

FÉDÉRATION INTERNATIONALE DE MOTOCYCLISME



December 2012

2013 Anti-doping information

Therapeutic Use Exemption (TUE)

Dear Sir or Madam,

The FIM Anti-Doping Code (CAD) which will come into force on 1st January 2013, has been revised in accordance with the 2013 WADA World Anti-Doping Code and the new International Standard for Therapeutic Use Exemptions (ISTUE). The most significant changes to the "List of prohibited substances & methods" for 2013 are the following:

You still need a "<u>TUE"</u> (Therapeutic Use Exemption) for:

ALL treatments involving the use of a prohibited substance or method detailed as such in the "List of prohibited substances & methods". (Please refer to the FIM Anti-Doping Code, available on http://www.fim-live.com/en/fim/fim-organisation/medical/ride-clean-corner/

including:

• Terbutaline (Beta-2 agonists for use in Asthma)

• Glucocorticosteroids (GCS) (prohibited in-competition) when administered by oral, intravenous, intramuscular or rectal routes

However you <u>NO LONGER</u> need a "TUE" for the following specific substance that is <u>no longer prohibited</u>:

• Formoterol by inhalation up to a maximum daily therapeutic dose of 54 micrograms over 24 hours (if more than 40ng/ml Formoterol is detected in urine, this will be considered a Adverse Analytical Finding (positive case), unless the rider proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of the stated therapeutic inhaled dose.

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NO TUE is required for:

- <u>Salbutamol by inhalation (max. 1600mcg over 24 hours) & Salmeterol by</u> <u>inhalation (inhaled Beta-2 agonists for use in Asthma)</u>
- <u>Glucocorticosteroids (GCS)</u> administered by intraarticular (in the joint), periarticular (around the joint), peritendinous (around the tendon), epidural (in the spine), intradermal (in the skin) and by inhalation routes

Salbutamol exceeding 1000 nanograms per millitre in the urine will still be prohibited. In such cases, there will be a presumption that the substance was not taken by inhalation and the rider will have the responsibility to demonstrate through a controlled pharmacokinetic study that the level found in his urine was the result of therapeutic inhaled use (maximum 1600 micrograms over 24 hours).

• Topical use of Glucocorticosteroids (GCS) (=not prohibited) Topical GCS preparations when used topically (auricular, buccal, dermatological, gingival, nasal, ophthalmic and perianal disorders) are not prohibited and do not require a TUE.

• <u>Pseudoephedrine</u>: is prohibited above 150 microgramms per millilitre. We would strongly advise you to check for and avoid this substance as it is a common ingredient of freely available and frequently used preparations for the treatment of colds and flu.

Intravenous infusions

Intravenous infusions and/or injections greater than 50ml per 6 hour period are prohibited except for those legitimately received in the course of hospital admissions or clinical investigations.

A <u>Stimulants</u>

As a reminder, some stimulants may be available under several other names, for example "methylhexaneamine", sometimes presented as dimethylamylamine, pentylamine, geranamine, Forthane, 2- amino-4-methylhexane, geranium root extract or geranium oil





REMINDER:

1) What is a Therapeutic Use Exemption (TUE)?

Riders, like anyone else, may have illnesses or conditions that require them to take particular medications. If the substance(s) a rider is required to take to treat an illness or condition is contained in the List of prohibited substances, then a TUE is required and after examination and approval by the FIM TUE Board a TUE certificate is issued which authorises the rider to take the required medicine.

Riders have the possibility to apply for, in association with their physician, a **Therapeutic Use Exemption "TUE**", i.e. permission to use, for therapeutic purposes only, substances or methods contained in the list of prohibited substances or methods whose use is otherwise forbidden.

2) What are the criteria for granting a TUE?

The criteria are:

- ➤ a) The rider would experience a significant impairment to health if the prohibited substance or prohibited method were to be withheld in the course of treating an acute or chronic medical condition.
- b) 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 is not considered an acceptable therapeutic intervention.
- c) There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance or method.
- d) The necessity for the use of the otherwise prohibited substance or method cannot be 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 use.

3) Riders competing in FIM World Championships or Prize events

According to article 4.4.2 of the FIM Anti-Doping Code, riders competing in FIM World Championship or Prize events shall submit to the FIM Executive Secretariat a **TUE** application using the appropriate FIM TUE application form.

The application form must be LEGIBLE, in either <u>English or French and submitted</u> no later than **30 days** before their participation at the event. A <u>TUE application form</u> can be downloaded from the FIM website: <u>http://www.fim-live.com/en/fim/fim-organisation/medical/ride-clean-corner/</u>.

The TUE application shall include a complete medical file including the results of all examinations, laboratory investigations and imaging studies relevant to the application with a clear explanation of why an alternate non-prohibited medication is not being prescribed.





4) FIM TUE Board

A board of doctors will promptly evaluate the requests of riders competing in FIM World Championships or Prize events in strict accordance with the "International Standard for Therapeutic Use Exemption "TUE" (available on the WADA site <u>www.wada-ama.org</u>) and, if the exemption is granted, will send to the rider the "<u>Certificate of Approval for Therapeutic Use</u>" which will state an expiry date. In case of refusal the rider will be informed accordingly.

Applications for TUEs 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, or the TUE Board to consider, an application prior to doping control.

5) Riders competing in an International or National event

According to Article 4.4.3 of the FIM Anti-Doping Code, riders who need to use a Prohibited Substance or a Prohibited Method for therapeutic reasons <u>must obtain a</u> <u>TUE from their National Anti-Doping Organisation (NADO)</u> or other body designated by their FMN, as required under the rules of their NADO. The FMN shall promptly report any such TUE to the FIM and to WADA.

We would request that this information relating to the TUE procedures be distributed to all those concerned at the earliest opportunity. Further information can be obtained from the WADA site <u>www.wada-ama.org</u> and FIM web site <u>http://www.fim-live.com/en/fim/fim-organisation/medical/ride-clean-corner/</u>.

Please direct all queries concerning Anti-Doping issues to the FIM Anti-Doping Coordinator by e-mail to: <u>evelyne.magnin@fim.ch</u>.

We thank you for your attention and remain at your disposal for any further assistance.

Yours sincerely,

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Dr David McManus FIM TUE BOARD CHAIRMAN

Evelyne Magnin FIM ANTIDOPING COORDINATOR

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