

AFC TUE POLICY 2016

Preamble

This document outlines the procedures governing the application, approval, mutual recognition and administrative management of therapeutic use exemptions (TUEs) within AFC's jurisdiction and in accordance with Article 7 of the International Standard for Therapeutic Use Exemptions (ISTUE) as per 1 January 2016.

The AFC TUE Policy is based on the following documents:

- AFC Anti-Doping Regulations (ADR), effective from 1 January 2015, most recently amended 12 May 2016;
- World-Anti Doping Code (WADC), effective from 1 January 2015;
- ISTUE, effective from 1 January 2016.

1. Scope

- 1.1. The purpose of the AFC TUE Policy is to ensure that the process of granting TUEs is the same for all players participating in AFC competitions and is harmonised across football.
- 1.2. The WADC permits players and their doctors to apply for TUEs, i.e. for permission to use, for therapeutic purposes, substances or methods contained in the most current edition of the WADA Prohibited List for which use is otherwise prohibited.
- 1.3. The AFC 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.
- 1.4. This AFC TUE Policy applies to all players participating in AFC competitions as well as those in an AFC Registered Testing Pool (AFC Elite Testing Pool and AFC Pre-Competition Testing Pool) (RTP). To facilitate participation in international competitions, the AFC has agreed in a declaration to adopt this AFC TUE policy and ensure that it is consistent with the FIFA TUE policy.

2. Granting body

- 2.1. The AFC Medical Committee has overall responsibility for approving applications for TUEs. It delegates the evaluation and the approval of TUEs to the AFC TUE Advisory Group. The AFC TUE Advisory Group includes three (3) 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 AFC TUE Advisory Group may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.
- 2.2. The AFC TUE Advisory Group aims to render their decision within twenty-one (21) days of receipt of all requested information.

- 2.3. In compliance with Article 4.4.3 of the WADC, the AFC TUE Advisory Group grants TUE approvals for:
- 2.3.1. players registered to participate in all AFC competitions (for AFC competitions, see **Annexe 1 of this Policy**); or
 - 2.3.2. players designated as being within an AFC RTP.
- 2.4. Accordingly, TUE applications for the recognition or grant of a TUE must be sent to the AFC Anti-Doping Unit for the attention of the AFC TUE Advisory group unless there is an agreement of mutual recognition with other granting bodies (see Table 1 below, and Article 6 of this Policy) in accordance with Article 7 of the ISTUE.

Level of Play	Application submitted to	Application submitted by
National players participating in domestic competitions only	National Anti-Doping Agency (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 AFC level; or who are part of an AFC RTP; or who are part of the FIFA Elite Testing Pool	AFC	Player
International players participating in AFC club competitions; or who are part of an AFC RTP; or who are part of FIFA Elite Testing Pool	AFC	Player
International players participating in FIFA competitions; or who are part of FIFA Pre-Competition Testing Pool	FIFA TUEs granted by the AFC are automatically recognised by FIFA	Player
Players in FIFA International Registered Testing Pool	FIFA TUEs granted by the AFC are automatically recognised by FIFA	Player

Table 1: Granting bodies for TUEs in football

3. **Criteria for granting TUEs**

- 3.1. TUE applications submitted to the AFC shall be evaluated according to the criteria for granting a TUE defined in Article 4 of the ISTUE and Annexe B of the AFC ADR.

4. **Confidentiality of information**

- 4.1. The collection, storage, processing, disclosure and retention of personal information by the AFC in the TUE application process shall comply with the International Standard for the Protection of Privacy and Personal Information.

- 4.2. 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 AFC TUE Advisory Group to be distributed to other relevant anti-doping organisations with testing and/or results management authority over the player and AFC Member Associations under the provisions of the WADC.

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

- 4.4. The members of the AFC TUE Advisory Group, all independent experts and the staff of the AFC 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:

4.4.1. all medical information and data provided by the player and doctor(s) involved in the player's care; and

4.4.2. all details of the application including the name of the doctor(s) involved in the process.

- 4.5. Should the player wish to revoke the right of the AFC TUE Advisory Group or any TUEC to obtain any health information on their 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.

- 4.6. The AFC shall retain personal information obtained in the TUE process for a period of ten (10) years.

