

# **The International Standard for Therapeutic Use Exemptions (ISTUE) and its application in New Zealand**

## **- Some common Questions & Answers**

**(Note that new information re “FEV” and “declarations” has been added on March 5 2009.)**

### **What is a Therapeutic Use Exemption (TUE)?**

A Therapeutic Use Exemption (TUE) is a special application to use a prohibited substance for the treatment of any illness. Strict criteria must be met and in most cases it is necessary to provide a supportive letter from two doctors one of whom must be a specialist in the relevant area. Without a TUE, an athlete returning an adverse finding will have committed an anti-doping rule violation irrespective of the medical circumstances.

### **What has changed to TUE processes in 2009?**

The major changes are:

1. There is no longer a category known as “Abbreviated” TUE’s. However, abbreviated TUE’s issued prior to January 1 2009 remain valid until the expiry date shown, or December 31 2009, whichever comes sooner.
2. International and National Athletes who require asthma medication must follow new requirements which replace the old Abbreviated process. These requirements are explained in a later answer.
3. Drug Free Sport NZ has defined which athletes are required to meet the requirements of the International Standard in full and clarified what other athletes must do in the event that they are tested and produce an adverse finding (this is explained below).

### **What are the criteria for gaining a TUE?**

The main criteria are that:

- The athlete would experience significant health problems without taking the prohibited substance or method,
- The therapeutic use of the substance would not produce significant enhancement of performance, and
- There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance or method.

### **Who must obtain a TUE?**

All sports that recognise the World Anti-Doping Code have incorporated the WADA Prohibited List into their rules. These rules apply to all athletes within the sport. From a practical point of view Drug Free Sport NZ, as a National Anti-doping Organisation, has the right to apply those rules and, in particular, the TUE process to defined groups of athletes. Your specific responsibility to this process will depend on which category of athlete you are in.

### **What are the different categories of athletes and what are their responsibilities?**

There are 3 categories of athletes and their definition and responsibilities are as follows:

#### **International level athletes.**

These are athletes who are a/ in the Registered Testing Pool of their International Federation (IF) or b/ participating in an “International Event” which has been so designated by the IF for these purposes (not all events which include athletes from more than one country are “international events” - refer to the IF web site for a list).

International level athletes must comply with the ISTUE in full and apply directly to their IF for a TUE according to the procedures set down by that IF. In most cases the relevant form and procedure will be available on the IF web site. (In some cases the IF will recognise a TUE previously granted at national level.)

### National level athletes.

These are athletes who are a/ not International level but are in the Drug Free Sport NZ Registered Testing Pool (i.e. provide daily whereabouts information) or b/ in any wider testing pool designated by Drug Free Sport NZ (e.g. as part of a "long list" of potential members of an Olympic or Paralympic Team) - in which case the athlete will be informed or c/ qualify to participate in the designated "national championships" of specified sports (see list at appendix 2).

These athletes must comply with the ISTUE in full and apply directly to Drug Free Sport NZ for a TUE using the form and according to the procedures set out at [www.drugfreesport.org.nz](http://www.drugfreesport.org.nz).

One point of difference for these athletes is that while they must meet all the criteria set out in annex 1 of the ISTUE with respect to the use of beta 2 agonist drugs (e.g. ventolin) they do not need to make an application for a TUE in advance of use. However in the event of an adverse finding they will be required to submit a "medical file" substantiating the use of the prohibited substance as part of a retrospective TUE process.

### Other athletes.

Athletes who are not in one of the above categories are still subject to anti-doping rules and may still be tested. In particular they should not use any prohibited substance unless it is medically necessary to do so and alternatives are not available. They do not, however, need to make application for a TUE except in the event that they are tested and the presence of a prohibited substance is reported. In that case they will be notified and asked to submit a retrospective TUE application which demonstrates that the main TUE criteria have been met. In such cases the Committee will not require an application to have the level of support that would be necessary for national level athletes and, in particular, a lower bar will be set with respect to justification of use of beta 2 agonists and glucocorticosteroids. In both cases documentation confirming the proper diagnosis of the medical condition will be required but specialist support will not be necessary nor will spirometry test results.

