

THERAPEUTIC USE EXEMPTIONS IN FOOTBALL

The TUEs have been back to the front pages of media after the decision of UEFA to sanction the Player Samir Nasri with 6 months of suspension for UEFA rejected his retroactive application for a Therapeutic Use Exemption. The purpose of this article is the review of this kind of authorizations to use prohibited substances or methods to help comprehending the case, their regulations, their use, request process, recent decisions and their application within the football world.



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I. Introduction

After the scandal occurred in 1998 (Case FESTINA) the sports world initiated (impulsed by the IOC) the creation of a common protection policy, as a result, in the World Conference on Doping held in Lausanne in February 1999, it was produced the Lausanne Declaration on Doping in Sport.





Nine months after, in November 1999, the World Anti-Doping Agency (WADA) was created to promote and coordinate the fight against doping in sport at an international level. This way the sports world tried to put an end to this dangerous, unfair and unhealthy practice.

WADA is an independent organization whose field of action is distributed in seven areas:

- 1. The Code
- 2. Anti-doping education
- 3. Coordination
- 4. Out-of-competition testing,
- 5. Science and Medicine
- 6. Anti-Doping Development
- 7. Athletes Education

WADA controls and develops the World Anti-Doping Program that consists of 3 elements, the Code, International Standards and Models of Best Practices.

The Code, which must be incorporated by all International and National Federations, in 3 steps, Acceptance, Implementation and Compliance, its origin is the **Copenhagen Declaration against Doping in Sport** held in 2003 and signed originally by 51 countries, now are 186.

The purpose of this article is the review of Therapeutic Use Exemptions regulations in sports and particularly within football, which is included in the World Anti-Doping Program as a Level 2 mandatory International Standard that establishes a global common process for granting TUE's across sports and countries.

II. What is a Therapeutic Use Exemption

Defined as WADA itself, a TUE is:

Athletes, like all people, may have illnesses or conditions that require them to take particular medications or undergo procedures. If the medication or method an athlete requires to treat an illness or condition happens to fall under the Prohibited List, a Therapeutic Use Exemption (TUE) may give that athlete the authorization to take the needed medicine or method. TUEs are granted according the International Standard for TUEs (ISTUE), a document outlining the conditions, the stakeholder responsibilities and the TUE process.¹

¹ https://www.wada-ama.org/en/questions-answers/therapeutic-use-exemption-tue



The scope of TUEs is to grant the opportunity to compete to athletes that have a health problem that would prevent them to participate in sports ensuring that they do not obtain an unfair advantage over the rest of competitors.

The Organization that will decided on the TUEs application will depend on the level of the athlete's play, whether he/she is considered a national or international athlete and the rules of the Federation.

a. Regulatory Framework

TUEs were regulated firstly by WADA, in 2004 through the International Standards for TUEs (2015 version is currently in force), and then every Federation, national or International, in accordance with them has the competence to regulate their own process. The International Standards were adopted in order to establish²:

- a. The conditions that must be satisfied in order for a Therapeutic Use Exemption (or TUE) to be granted
- b. the responsibilities imposed on Anti-Doping Organizations in making and communicating TUE decisions
- c. the process to apply
- d. the process for an Athlete to get a TUE granted by one Anti-Doping Organization recognized by another Anti-Doping Organization;
- e. the process for WADA to review TUE decisions; and
- f. the strict confidentiality provisions that apply to the TUE process

The TUE is regulated in Article 4.4 of the WADA Code, which establishes that International-Level Athletes should apply to his or her International Federation, and those that are not at that level, should apply to his or her National Anti-Doping Organization. As an additional possibility, it also provides that Major Sporting Events Organizations (i.e. the IOC establishes its own regulations for every Olympic Games) may require Athletes to apply for a TUE if an athlete wants to participate, irrespective if they have already one.

