

FÉDÉRATION INTERNATIONALE DE MOTOCYCLISME



January 2018

2018 Anti-doping information Therapeutic Use Exemption (TUE)

Dear Sir or Madam,

The 2018 FIM Anti-Doping Code (CAD) coming into force on 1st January 2018, has been revised in accordance with the 2018 WADA World Anti-Doping Code and the new International Standard for Therapeutic Use Exemptions (ISTUE). The highlights of the "List of Prohibited Substances & Methods" for 2018 are the following:

You 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 "2018 List of prohibited substances & methods". (Please refer to the FIM Anti-Doping Code, available on http://www.fim-live.com/en/fim/the-commissions/medical/ride-clean/

including:

ALL BETA-2 AGONISTS (S.3):

• Including Terbutaline (Beta-2 agonist for use in Asthma) (TUE required)

Except for: (NO TUE required)

- <u>Inhaled Salbutamol</u> (max. 1600mcg over 24 hours in divided doses, not to exceed 800 micrograms every 12 hours starting from any dose;) &
- <u>Inhaled Salmeterol (max 200 mcg over 24 hours)</u> (inhaled Beta-2 agonists for use in Asthma)
- Inhaled Formoterol maximum delivered dose of 54 micrograms over 24 hours

The presence in urine of salbutamol in excess of 1000ng/mL or formoterol in excess of 40ng/mL is not consistent with therapeutic use of the substance and will be considered as an Adverse Analytical Finding (AAF) unless the rider 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.

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S9.GLUCOCORTICOIDS (GCS)

- **Glucocorticosteroids (GCS)** (prohibited in-competition) when administered by **oral**, **intravenous**, **intramuscular** or **rectal** routes
- <u>Glucocorticoids (GCS)</u> administered by intraarticular (in the joint), periarticular (around the joint), peritendinous (around the tendon), epidural (in the spine), intradermal (in the skin) <u>and by inhalation</u> routes (=NO TUE required)
- Topical use of Glucocorticosteroids (GCS) (NO TUE required) GCS preparations when used topically (auricular, buccal, dermatological, gingival, nasal, ophthalmic and perianal) are not prohibited and do not require a TUE.



All stimulants are prohibited.

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

- **Pseudoephedrine (S.6. Stimulants)**: Prohibited when the concentration in urine is greater than 150 micrograms per millilitre.
- **Ephedrine and methylephedrine:** Prohibited when the concentration of either in urine is greater than 10 micrograms per milliliter.
- **Epinephrine (adrenaline):** <u>not prohibited in local administration, e.g. nasal,</u> <u>ophthalmologic, or co-administration with local anesthetic agents</u>.

We would strongly advise you to check for and avoid these substances as they are a common ingredient of freely available and frequently used preparations for the treatment of colds and flu.

 Intravenous infusions and/or injections greater than a total of 100mL per 12 hour period are prohibited except for those legitimately received in the course of hospital treatments, surgical procedures or clinical diagnostic investigations.

We draw your attention that as from 01.01.2016, the FIM was removed from the list of the sports federations prohibiting alcohol <u>as a doping agent</u>. However, for safety reasons, the consumption/use of alcohol (ethanol) is prohibited in-competition in motorcycle sport <u>in accordance with the FIM Medical Code</u> (threshold violation equivalent to a blood alcohol concentration of 0.10 g/L). New procedure under Appendix V is included in the FIM Medical Code <u>http://www.fim-live.com/en/fim/the-commissions/medical/</u>

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REMINDER:

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

Riders, like all others, may have illnesses or conditions that require them to take particular medications. If the medication a rider is required to take to treat an illness or condition happens to be included in the Prohibited List, a TUE may give that rider the authorisation to take the necessary medicine.

2) What are the criteria for obtaining a TUE?

The criteria are:

- a) The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the Rider 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 Rider'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) Riders competing in FIM World Championships or Prize events (International 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 Administration 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/the-commissions/medical/ride-clean/</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-</u>





<u>ama.org</u>) and, if the exemption is granted, will send to the rider the "<u>Certificate of</u> <u>Approval for Therapeutic Use</u>" which will state an expiry date. In case of refusal the rider will be informed accordingly.

5) Retroactive TUEs

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 other exceptional circumstances, there was insufficient time or opportunity for the rider to submit, or for the TUE Board to consider, an application for the TUE prior to sample collection; or
- c. The application rules required the rider or permitted the riders (see Code Article 4.4.5 of the FIM Anti-Doping Code) to apply for a retroactive TUE; or

Comment: Such riders are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.1 of the Anti-Doping Code, in case an application for a retroactive TUE is necessary following Sample collection.

d. It is agreed, by WADA and by the Anti-Doping Organisation to whom the application for a retroactive TUE is or would be made, that fairness requires the grant of a retroactive TUE.