5. **TUE Application process**

- 5.1. A TUE shall only be considered on receipt of a completed application form that must include all relevant documents (see **Annexe 3 of this Policy**) and follow the principles laid out in Annexe B of the AFC ADR.

- 5.2. The following players must obtain a TUE from AFC (*cf.* Article 2) unless they are in possession of a TUE which has been granted by FIFA or another confederation according to Article 4.4.3 of the WADC and is automatically recognised by the AFC:
 - 5.2.1. players in any AFC RTP; and
 - 5.2.2. players participating in any AFC competition.
- 5.3. The player should submit an application for a TUE no less than thirty (30) days before they need the approval (e.g. for an AFC competition), unless it is an emergency or exceptional situation.
- 5.4. The TUE application form which appears as an annex in the ISTUE has been modified by the AFC to include additional requests for information, as set out in **Annexe 3 of this Policy**.
- 5.5. The TUE application form is in English and has to be completed in fully legible writing. The medical file including all documents and reports must also be provided in English. Where translated, the translation must be completed by an accredited translation service.
- 5.6. The TUE application must:
 - 5.6.1. identify the player's affiliation, and the specific competition, if applicable, for which the application is being made;
 - 5.6.2. 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; and
 - 5.6.3. 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*".
- 5.7. 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 of this Policy**.
- 5.8. Any additional relevant investigations, examinations or imaging studies requested by the AFC TUE Advisory Group before approval shall be undertaken at the expense of the applicant, their Member Association, or their club.
- 5.9. 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.

- 5.10. 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.
- 5.11. In normal circumstances, the decisions of the AFC 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 AFC 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 AFC 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, an AFC RTP, or to a player participating in an AFC 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 it.
- 5.12. 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 AFC TUE Advisory Group, accompanied by an application fee. Until the review process has been completed, the original decision of the AFC TUE Advisory Group shall remain in effect.
- 5.13. 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.
- 5.14. The WADA TUEC is required to explain in detail all medical aspects which led to the reversal of a decision by the AFC TUE Advisory Group in language comprehensible to lay people (e.g. the player).
- 5.15. WADA, at the request of a player or on its own initiative, may review the granting or denial of any TUE by the AFC. Decisions by WADA reversing the granting or denial of a TUE may be appealed exclusively to Court of Arbitration for Sport, by those parties set out in the AFC ADRs .
- 6. Mutual recognition of TUE approvals**
- 6.1. The AFC TUE Advisory Group recognises TUE approvals granted by FIFA and other Confederations.
- 6.2. National Anti-Doping Organisation (NADOs) do not have authority to grant TUEs for players in an AFC RTP or players participating in AFC competitions, provided that such players are international-level players according to the AFC ADRs. A TUE granted by a NADO is not automatically valid at international level and is not automatically recognised by the AFC.

- 6.3. However, in the case of players joining an AFC RTP or participating in an AFC competition at short notice, the AFC TUE Advisory Group may recognise a TUE granted by a NADO in accordance with Article 4.4.3 of the WADC. When considering such applications, the AFC TUE Advisory Group shall ensure, that:
- 6.3.1. the respective NADO follows the AFC's criteria (in accordance with the ISTUE) for granting a TUE, in particular with regard to asthma treatment;
 - 6.3.2. the original application form, including all medical information submitted to the granting body, is provided to the AFC TUE Advisory Group (if the original application is not in English, it must be translated); and
 - 6.3.3. the AFC TUE Advisory Group establishes the conformity of the application with the AFC TUE Policy.

7. TUE approvals

- 7.1. The AFC is required to provide WADA with all TUEs approved for players who form part of an AFC RTP or who participate in AFC competitions, as well as all supporting documentation.

Important note:

Regardless of WADA provisions with regards to the declaration of substances used by players (the WADA "Declaration of Use" was abolished in 2011), please note Article 2.3 of Annexe D of the AFC ADR: *"The team doctor shall enter in legible handwriting on Form 0-1 any medication 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"*.

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

8. Administration

- 8.1. This Policy enters into force on 10th August 2016 and is immediately applicable.
- 8.2. It replaces any previous Policy.