² Scope of the International Standards for TUEs, Part One, article 1.





b. Requisites for its request

ISTUE establish that in order to have a TUE Granted, the athlete will have to show that each of the following conditions is met:

- a. The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.
- b. The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition.
- c. There is no reasonable Therapeutic alternative to the Use of the Prohibited Substance or Prohibited Method.
- d. The necessity for the Use of the Prohibited Substance or Prohibited Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method which was prohibited at the time of such Use.³

The TUE application process is established in article 6 and provides that in case of substances prohibited In-Competition only, the request shall be filed at least 30 days before the next competition unless it is an emergency or exceptional situation. Any other shall be lodged before the corresponding competent bodies as soon as possible always using the *TUE application form* provided by them.

The athlete shall attach to the form all relevant information attesting to the need for the Athlete to Use the Prohibited Substance or Method, accompanied by the statement of a qualified physician. The application's content shall be completely confidential.

The Competent body will establish the corresponding *Therapeutic Use Exemption Committee* (*TUEC*) that will decide on any applications for TUEs.

If a TUE is granted by International Federation of National Anti-Doping Organization, this must be reported promptly to WADA through ADAMS.

WADA can then, on its own accord, review the IF's decision to grant or deny the TUE.

³ Obtaining a TUE, the International Standards for TUEs, Part two, article 4.0





c. Retroactive request

WADA also decided to establish the possibility to grant a TUE retroactively when the circumstances prevent the request to be filed before the use of the Prohibited Substance or Method. The process is identical to a regular TUE application but there are some requisites that have to be met in accordance with the ISTUE:

- a. Emergency treatment or treatment of an acute medical condition was necessary; or
- b. Due to other exceptional circumstances, there was insufficient time or opportunity for the athlete to submit, or the TUEC to consider, an application for the TUE prior to Sample collection; or
- c. The applicable rules required the athlete or permitted the athlete to apply for a retroactive TUE.
- d. It is agreed, by WADA and by the ADO to whom the application for a retroactive TUE is or would be made, that fairness requires the grant of a retroactive TUE.

The existence of a medical emergency or acute medical situation will be considered by the TUEC when deciding the Retroactive TUE Request. But generally speaking it exists when the athlete's medical condition justifies immediate Administration of a Prohibited Substance or Method and failure to treat immediately could significantly put the athlete's health at risk.⁴

III. FIFA and UEFA TUE Regulations

a. FIFA

The FIFA Medical Committee is the TUEC appointed by FIFA for approving applications for TUEs. 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 Players treatments.

In compliance with art. 4.4.3 of the WADC, the FIFA TUE Advisory Group recognizes 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

⁴ https://www.wada-ama.org/en/questions-answers/therapeutic-use-exemption-tue FAQ 9





• Players designated by FIFA or a Confederation as being within FIFA or the Confederation's registered testing pool.

Taking into account the level of play, the application will have to be sent (always by the Player) to a different body, as follows:

Level of play	TUE application to be sent to	Application to be submitted by
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
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
Players in FIFA international registered testing pool	FIFA TUEs granted by confederations are automatically recognised	Player

Table 1: Granting bodies for TUEs in football

As it can be noticed⁵, the confederations (UEFA, AFC, CONMEBOL, CONCACAF, CAF, OFC), have their own responsibility in granting the TUEs.

FIFA criteria are established in Annexe B of the FIFA ADR and are in absolute compliance with the WADC. The process

⁵ Table 1 FIFA TUE Policy.





a. UEFA

UEFA's TUE Committee is the relevant TUEC created by UEFA to decide on TUE applications. And it is the competent body to grant a TUE to all the players playing in a UEFA competition, or senior-level international friendly matches. Players playing Youth friendly matches that want to request a TUE shall apply to their NADO and if they are subsequently called up to play in an official UEFA youth competition, they must send the NADO TUE to UEFA for recognition before the start of the competition.

FIFA TUEs are on the contrary already valid for UEFA competitions not being necessary to recognize them.

UEFA TUE is valid for all UEFA competitions, all FIFA competitions, and also at national level.

UEFA ADR establishes the procedure to request TUE in its article 5, being also in compliance with the WADC, only having the particularity of the

IV. Jurisprudence

As in the case of Samir Nasri, the existence of a medical emergency or acute medical situation is usually the dispute when the retroactive TUE requests cases arrive to the CAS. There are not many cases that have to decide on this issue but we can establish that there are some that are worth to explain.

