are a diagnostic prerequisite for asthma or EIA in athletes.
    - 2) A comprehensive report of the clinical examination with a specific focus on the respiratory system to exclude mimics, assess the severity of airflow obstruction at rest, identify factors that might place the athlete at risk of a poor outcome and identify co-morbidities that may complicate management.
    - 3) A spirometry report containing the reading of the forced expiratory volume in one second (FEV<sub>1</sub>) at rest (peak expiratory flow measurements are not accepted) to demonstrate airway obstruction (reduced FEFV<sub>1</sub>/FVC ratio).
    - 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 or a response not meeting the requirements of the standard diagnostic test 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. Bronchial provocation may be performed by the use of physiological (exercise or eucapnic voluntary hyperventilation tests) or pharmacological (methacholine, mannitol, hypertonic saline, histamine) challenge tests of hyperventilation. A test-specific decrease in FEV<sub>1</sub> following the administration of a provocative agent is considered to be diagnostic and comparable to the stimulus of exercise. A positive response to any one of the above provocation tests is required to confirm bronchial hyperresponsiveness. If not, a review of the medical file will be required.
    - 6) Spirometry and other diagnostic test results should be submitted together with the report by the examining respiratory physician. The relevant test results should not be older than four years at the time of application.
    - 7) Exact name, speciality, address (including telephone, e-mail, fax) of the examining physician.

7. TUEs for asthma shall be granted for four years in the case of chronic asthma and EIA. For a TUE to be renewed after that period, the results of 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.

## **Annexe 3**

FIFA TUE application form

## **SUMMARY**

### **PROHIBITED LIST AND TUE REQUIREMENTS 2011**

#### **Requirements for granting a TUE\***

- All players using prohibited medication who participate in a FIFA competition or who are part of the FIFA registered testing pool require a TUE granted by the FIFA TUE advisory group or by a confederation (automatically recognised).
- Applications to FIFA should be submitted at least 21 days prior to the competition.
- TUEs granted by NADOs require the submission of the complete medical file to the FIFA TUE advisory group so that it can be determined whether such TUEs are recognised.
- TUE application form: fully complete all sections, including the medical history and the generic name of the medication, in legible handwriting and in one of the four FIFA languages.

#### **Declaration of Use**

The Declaration of Use has been abolished for 2011 and is **no longer required for any substance**.

But please note **article 1.3 of appendix E of the FIFA Anti-Doping Regulations**:

*"The team doctor shall enter in legible handwriting on Doping Control Form 0-1 any medicaments taken by players or administered to them in the 72 hours preceding the match, indicating the name of the substance, the dose, when and for how long prescribed and the method of administration."*

#### **Further important points:**

- Platelet-derived preparations (PRPs) do not require a TUE.
- Beta-2-agonists:
  - Salbutamol and salmeterol do not require a TUE.
  - All other beta-2-agonists require a TUE.
  - Salbutamol: carefully advise on inhaler use and prescribe maximal dose (urine threshold).
- Glucocorticosteroids:
  - All glucocorticosteroids administered by oral, intravenous, intramuscular or rectal routes in competition require a TUE.
  - All other administration routes do not require a TUE.

\*See FIFA TUE Policy 2011 for details.

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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 (selected by the FIFA Anti-Doping Unit; player informed by the respective member association), the elite testing pool (as defined by the respective confederation), the FIFA pre-competition testing pool (FIFA Women's World Cup 2011™ teams)). To facilitate participation in international competitions, all confederations have agreed 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 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 their decision within 21 days of receipt of all requested information.

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

- FIFA competitions (FIFA competitions 2011, see annexe 1);
- FIFA 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 TUEs granted by confederations are automatically recognised	Player and/or representative team physician
Players in FIFA international registered testing pool	FIFA TUEs granted by confederations are automatically recognised	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 in the TUE process by FIFA comply 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 ADR, appendix C.

- The following players must obtain a TUE from FIFA (see also 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

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- The player should submit an application for a TUE no less than twenty-one (21) days before he needs the approval (e.g. for a FIFA competition).
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- The application must identify the player's affiliation, and the specific competition, if applicable, for which the application is being made.
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- 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 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 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).
- WADA, at the request of a player or on its own initiation, may review the granting or denial of any TUE by FIFA. Decisions by WADA reversing the granting or denial of a TUE may be appealed exclusively to CAS by the player or FIFA.

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

- The FIFA TUE advisory group recognises TUE approvals granted by confederations for players within FIFA's registered testing pool and players participating in 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 in 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 the categories above 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 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. TUE approvals**

FIFA is required to provide WADA with all TUEs approved for players who are part of the FIFA international registered testing pool, the FIFA pre-competition testing pool or who participate in FIFA competitions, as well as all supporting documentation.

