

## 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 2017.

The FIFA TUE Policy is based on the following documents:

- FIFA Anti-Doping Regulations (ADR), effective from 1 January 2017;
- World-Anti Doping Code (WADC), effective from 1 January 2017;
- International Standard for Therapeutic Use Exemptions (ISTUE), effective from 1 January 2017.

### 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 to apply for TUEs, i.e. for permission to use for therapeutic purposes substances or methods contained in the 2017 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 International Competitions for which FIFA has indicated that a TUE from FIFA is required 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) and the FIFA pre-competition testing pool (2018 FIFA World Cup™ 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 doctors 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. 4.4.3 of the WADC, the FIFA TUE Advisory Group recognises or grants TUE approvals for International Level Players which includes Players who:

- Participate in FIFA International Competitions and/or Competitions under the jurisdiction of a Confederation (for FIFA competitions in 2017, see Annexe 1); or
- Players designated by FIFA or a Confederation as being within FIFA or the Confederation's registered testing pool.

Accordingly, TUE applications for the recognition or grant of a TUE for International-Level Players 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) in accordance with Article 7 of the ISTUE.

<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
International players called up to compete in international team competitions and friendly matches at confederation level; FIFA elite testing pool	Confederation	Player
International players participating in international club competitions, or who are part of FIFA elite testing pool	Confederation	Player
<b>International players participating in FIFA competitions (incl. FIFA World Cup™ qualifying matches) or who are part of FIFA pre-competition testing pool</b>	<b>FIFA TUEs granted by confederations are automatically recognised</b>	<b>Player</b>
<b>Players in FIFA international registered testing pool</b>	<b>FIFA TUEs granted by confederations are automatically recognised</b>	<b>Player</b>

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 Annexe B of the FIFA ADR.

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

The collection, storage, processing, disclosure and retention of personal information by FIFA in the TUE process shall 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 and International Standards 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 with Testing and/or results management authority over the player 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 and shall sign appropriate confidentiality agreements. In particular, they shall keep the following information confidential:

- a. All medical information and data provided by the player and doctor(s) involved in the player's care.
- b. All details of the application including the name of the doctor(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 doctor 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 on 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 Annexe B of the FIFA ADR.

- 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 or a NADO according to art. 4.4.3 WADC 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 thirty (30) days before he needs the approval (e.g. for a FIFA competition), unless it is an emergency or exceptional situation.
- The TUE application form that 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 provided by FIFA in English, French, Spanish and German and has to be completed in fully legible writing in one of the four FIFA languages. The medical file, including all documents and reports, must also 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, salmeterol and formoterol 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 doctor 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 using 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 or the FIFA pre-competition testing pool or to a player participating in a FIFA competition, the player and WADA shall promptly be provided with approval that includes information pertaining to the duration of the TUE and any conditions associated with it.

- A player may request a review by the WADA TUEC in accordance with Article 4.4.6 of the WADC. 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 initiative, 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 the Court of Arbitration for Sport by the player, the Player's NADO 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 to grant TUEs for players known to be in FIFA's registered testing pool or players participating in FIFA competitions, provided that such players are international-level players according to FIFA Anti-Doping Regulations. A TUE granted by a NADO is not automatically valid at international level.
- However, in the case of players joining FIFA's registered testing pool or participating in a FIFA competition at short notice, the FIFA TUE Advisory Group recognises TUEs granted by NADOs in accordance with Article 4.4.3 of the WADC. When considering such applications, the FIFA TUE Advisory Group shall ensure, that:
  - the respective NADO follows FIFA's criteria (in accordance with the International Standard for Therapeutic Use Exemptions) 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 must 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 or the FIFA pre-competition testing pool or who participate in FIFA competitions, as well as all supporting documentation.

### Important note:

Regardless of WADA provisions with regard to the declaration of substances used by players (the WADA "Declaration of Use" was abolished in 2011), please note article 2.3 of appendix D 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." This applies to both non-prohibited and prohibited medication.

For more detailed information on the TUE application and granting process, please refer to the WADA International Standard for TUEs at: <http://www.wada-ama.org/en/Science-Medicine/TUE/>

For more detailed information on the requirements for TUE applications in relation to particular diseases, please refer to the WADA Medical Information to Support the Decisions of TUECs at: <http://www.wada-ama.org/en/Science-Medicine/TUE/>

## Annexe 1

The following FIFA competitions in 2017 require a TUE granted by FIFA or a TUE issued by another anti-doping organisation that has been recognised by FIFA:

- FIFA Beach Soccer World Cup Bahamas 2017
- FIFA U-20 World Cup Korea Republic 2017
- FIFA Confederations Cup Russia 2017
- FIFA U-17 World Cup India 2017
- FIFA Club World Cup UAE 2017

## Annexe 2

### 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 emergencies, 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.

From 1 January 2010, salbutamol and salmeterol, and from 1 January 2012 formoterol, when taken by inhalation and in therapeutic doses, have been removed from the WADA Prohibited List.

**Important note:** The beta-2-agonists salbutamol and formoterol are not prohibited, but are only allowed up to a maximum dose of 1,600 micrograms over 24 hours (salbutamol) or 54 micrograms over 24 hours (formoterol). It is important to consider these dosage limits when prescribing these substances and when instructing players on the correct use of them, as the use of higher doses might potentially lead to a player exceeding the corresponding urine thresholds as defined in the Prohibited List. The presence in urine of salbutamol in excess of 1,000 ng/mL or formoterol in excess of 40 ng/mL is presumed not to be an intended therapeutic use of the substance and will be considered as an adverse analytical finding unless the athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of taking the therapeutic inhaled dose up to the maximum indicated above.

For all beta-2-agonists other than salbutamol, salmeterol and formoterol, 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 or according to art. 4.4.3 WADC).
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, except in accordance with Article 4.3 of the ISTUE).
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 and on the FIFA Doping Control Form 0-2 including medications used 7 days prior to a testing, which shall be completed by the team doctor 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 doctor) 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 FIFA Doping Control Form 0-1 completed by the team doctor 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, salmeterol or formoterol 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: 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.

- b) 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.
  - c) 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).
  - 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. 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 hyper-responsiveness. If not, a review of the medical file will be required.
  - f) Spirometry and other diagnostic test results should be submitted together with the report by the examining respiratory doctor. The relevant test results should not be older than four years at the time of application.
  - g) Exact name, speciality, address (including telephone, e-mail and fax details) of the examining doctor.
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 doctor or a doctor experienced in treating players for asthma during the period granted shall be submitted to the FIFA TUE Advisory Group.

## **Annexe 3**

FIFA TUE application form