One of the most famous cases, and the first cases deciding on the existence of a medical emergency or acute medical situation was case 2005/A/990⁶; an ice hockey player had to receive emergency medical assistance after suffering an incident during a game. When he was brought to hospital he was suffering an acute heart incident diagnosed as "Postcardio cardiosclerosis". In order to recover him the doctor gave him intravenous and intramuscular injections, including Nandrolone, a steroid that was and still is nowadays a prohibited substance included in the WADA list.

Some days later, after a doping control, he was found in breach of the ADR as norandrosterone was found in his sample. IIHF imposed a two-year suspension on the Player.

⁶ P. v. IIHF, award of 24 August 2006





The Player appealed to the CAS and argued that not being conscious it was impossible for him to control or prevent any action the Doctor took to save his life. The IIHF contested his arguments by applying the WADA code, which establishes the responsibility of the athletes of every substance that enter into his body and that he should have had to request the doctors to disclose any medicine they used on him before participating in the next match.

The Panel found that the circumstances present when the player entered into contact with the substance where unique and he was absolutely unable to bear any responsibility on the treatment he received, the decision upheld the Appeal and removed the sanction imposed on the Player.

As a second example is one of the few cases in football were this issue has been considered⁷. A Football Player suffering from sore throat, diarrhea and feeling sluggish⁸ decided to call the team's doctor, who prescribed a common cold medication generally prescribed in Japan, for two days. The Player continued suffering the same symptoms few days after and the Doctor diagnosed him with "General fatigue", "Appetite Loss", "Diarrhoea", "Nausea", "Oral intake: difficult", and "Body temperature 38.5 degrees C" and suggested an intravenous infusion of normal saline and vitamin B1.

Following the Doctor's Team the Player received an intravenous infusion of two packs of 100ml of saline and 100mg of vitamin B1, without having requested priory a TUE. The Doctor justified the use of that prohibited method by saying:

On 23 April, symptoms (fever, pharyngeal pain, general fatigue, abdominal pain, loss of appetite) due to the above mentioned disease were found. As it was difficult for the patient to take in liquid and food orally, normal saline 200ml and vitamin B1 100mg were administered as an intravenous infusion.

The Japanese league Doping Control Committee considered that the infusion infringed the J. League Anti-Doping Regulations and the Player was suspended for 6 official games.

In his analysis the Panel considered that the Player had no capacity to evaluate the professional judgment of the treating medical practitioner, but also that at the time the J League had not adopted those provisions of the WADA Code which related to sanctions⁹.

The Appeal was upheld and the sanction imposed on the Player was cancelled.

⁹ CAS 2008/A/1452 Award page 18 paragraph 18





⁷ CAS 2008/A/1452 Kazuki Ganaha v/ Japan Professional Football League, award of 26 May 2008

⁸ CAS 2008/A/1452 Award page 2 paragraph 6

CAS case 2015/A/4355 J. & Anti-Doping Denmark (ADD) v. International Paralympic Committee (IPC), award of 26 May 2016 (operative part of 18 March 2016) dealt with a TUE Request for a beta blocker, Carvedilol, without which the Athlete's life would be at risk due to an Cardiomyopathy, which results in the progressive deterioration of the heart and can lead to heart failure and associated complications. The Athlete suffered from dilated cardiomyopathy with ejection fraction reduced to 25 percent.

Carvedilol is a third generation vasodilating non-cardioselective beta-adrenoceptor antagonist, which lacks intrinsic sympathomimetic activity ("ISA") and inverse agonism. ISA is characteristic of pindolol while inverse agonism is characteristic for the classical betaadrenoceptor antagonist, propranolol, and the cardioselective drug, metoprolol. That Carvedilol lacks ISA and inverse agonism explains why it has less effect on heart rate at rest compared to pindolol, which increases heart rate, and propranolol, which reduces heart rate.

