

5. WMA THERAPEUTIC USE EXEMPTIONS

Introduction

5.1

Athletes with a documented medical condition requiring the use of a Prohibited Substance or Prohibited Method must obtain a TUE in accordance with the following provisions.

5.2

An application for a TUE for the use of a Prohibited Substance or a Prohibited Method is required:

- (a) Out-of-Competition -for the use of the substances and methods listed in the Prohibited List as being prohibited at all times (see S1-S5 and M1-M3 of the Prohibited List); and
- (b) In-Competition -for the use of the substances and methods listed in the Prohibited List as being prohibited at all times (see S1-S5 and M1-M3) and for the use of the substances and methods listed as being prohibited In-Competition only (see S6-S9). For the use of glucocorticosteroids (S9), the requirements are more specifically as follows:
 - (i) use by a systemic route -use of a glucocorticosteroid by a systemic route is prohibited and a TUE must be obtained;
 - (ii) use by a non-systemic or inhaled route -use of a glucocorticosteroid by a non-systemic or inhaled route is not prohibited but requires a declaration of use (in accordance with 5.32-5.34 below); (iii) for the use of topical preparations when used for dermatological (including iontophoresis/phonophoresis), auricular, nasal, ophthalmic, buccal, gingival and perianal disorders -such preparations are not prohibited and do not require either a TUE or a declaration of use.

5.3

Applications for a TUE which are made by Masters must be submitted to the WMA in accordance with the procedures set out below (regardless of whether or not the Athlete has previously obtained a TUE for the same substance or method at national level).

5.4

Applications for a TUE in all other cases must be submitted to the appropriate TUE body established within the Athlete's National Federation, or by such other body as may be designated by the Athlete's National Federation to review TUE cases, or which otherwise has competent authority to grant TUE's in the Country or Territory of the National Federation. All such applications should be reviewed in accordance with the principles set out in this Chapter 5 below. An Athlete may not apply for a TUE to more than one body at a time.

The WMA TUE Sub-Committee

5.5

The WMA Council shall appoint a specific body to review TUE applications submitted to the WMA that are referred to it in accordance with WMA Anti-Doping Rules and these Anti-Doping Regulations. This body shall be established as a Sub-Committee of the WMA Anti-doping and Medical Committee (the "WMA TUEC"). The Chairman of the Anti-Doping and Medical Committee shall also be the Chairman of the WMA TUEC.

5.6

The WMA TUEC shall include, in addition to the Chairman, a Secretary, at least five (5) physicians with experience in the care and treatment of Athletes and with a sound knowledge of clinical, sports and exercise medicine. The Chairman of the Anti-Doping and Medical Committee shall have authority at any time to appoint an additional person or persons to the

WMA

TUEC, as may be required, either on a temporary or on a permanent basis. In normal circumstances, a minimum of three members of the WMA TUEC shall review each TUE application.

5.7

In order to ensure a level of independence of decision-making, a majority of the members of the WMA TUEC reviewing a TUE application should not have any official day to day responsibility within the WMA. All members of the WMA TUEC will in any event sign a conflict of interest agreement. No member of the WMA TUEC shall adjudicate on a TUE application submitted by an Athlete from (or representing) his own country.

5.8

The members of the WMA TUEC may exchange views on TUE applications by any appropriate means, including by e-mail, telephone, facsimile or in person.

5.9

The WMA TUEC may, in the course of reviewing a TUE application, seek from external, independent experts (including, where appropriate, from the IAAF or WADA TUE Committee and/or the IOC TUE Committee, any additional medical or scientific advice as it may deem to be necessary.

5.10

The WMA TUEC may, in the course of exercising its function, refer to the Council for its opinion or guidance, either in relation to a particular case or on any matter of general policy that may arise.

Confidentiality of Information

5.11

The members of the WMA TUEC and all WMA members involved in the administration of TUE applications under these Anti-Doping Regulations shall conduct their activities in strict confidence. All members of the WMA TUEC and all WMA Members involved will sign confidentiality agreements. In particular, the following information shall be kept confidential:

- (a) all medical information and data provided by the Athlete and physician(s) involved in the Athlete's care;
- (b) all details of the application including the name of the physician(s) involved in the process.

5.12

Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the Athlete involved.

5.13

Should the Athlete wish to revoke the right of the WMA TUEC or IAAF TUEC to obtain any health information on his behalf, the Athlete must notify his medical practitioner in writing of the fact. As a consequence of such a decision, the Athlete will not receive approval for a TUE or renewal of an existing TUE.