This is a provision of the World Anti-doping Code designed to make it clear to athletes, in youth and masters sport for example, that they do not have to submit an advance TUE application unless they qualify as national level athletes.

## **How does a national level athlete apply to Drug Free Sport NZ for a TUE?**

An athlete requiring medication must first determine whether or not it is prohibited. If it is and it is clear that there is no reasonable alternative medication then a TUE is necessary. In most cases this should be applied for and approval received before the medication is administered. If administration is urgent then it should not be delayed but application for a retrospective TUE should be submitted immediately.

A TUE form can be downloaded from [www.drugfreesport.org.nz](http://www.drugfreesport.org.nz) and should be completed by the appropriate doctor and signed by the athlete.

It is essential that all relevant supporting documentation, including specialist support, is provided at the outset. It is not sufficient for the form, containing a few hand written comments, to be submitted on its own.

The TUE application can be sent:

By fax to (09) 5800381, by post to PO Box 17451, Greenlane, Auckland 1546, or e-mail to [sarah@drugfreesport.org.nz](mailto:sarah@drugfreesport.org.nz)

It is unusual for an answer not to be received within a week, frequently it is sooner.

## **What must a national level athlete do to be permitted to use asthma medication?**

Typically asthma is treated with two types of substance; glucocorticosteroids to prevent asthma symptoms and/or beta 2 agonists to relieve symptoms. These are most commonly administered by inhalation or orally. Requirements in each case are as follows:

- Inhaled glucocorticosteroids such as Pulmicort must have their use declared to DFSNZ either in advance of a drug test or at the time of a test. See below. (Note that nasal sprays such as Flixonase require no action.)
- Oral glucocorticosteroids such as prednisone require a TUE in advance unless for emergencies when application must be made immediately following administration.
- Inhaled beta 2 agonists (formoterol, salbutamol, salmeterol and terbutaline only) commonly represented by such medicines as Ventolin and Bricanyl require the preparation of a "medical file" which may be submitted to DFSNZ in advance but otherwise made available in the event of an adverse finding report from the lab. The file must meet the requirements set out in annex 1 of the ISTUE. See appendix 1 to this document.
- Oral beta 2 agonists such as Ventolin syrup require a TUE in advance.

### **What are the rules regarding glucocorticosteroid use?**

There is no change regarding the use of "systemic" glucocorticosteroids (that is intravenous, intra-muscular, oral and rectal administration) and they continue to require a TUE. Glucocorticosteroids used by non systemic routes, namely intraarticular, periarticular, peritendinous, epidural, intradermal injections and inhaled routes must be declared, preferably in advance, but at least at the time of any doping control test. (See appendix 3 for declaration process.)

Topical use of these substances is not restricted and no TUE or declaration is required.

Note that glucocorticosteroids are not prohibited out of competition however if there is any prospect of a trace of systemic use being present during an in competition test then a TUE should be obtained.

### **What happens if I am granted a TUE?**

TUE's are granted for a specific medication with a defined dosage. They are also granted for a specific period of time and do expire. The athlete needs to comply with all the treatment conditions outlined in the TUE Application. Once a TUE has been granted by Drug Free Sport NZ, it will inform WADA, who will then have the opportunity to review this decision. If the decision does not conform to the International Standard, WADA may reverse it and deny the TUE.

### **How can I get more information about TUE requirements?**

The best source of information is the website [www.drugfreesport.org.nz](http://www.drugfreesport.org.nz) where there is a section on TUE's and resources such as the 2009 Athlete Handbook and the International Standard for Therapeutic Use Exemptions can be accessed.

You can call the Drug Free Sport NZ office on (09) 5820524 or 0800 Drugfree (378437) to speak to a staff member during office hours and emergency after hours numbers are provided.