Having received a TUE from the ADD, the IPC refused to recognize it. WADA granted a 2y TUE to the athlete allowing the athlete to represent Denmark in London 2012 Summer Paralympics. In 2014 the Athlete was granted a new TUE by the ADD and the IPC refused again to recognize it, but WADA upheld the IPC's decision because even recognizing that without that medicine athlete's life would be at danger and that the treatment is the most accurate for his health conditions, it was

"...not possible to categorically exclude a potential beneficial effect of carvedilol on the shooting performance of this Athlete ... and that the condition set forth in Art. 4.1 b) 11 ISTUE is therefore not met" 12

The Panel concluded that the relevant "state of health", in Paralympic sports in particular, is not one without any limitation and without any handicap, what is relevant is the difference of the state of health of a Paralympic athlete with or without the use of a medication needed for his or her particular, additional sickness. What has to be proven is if it is highly unlikely that the use of a substance will produce any additional enhancement of performance by this Athlete who would compete against other athletes of his class. The decision upheld the appeal filed by the Athlete and a 4years TUE was granted.

¹² CAS 2015/A/4355 Award, paragraph 2.18





¹⁰ CAS 2015/A/4355 Award, paragraph 2.5

¹¹ The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition

More recently, there have been other cases related to TUEs' requests, for example CAS 2016/A/4512 World Anti-Doping Agency (WADA) v. Turkish Football Federation (TFF) & Ahmet Kuru, award of 21 November 2016, were a Football Player requested a TUE for clomiphene, a substance present in some medicaments to treat infertility, to the TFF, the request was rejected and the Player was warned:

"We remind that substance may be found in the sample taken and that this will result in commencement of disciplinary process in the event that you keep going using such medication and that you undergo a doping control" 13

The Player underwent an in-competition doping control after a match; the resulting analysis revealed the presence of the substance for which he requested had the TUE. The TFF imposed a sanction of 6 months and WADA appealed it on the basis that the reduction applied by the Federation had no grounds and requested a 4 years period of ineligibility.

The Sole Arbitrator considered that the approach of the TFF Disciplinary bodies to consider the absence of intention to cheat, as the main ground to reduce the sanction were not sufficient and upheld the appeal and increased the sanction to a 4 years period of ineligibility.

V. Controversy

The use and abuse of TUE applications has appeared in the media every time a new doping scandal pops up, reason why this article may be useful to explain how they work and shall be requested.

A recent report published by UK's Digital, Culture, Media and Sport Committee ('DCMS Committee') on 'Combatting doping in sport'¹⁴, found that the TUE system is open to abuse and raises a question "if an athlete is so ill that they can only compete using a drug that is otherwise banned during competition, then why are they competing at all? From the expert evidence received by the Committee, a case can be made that better management of an athlete's long term health conditions, and particularly asthma, should remove the need to apply for a TUE. ¹⁵

https://publications.parliament.uk/pa/cm201719/cmselect/cmcumeds/366/36602.htm

¹⁵ DSMS Committee report Combating Doping in Sport paragraph 106





¹³ CAS 2016/A/4512 Award, paragraph 6

¹⁴ Combating Doping in Sport

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On the other side recent studies have determined that for some reason elite athletes are more likely to suffer from asthma. If the percentage of population that suffers it is around the 7%, in elite athletes this percentage reaches the 10%, and in some endurance sports, it reaches the 20%.

According to the Spanish Society of Pneumology and Thoracic Surgery (SEPAR), it is a specific kind of asthma, called exercise-induced asthma, manifested by exercise-induced bronchospasm (obstruction of the respiratory tract in the following minutes to sports practice). The experts of this organization consider that the causes of this high prevalence should be looked for in the training characteristics of the elite athletes that may imply an overexposure to irritating substances or with the capacity to induce asthma¹⁶.

It seems crystal clear that TUEs are useful in order to not put hurdles to athletes with health problems that shall be treated appropriately, but also that some of those treatments may grant them an unfair advantage, therefore as the DCMS report establishes, the system is open to abuse and considering the competitiveness in modern sports the temptation is there, but from the SEPAR report it also seems that the same competitiveness is forcing athletes beyond their limits causing specific diseases that need to be treated.

¹⁶ Asthma induced by effort and sport. A practical update https://separcontenidos.es/revista3/index.php/revista/article/view/90/88



