



FIM RIDE CLEAN

January 2019

2019 Anti-doping information Therapeutic Use Exemption (TUE)

Dear Sir or Madam,

The 2019 FIM Anti-Doping Code (CAD) coming into force on 1st January 2019, has been revised in accordance with the 2019 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 2019 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 "2019 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.

11 ROUTE DE SUISSE CH – 1295 MIES

FOUNDED 1904

TEL +41 22 950 95 00 FAX +41 22 950 95 01 Info@fim.ch WWW.FIM-LIVE.COM





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.

For safety reasons, the consumption/use of alcohol (ethanol) is prohibited incompetition 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>





REMINDER:

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

You, like all others, may have illnesses or conditions that require you to take particular medications. If the medication you are required to take to treat an illness or condition happens to be included in the Prohibited List, a TUE may give you 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 you 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 your 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) If you compete in FIM World Championships or Prize events (International events)

According to article 4.4.2 of the FIM Anti-Doping Code, if you compete in FIM World Championship or Prize events, you 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 your 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 your request if you compete 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 you the "<u>Certificate of</u>





<u>Approval for Therapeutic Use</u>" which will state an expiry date. In case of refusal you 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 you to submit, or for the TUE Board to consider, an application for the TUE prior to sample collection; or
- c. The application rules required or permitted you (see Code Article 4.4.5 of the FIM Anti-Doping Code) to apply for a retroactive TUE; or

Comment: You are strongly advised to have a medical file prepared and ready to demonstrate your 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) If you compete in a National event

According to Article 4.4.2 of the FIM Anti-Doping Code, if you need to use a Prohibited Substance or a Prohibited Method for therapeutic reasons, you <u>must</u> <u>obtain a TUE from your National Anti-Doping Organisation (NADO)</u> or other body designated by your FMN, as required under the rules of your NADO. Your FMN shall promptly report any such TUE to the FIM and to WADA.

7) Is my Authorisation for a Therapeutic Use Exemption granted by my National Anti-Doping Organisation recognised for the FIM Word Championships & Prize events?

If you have a TUE granted by your National Anti-Doping Organisation for the substance or method in question, that TUE is not automatically valid for international-level Competition.

However, you may apply to FIM to recognize that TUE, in accordance with Article 7 of the International Standard for Therapeutic Use Exemptions. If that TUE meets the criteria set out in the International Standard for Therapeutic Use Exemptions, then FIM shall recognize it for purposes of international-level competition as well.





If FIM considers that the TUE does not meet those criteria and so refuses to recognize it, FIM shall notify you and your national anti-doping organisation promptly, with reasons.

8) What shall I do if FIM refuses to recognize the TUE granted by my National Anti-Doping Organisation?

You and your national anti-doping organisation shall have **21 days** from such notification to refer the matter to WADA for review in accordance with Article 4.4.6. If the matter is referred to WADA for review, the TUE granted by the National Anti-Doping Organisation remains valid for national-level competition and Out-of-Competition Testing (but is not valid for international- level Competition) pending WADA's decision. If the matter is not referred to WADA for review, the TUE becomes invalid for any purpose when the 21-day review deadline expires.

9) 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).

10) What should I do if I am notified for doping control while using a prohibited substance under a granted TUE?

When filling out the doping control form, you have to make sure that you declare the substance or medication being used and that you specify that a TUE has been granted. If you have easy access to a copy of the TUE Approval form, it is preferable but not mandatory that you show it to the doping control official.

11) 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 your test will be recorded as negative.

12) What can you do if your TUE is denied by the FIM?

Under Art.4.4 (Code), if your TUE is denied by the FIM or your National Anti-Doping Organisation (NADO), you may ask WADA to review the decision, provided you are either:

- belonging to the FIM Registered Testing Pool (FIM RTP);
- belonging to a National Registered Testing Pool (NRTP); or
- 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 you to include your full contact details, including your e-mail address. WADA will inform you whether or not your case can be reviewed by WADA's Therapeutic Use Exemption Committee (TUEC), as per article 8.0 of the ISTUE;

b) You will be asked to pay WADA an administrative fee. If your 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 you 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. You are 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.)

13) What can you do if WADA upholds the granting authority's decision not to grant the TUE?

For riders applying to the FIM:

You 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 Organisation:

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

14) Will the information on my TUE Application remain confidential?

All the information contained in your TUE Application will be kept strictly confidential as medical data.

15) Where can you 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. You may also contact the FIM or NADO for more information.





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

Yes. You 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,

3.13 1

Dr David McManus FIM Medical Director

CMIBur/01/2019

Evelyne Magnin FIM ANTI-DOPING COORDINATOR