Comment to 4.3 (d) of the Anti-Doping Code: If WADA and/or the Anti-Doping Organisation do not agree to the application of Article 4.3 (d) of the Anti-Doping Code, that may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.

6) Riders competing in a National event

According to Article 4.4.2 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.

7) What happens if a rider is granted a TUE?

TUEs are granted for a specific medication with a defined dosage. They are also granted for a specific period of time and do expire. The rider needs to comply with all the treatment conditions outlined in the TUE Application.





Once a TUE has been granted by the FIM or National Anti-Doping Organization (NADO), it will inform WADA, who will then have the opportunity to review this decision. If the decision does not conform to the International Standard for TUEs, WADA may reverse it and deny the TUE. WADA's decision is not retroactive.

8) What can a rider do if WADA reverses the original decision granting him/her a TUE?

The rider or his granting authority can appeal to the Court of Arbitration for Sport (CAS) for a final decision, in accordance with Art. 13 (Code).

9) What should a rider do if he/she is notified for doping control while using a prohibited substance under a granted TUE?

When filling out the doping control form, he/she has to make sure that he/she declares the substance or medication being used and that he/she specifies that a TUE has been granted. If he/she has easy access to a copy of the TUE Approval form, it is preferable but not mandatory that he/she shows it to the doping control official.

10) What will happen if the prohibited substance is detected during the analysis?

When the doping control authority receives the report from the laboratory, an initial review will take place to verify that the TUE is still in effect and that the results of the analysis are consistent with the TUE granted (nature of substance, route of administration, dose, time frame of administration, etc.). If the review proves satisfactory, the result of his/her test will be recorded as negative.

11) What can a rider do if his/her TUE is denied by the FIM?

Under Art.4.4 (Code), if his/her TUE is denied by the FIM or his/her National Anti-Doping Organization (NADO), he/she may ask WADA to review the decision, provided he/she is either:

- A rider belonging to the FIM Registered Testing Pool (FIM RTP);
- A rider belonging to a National Registered Testing Pool (NRTP); or
- A rider competing in a FIM World Championship or Prize event for which a TUE is required.

The review process is as follows:

a) The request for review must be sent via registered letter to WADA's Medical Director within 21 days of the decision by the TUE granting authority. We ask him/her to include his/her full contact details, including his/her e-mail address. WADA will inform him/her whether or not his/her case can be reviewed by WADA's Therapeutic Use Exemption Committee (TUEC), as per article 8.0 of the ISTUE;

b) He/she will be asked to pay WADA an administrative fee. If his/her request is accepted by WADA, further information will be provided regarding payment of this fee;





c) WADA's TUEC will review the same documentation as the TUE granting authority. WADA may ask him/her to provide additional information or documents;

d) WADA's TUEC will render its decision of its acceptance to review the case;

e) The original denial of the TUE will remain in effect until WADA's TUEC reaches a decision. He/She is therefore not permitted to use the substance while waiting for the decision from WADA's TUEC. If the TUE is granted by WADA's TUEC, the TUE immediately goes into effect in accordance with the conditions outlined by WADA's TUEC.

f) WADA's TUEC's decision may be appealed to the Court of Arbitration for Sport (CAS.)

12) What can a rider do if WADA upholds the granting authority's decision not to grant the TUE?

For riders applying to the FIM:

He/she can then appeal the FIM decision to CAS for a final decision, in accordance with Art. 13.

For riders applying to a National Anti-Doping Organization:

He/she can then appeal the NADO decision to an independent review body in his/her country. If this body grants him/her the TUE, WADA could appeal this decision to CAS for a final decision.

13) Will the information on the rider's TUE Application remain confidential?

Riders concerned about confidentiality should note that all the information contained in their TUE Application will be kept strictly confidential as medical data.

14) Where can a rider find out more about TUEs?

The procedures for applying for and granting a TUE are outlined in the <u>International Standard for TUEs</u>, published by WADA. He/she may also contact the FIM or NADO for more information.

15) Should riders declare all medications (prescription or otherwise) on the Doping Control Form at the time of doping control?

Yes. Riders are advised to declare all medications and other substances that are being taken or have been taken in the previous seven days.

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 www.wada-ama.org and FIM web site http://www.fim-live.com/en/fim/the-commissions/medical/ride-clean/





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 Ale

Evelyne Magnin FIM ANTI-DOPING COORDINATOR

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