ANNEXE 1

1. The following AFC competitions require a TUE granted by the AFC or a TUE issued by another anti-doping organisation that is recognised by the AFC:

National team competitions

- 1.1. AFC Asian Cup;
- 1.2. AFC Solidarity Cup;
- 1.3. AFC U-23 Championship;
- 1.4. AFC U-19 Championship;
- 1.5. AFC U-16 Championship;
- 1.6. AFC Women's Asian Cup;
- 1.7. AFC U-19 Women's Championship;
- 1.8. AFC U-16 Women's Championship;

Club team competitions

- 1.9. AFC Champions League;
- 1.10. AFC Cup;

Futsal competitions

- 1.11. AFC Futsal Championship;
- 1.12. AFC Futsal Club Championship;
- 1.13. AFC U-20 Futsal Championship;
- 1.14. AFC Women's Futsal Championship;

Beach Soccer competitions

- 1.15. AFC Beach Soccer Championship.

2. Any new AFC competitions approved by the AFC Executive Committee after the entering into force of this Policy shall be deemed to be included on this list.

ANNEXE 2

Application for Asthma treatment

General Comments by the AFC Medical Committee

1. The diagnosis of asthma demands the synthesis of medical history with respiratory symptoms, physical examination and appropriate laboratory and/or field tests. The AFC TUE Advisory Group emphasises that the mainstay of treatment for asthma is inhaled glucocorticosteroids (GCSs) with the use of the beta-2-agonists for emergencies, breakthrough symptoms or pre-exercise only. Exclusive use of the beta-2-agonists is only rarely indicated. The overuse of short and long-acting beta-2-agonists lead to tolerance and has detrimental health effects.
2. As per 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, and are not prohibited, but are only allowed up to 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 1000 ng/mL or formoterol in excess of 40ng/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 results was the consequence of taking the therapeutic inhaled dose up to the maximum indicated above.

3. For all beta-2-agonists other than salbutamol, salmeterol and formoterol the following applies:
 - 3.1. for all players included in an AFC RTP and for all players participating in AFC competitions, the use of beta-2-agonists requires a TUE approved by the AFC (or FIFA or a confederation according to Article 4.4.3 of the WADC);
 - 3.2. any player who has applied for a TUE and who was denied such TUE may not use the substance without the prior grant of a TUE (no retroactive TUE shall be permitted, except in accordance with Article 4.3 of the ISTUE);
 - 3.3. as with all medication used by players during the seventy two (72) hours prior to a competition, the use of beta-2-agonists must be declared on the AFC Doping Control Form 0-1 and on the AFC Doping Control Form 0-2 including medications used seven (7) days prior to a testing, which is to be completed by the team doctor at the time of testing (*cf.* Article 7).

4. The TUE application for the use of the substances listed above needs to clearly establish whether the diagnosis is:
 - 4.1. exercise-induced asthma (**EIA**); (some patients require only pre-exercise treatment);
 - 4.2. mild or more severe chronic, persistent asthma with an exercise-induced component (daily anti-inflammatory therapy plus pre-exercise treatment required);
 - 4.3. bronchial hyper-reactivity during exercise following an upper respiratory tract infection (therapy of shorter duration up to three (3) months).
5. If applicable, players must declare (through their doctor) the concomitant use of inhaled glucocorticosteroids on the TUE application form (see **Annexe 3 of this Policy**) 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 AFC 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 or 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:
 - 6.1. a complete medical history: recurrent symptoms of bronchial obstruction such as chest tightness, wheezing and cough provoked by hyperventilation, exercise or other stimuli, are a diagnostic prerequisite for asthma or EIA in athletes;
 - 6.2. 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;
 - 6.3. a spirometry report containing the reading of the forced expiratory volume in one second (FEV1) at rest (peak expiratory flow measurements are not accepted) to demonstrate airway obstruction (reduced FEFV1 / FVC ratio);
 - 6.4. 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);
 - 6.5. 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 FEV1 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;
- 6.6. 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 (4) years at the time of application;
 - 6.7. exact name, specialty, address (including telephone, e-mail, fax details) of the examining doctor.
7. TUEs for asthma shall be granted for four (4) 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 AFC TUE Advisory Group.