TUE Application Process

5.14

For Masters Athletes requiring the use of a Prohibited Substance or Prohibited Method in accordance with 5.2 above, a TUE application process is to be used as set out below.

5.15

A TUE application to the WMA TUE Secretary must be submitted on the relevant WMA/IAAF

TUE Application form.

5.16

A TUE application for the use of a Prohibited Substance or a Prohibited Method In-Competition must be submitted to the WMA Secretary no less than 30 days before the Athlete participates in the Competition in question.

5.17

A TUE application by a Master Athlete will not be considered for retroactive approval except in cases where:

- (a) emergency treatment or treatment of an acute medical condition was necessary, or
- (b) due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit an application, or for an application to be reviewed, prior to the Athlete submitting to Doping Control.

5.18

The TUE application must be legible and complete. It will only be considered to be complete if all boxes on the TUE Application Form have been properly filled in and if it is accompanied by all supporting medical documents as follows:

- (a) a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application;
- (b) a statement by an appropriately qualified physician at Testing to the necessity of the otherwise Prohibited Substance or Prohibited Method in the treatment of the athlete and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of such condition;
- (c) the dose, frequency, route and duration of administration of the otherwise Prohibited Substance or Prohibited Method in question must be specified in the application and, in case of change, a new application must be submitted; and
- (d) in the case of TUE applications for the use of Beta-2 Agonists all supporting medical documents required by the WMA Beta-2 Agonists Protocol. Full details of the documentation required for such applications are set out in the IAAF Beta-2 Agonists Protocol on the IAAF and WMA website.
- (e) with reference to (d) above - there are some exceptions for the use of inhalers. The following three inhalers do NOT need a TUE but must be declared if an athlete is called for testing and the athlete must then retrospectively produce medical evidence, as in the case of all other inhalers. Failure to produce satisfactory medical evidence will result in a review for a sanction.

- ***Inhaled salbutamol: maximum 1600 micrograms over 24 hours in divided doses not to exceed 800 micrograms over 12 hours starting from any dose;***
- ***Inhaled formoterol: maximum delivered dose of 54 micrograms over 24 hours;***
- ***Inhaled salmeterol: maximum 200 micrograms over 24 hours.***

The presence in urine of salbutamol in excess of 1000 ng/mL or formoterol in excess of 40 ng/mL is not consistent with therapeutic use of the substance and will be considered as an Adverse Analytical Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of a therapeutic dose (by inhalation) up to the maximum dose indicated above.

5.19

The TUE application must list any previous and/or current requests for permission to use an otherwise Prohibited Substance or Prohibited Method, the body to whom that request was made, and the decision of that body.

5.20

Any additional relevant investigations, examinations or imaging studies that may be requested will be undertaken at the expense of the applicant or his National Federation.

5.21

The applicant for a TUE must provide written consent in his application for the transmission of all information concerning the application to members of the WMA TUEC and, as required, other independent medical or scientific experts, and to all necessary staff involved in the management, review or appeal of TUE's.

5.22

The applicant must also provide written consent for the decision of the WMA TUEC as regards his TUE application to be notified to other relevant organisations pursuant to IAAF Rule 34.9.

5.23

An Athlete shall not be permitted to use the Prohibited Substance or Prohibited Method for which the TUE application has been submitted until such time as a TUE has been granted in accordance with these Anti-Doping Regulations.

Adjudication of TUE's by the WMA TUEC

5.24

Only TUE applications that are legible and complete in accordance with 5.18 above shall be adjudicated by the WMA TUEC. If a TUE application is not legible and complete, it shall be returned to the applicant. If the Athlete still wishes to use the Prohibited Substance, he shall be required to re-submit his TUE application to the WMA in legible and complete form together with any missing information/documents.