International Athletes may need to consult their International Federation web site or by e-mail to determine their exact requirements.

## Appendix 1

International and National level athletes who may require the use of inhaled beta 2 agonists must meet the requirements specified in Annex 1 of the ISTUE which is as follows:

### **Minimal requirements for the medical file to be used for the TUE process in the case of asthma and its clinical variants.**

The file must reflect current best medical practice to include:

- 1) A complete medical history
- 2) A comprehensive report of the clinical examination with specific focus on the respiratory system
- 3) A report of spirometry with the measure of the Forced Expiratory Volume in 1 second (FEV1)
- 4) If airway obstruction is present, the spirometry will be repeated after inhalation of a short acting Beta-2 Agonist to demonstrate the reversibility of bronchoconstriction\*
- 5) In the absence of reversible airway obstruction, a bronchial provocation test is required to establish the presence of airway hyperresponsiveness
- 6) Exact name, speciality, address (including telephone, e-mail, fax) of the examining physician.

\*Note: WADA Guidelines with respect to spirometry state: "A 12% increase in FEV1 following beta-2 agonist use is considered to be the standard diagnostic test for the reversibility of bronchospasm."

## Appendix 2

Athletes who qualify to compete in the following events are designated "National Level" athletes and must fulfil all requirements of the ISTUE. Athletes participating in championships in other sports do not qualify as "national level" athletes unless they do so by one of the other criteria.

This list of events and categories is current as of January 1 2009. The list may be updated during 2009. Please refer to [www.drugfreesport.org.nz](http://www.drugfreesport.org.nz) for a current list.

<b>SPORT</b>	<b>DESIGNATED NATIONAL CHAMPIONSHIPS</b>
<b>ATHLETICS</b>	National Track and Field Championships
<b>BASKETBALL</b>	National League
<b>BOXING</b>	National Championships
<b>CANOEING</b>	National Championships (Sprint)
<b>CRICKET</b>	State Championship / State Shield / State League (women)
<b>CYCLING</b>	National Track Champs, National Road Champs
<b>FOOTBALL</b>	National League Men and Women
<b>HOCKEY</b>	National League Men and Women
<b>NETBALL</b>	ANZ Championships
<b>ROWING</b>	National Championships
<b>RUGBY UNION</b>	Super 14 and Air NZ Cup (Div 1)
<b>SWIMMING</b>	National Championships (March)
<b>TRIATHLON</b>	Olympic Distance, Ultra Distance (Ironman)
<b>WEIGHTLIFTING</b>	National Championships

### **Appendix 3**

The International Standard for Therapeutic Use Exemptions refers to declarations as follows:

#### *8.0 Declaration of Use Process*

*8.1 It is acknowledged that some substances included on the List of Prohibited Substances are used to treat medical conditions frequently encountered in the athlete population. For monitoring purposes, these substances, for which the route of administration is not prohibited, will require a simple declaration of use. These are strictly limited to: Glucocorticosteroids used by non systemic routes, namely intraarticular, periarticular, peritendinous, epidural, intradermal injections and inhaled route.*

*8.2 For the mentioned substances, the declaration of Use should be done through ADAMS where reasonably feasible and in accordance with the Code by the Athlete at the same time as the Use starts. This declaration should mention the diagnosis, the name of the substance, the dose undertaken, the name and the contact details of the physician.*

*In addition, the Athlete must declare the Use of the substance in question on the Doping Control form.*

In practice most New Zealand athletes do not use "ADAMS" (the WADA international clearing house software.). To provide an alternative DFSNZ has lodged a form on its web site [www.drugfreesport.org.nz](http://www.drugfreesport.org.nz) for this purpose. Alternatively a declaration can be made by e-mail to [sarah@drugfreesport.org.nz](mailto:sarah@drugfreesport.org.nz) or fax to 09 580 0381. DFSNZ will forward the declaration to the relevant International Federation or other party as required.

Declaration at the time of a test needs to be of the "use of the substance" only.