## **Important note:**

The former "Declaration of Use" (valid in 2009 and 2010) has been removed from the 2011 Prohibited List and the ISTUE and is therefore no longer required for any substance. Regardless of this, please note article 1.3 of appendix E of the FIFA ADR: "The team doctor shall enter in legible handwriting on Doping Control Form 0-1 any medicaments taken by the players or administered to them in the 72 hours preceding the match, indicating the name of the substance, the dose, when and for how long prescribed and the method of administration."

## **Annexe 1**

The following FIFA competitions in 2011 require a TUE granted by FIFA or a TUE issued by another anti-doping organisation that has been mutually recognised by FIFA:

- FIFA U-17 World Cup Mexico 2011
- FIFA Women's World Cup Germany 2011™
- FIFA U-20 World Cup Colombia 2011
- FIFA Beach Soccer World Cup 2011
- FIFA Club World Cup 2011

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

1. For all players included in the FIFA registered testing pool and for players participating in a FIFA competition, the use of beta-2-agonists requires a TUE approved by FIFA (or a confederation).
2. 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).
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 (see also section VII).
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 3) so that it can be determined whether medical best practice is being applied (the use of inhaled glucocorticosteroids also needs to be declared on the 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 beta-2-agonists other than salbutamol or salmeterol by inhalation must have a medical file justifying this use and meeting the requirements outlined below to reflect current best medical practice:
    - 1) A complete medical history: recurrent symptoms of bronchial obstruction such as chest tightness, wheezing and coughing provoked by hyperventilation, exercise or other stimuli, are a diagnostic prerequisite for asthma or EIA in athletes.
    - 2) A comprehensive report of the clinical examination with a specific focus on the respiratory system to exclude mimics, assess the severity of airflow obstruction at rest, identify factors that might place the athlete at risk of a poor outcome and identify co-morbidities that may complicate management.
    - 3) A spirometry report containing the reading of the forced expiratory volume in one second (FEV<sub>1</sub>) at rest (peak expiratory flow measurements are not accepted) to demonstrate airway obstruction (reduced FEFV<sub>1</sub>/FVC ratio).
    - 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 or a response not meeting the requirements of the standard diagnostic test 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. Bronchial provocation may be performed by the use of physiological (exercise or eucapnic voluntary hyperventilation tests) or pharmacological (methacholine, mannitol, hypertonic saline, histamine) challenge tests of hyperventilation. A test-specific decrease in FEV<sub>1</sub> following the administration of a provocative agent is considered to be diagnostic and comparable to the stimulus of exercise. A positive response to any one of the above provocation tests is required to confirm bronchial hyperresponsiveness. If not, a review of the medical file will be required.
    - 6) Spirometry and other diagnostic test results should be submitted together with the report by the examining respiratory physician. The relevant test results should not be older than four years at the time of application.
    - 7) Exact name, speciality, address (including telephone, e-mail, fax) of the examining physician.

7. TUEs for asthma shall be granted for four years in the case of chronic asthma and EIA. For a TUE to be renewed after that period, the results of 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.

## **Annexe 3**

FIFA TUE application form

## **SUMMARY**

### **PROHIBITED LIST AND TUE REQUIREMENTS 2011**

#### **Requirements for granting a TUE\***

- All players using prohibited medication who participate in a FIFA competition or who are part of the FIFA registered testing pool require a TUE granted by the FIFA TUE advisory group or by a confederation (automatically recognised).
- Applications to FIFA should be submitted at least 21 days prior to the competition.
- TUEs granted by NADOs require the submission of the complete medical file to the FIFA TUE advisory group so that it can be determined whether such TUEs are recognised.
- TUE application form: fully complete all sections, including the medical history and the generic name of the medication, in legible handwriting and in one of the four FIFA languages.

#### **Declaration of Use**

The Declaration of Use has been abolished for 2011 and is **no longer required for any substance**.

But please note **article 1.3 of appendix E of the FIFA Anti-Doping Regulations**:

*"The team doctor shall enter in legible handwriting on Doping Control Form 0-1 any medicaments taken by players or administered to them in the 72 hours preceding the match, indicating the name of the substance, the dose, when and for how long prescribed and the method of administration."*

#### **Further important points:**

- Platelet-derived preparations (PRPs) do not require a TUE.
- Beta-2-agonists:
  - Salbutamol and salmeterol do not require a TUE.
  - All other beta-2-agonists require a TUE.
  - Salbutamol: carefully advise on inhaler use and prescribe maximal dose (urine threshold).
- Glucocorticosteroids:
  - All glucocorticosteroids administered by oral, intravenous, intramuscular or rectal routes in competition require a TUE.
  - All other administration routes do not require a TUE.

\*See FIFA TUE Policy 2011 for details.