5.25

TUE applications will be granted by the WMA TUEC only in cases of clear and compelling need in strict accordance with the following criteria:

- (a) that the Athlete would experience a significant impairment to his health if the Prohibited Substance or Prohibited Method was to be withheld in the course of treating an acute or chronic medical condition.
- (b) that the therapeutic use of the Prohibited Substance or Prohibited Method would produce no additional enhancement of performance other than that which might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition. The use of any Prohibited Substance or Prohibited Method to increase "low-normal" levels of any endogenous hormone or physiological blood parameter though not considered an acceptable therapeutic intervention will be considered for Masters Athletes.
- (c) that it is possible without undue difficulty to monitor or control the dose, frequency, method of administration or other aspect of the use of a Prohibited Substance or Prohibited Method that may otherwise permit an enhancement of performance other than a return to a state of normal health;
- (d) that there is no reasonable therapeutic alternative to the use of the otherwise Prohibited Substance or Prohibited Method.
- (e) that the necessity for the use of the otherwise Prohibited Substance or Prohibited Method is not a consequence, either wholly or in part, of a prior non-therapeutic use of any Prohibited Substance on the Prohibited List.

- (f) in no circumstances, shall a TUE be granted to an Athlete if the WMA considers that he would thereby gain a competitive advantage over another Athlete.
- (g) In reaching its decision the WMA TUEC shall take into consideration the age of the competing athletes and all the medical information supplied, all relevant information shall be agreed by at least 3 medical doctors as per 5.6, before granting or denying any TUE

Decision of the WMA TUEC in TUE applications

5.26

In normal circumstances, a decision of the WMA TUEC should be completed within thirty (30) days of receipt of all relevant documentation. In case of a TUE application made in a reasonable time limit prior to a Competition, the WMA TUEC will use its best endeavours to complete the process before the start of the Competition. The decision of the WMA TUEC in respect of a TUE application will be conveyed to the Athlete in writing, with a copy sent to his National Federation, the relevant National Anti-Doping Organisation (if appropriate) and IAAF. Where a TUE has been granted, the Athlete and his National Federation will be provided promptly with a certificate of approval confirming the duration of the TUE and specifying any requirements or conditions that may have been attached to the granting of the TUE by the WMA TUEC.

5.27

Upon receiving a request by an Athlete for review, the IAAF TUE Commission ("IAAF TUESC") may reverse the decision of the WMA TUEC to deny a TUE. The Athlete shall provide to the IAAF TUESC all the information for a TUE as submitted initially to the WMA TUEC accompanied by an application fee as specified by WADA. Until the review process has been completed by the IAAF TUESC, the WMA TUEC decision will remain in effect. The review by the IAAF TUESC should be completed within thirty (30) days following the receipt of all information by IAAF. The decision of the IAAF TUESC shall be notified to the Athlete with a copy to the WMA.

5.28

IAAF-WADA can, on its own initiative, undertake a review of the decision of the WMA TUEC at any time. Where, following a review by the IAAF-WADA TUESC (including a review conducted upon the Athlete's request in accordance with paragraph 5.27 above), the IAAF-WADA TUESC's decision is to reverse the decision of the WMA TUEC, it shall provide its reasons for doing so in writing. If the decision regarding the granting of a TUE is reversed by IAAF-WADA upon review, the reversal shall not apply retroactively and shall not disqualify the Athlete's results during the period that the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the athlete.

5.29

A decision by IAAF-WADA reversing the grant or denial of a TUE by the WMA TUEC may be appealed exclusively to CAS either by the Athlete or the WMA in accordance with IAAF Rule 60.9

5.30

A decision of the WMA TUEC to deny a TUE, which is not reviewed by IAAF-WADA, may be appealed in accordance with IAAF Rule 60.9

Cancellation/Expiry of TUE's

5.31

A TUE will be cancelled if:

- (a) the Athlete does not comply with any requirements or conditions imposed on the granting

of the TUE by the WMA TUEC.

- (b) the term for which the TUE was granted by the WMA TUEC has expired.
- (c) the Athlete is advised that the granting of the TUE by the WMA TUEC has been withdrawn.

Declaration of Use Process

5.32

It is acknowledged that some substances included on the Prohibited List 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. The declaration of use process shall be strictly limited to the following: Glucocorticosteroids used by non-systemic or inhaled routes, including, but not limited to, intrarticular, intra-bursal, periarticular, peritendinous, intra-cystic, pulmonary, iontophoresis, anal, epidural, intrathecal and intradermal.

5.33

A declaration of use of the above substances should be made to WMA TUEC where reasonably feasible and at the same time as the use of the substance starts. The declaration of use should mention the diagnosis, the name of the substance, the dose undertaken and the name and contact details of the Athlete's physician.

5.34

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

5.35

Topical preparations when used for auricular, buccal, dermatological (including iontophoresis/phonophoresis), gingival, nasal, ophthalmic and perianal disorders are not prohibited and do not require either a TUE or a declaration of use.

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