

FÉDÉRATION INTERNATIONALE DE MOTOCYCLISME



November 2020

### 2021 Anti-doping information Prohibited Substances & Prohibited Methods Therapeutic Use Exemption (TUE)

Dear Sir or Madam,

The 2021 FIM Anti-Doping Code (CAD) coming into force on 1<sup>st</sup> January 2021, has been revised in accordance with the World Anti-Doping Code and the new International Standard for Therapeutic Use Exemptions (ISTUE). The highlights of the "List of Prohibited Substances & Methods" for 2021 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 "<u>2021 List of prohibited substances & methods</u>". (Please refer to the <u>FIM Anti-Doping Code</u>, available on

including:

S1 - ANABOLIC ANDROGENIC STEROIDS (AAS): PROHIBITED AT ALL TIMES (e.g. testosterone, DHEA, drostanolone, nandrolone, stanozolol, clenbuterol, etc.)

# S2 - PEPTIDE HORMONES, GROWTH FACTORS, RELATED SUBSTANCES, AND MIMETICS: PROHIBITED AT ALL TIMES

1. Erythropoietins (EPO) and agents affecting erythropoiesis

- 2. Pepetide hormones and their releasing factors (e.g. growth hormone, etc.)
- 3. Growth factors and growth factor modulators (ex.: Insulin-like growth factor 1 (IGF-1), etc.

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### S3 BETA-2 AGONISTS: PROHIBITED AT ALL TIMES

[e.g. Terbutaline (TUE required); Salbutamol; Salmeterol; etc.]

Except for: (NO TUE required)

- <u>Inhaled salbutamol</u>: max. 1600mcg over 24 hours in divided doses, not to exceed 800 micrograms over 12 hours starting from any dose;
- Inhaled formoterol: max. delivered dose of 54mcg over 24 hours;
- Inhaled salmeterol: max. 200 mcg over 24 hours;
- Inhaled vilanterol: max. 25mcg over 24 hour.

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.

# S4 - HORMONES AND METABOLIC MODULATORS: PROHIBITED AT ALL TIMES

- 1. Aromatase inhibitors (e.g. androstenol, anastrozole, formestane, etc.)
- 2. Anti-estrogenic Substances [anti-estrogens and selective estrogen receptor modulators (SERMS)], (e.g. clomifene, fulvestrant, tamoxifen, etc.)
- 3. Agents preventing activin receptor IIB activation, (e.g. myosatin inhibitors, etc.)
- 4. Metabolic modulators: (e.g. insulins, meldonium, etc.)





# **S5** - DIURETICS AND MASKING AGENTS: PROHIBITED AT ALL TIMES (ex.: Desmopressin, probenecid, furosemide, etc.)

#### Except for:

- Drospirenone; pamabrom; and topical ophthalmic administration of carbonic anhydrase inhibitors (e.g. dorzolamide, brinzolamide);
- Local administration of felypressin in dental anaesthesia.

The detection in a *Rider's* Sample at all times or *In-Competition*, as applicable, of any quantity of the following substances subject to threshold limits: formoterol, salbutamol, cathine, ephedrine, methylephedrine and pseudoephedrine, in conjunction with a diuretic or masking agent, will be considered as an *Adverse Analytical Finding (AAF)* unless the *Rider* has an approved *Therapeutic Use Exemption (TUE)* for that substance in addition to the one granted for the diuretic or masking agent.

### **S6 - STIMULANTS: PROHIBITED IN-COMPETITION**

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-4methylhexane, geranium root extract or geranium oil

- Substances of Abuse in this section: cocaine, MDMA/"ecstasy"
- **Cathine:** Prohibited when its concentration in urine is greater than 5 micrograms per millilitre
- **Ephedrine and methylephedrine:** Prohibited when the concentration of either in urine is greater than 10 micrograms per millilitre.
- **Pseudoephedrine:** Prohibited when the concentration in urine is greater than 150 micrograms per millilitre.

Except for:

- Bupropion, caffeine, nicotine, phenylephrine, phenylpropanolamine, pipradrol, and synephrine: These substances are included in the 2021 Monitoring Program and are not considered Prohibited Substances.
- Clonidine
- **Epinephrine (adrenaline):** not prohibited in local administration, e.g. nasal, ophthalmologic, or co-administration with local anaesthetic agents.
- Imidazole derivatives for topical use are added to the exceptions: brimonidine, clonazoline, fenoxazoline, indanazoline, naphazoline, oxymetazoline and xylometazoline.





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.

### **S7 - NARCOTICS: PROHIBITED IN-COMPETITION**

[e.g. Fentanyl, Methadone, Morphine, Oxycodone, etc.) & Substance of abuse in this section: Diarmophine (Heroin).

#### **S8 - CANNABINOIDS: PROHIBITED IN-COMPETITION**

All natural and synthetic cannabinoids, e.g.

- In cannabis (hashish, marijuana) and cannabis products,
- Substance of Abuse in this section: Natural and synthetic tetraydrocannabinols (THCs)
- Synthetic cannabinoids that mimic the effects of THC.

#### Except for:

#### • Cannabidiol (CBD)

However, the FIM Medical Dept would recommend extreme care regarding the use of CBD products as some may also contain other cannabinoids such as THC which are prohibited and this may not be included in the list of ingredients on the product label.





### S9 - GLUCOCORTICOIDS (GCS): PROHIBITED IN-COMPETITION

All Glucocorticosteroids are prohibited when administered by oral, intravenous, intramuscular or rectal routes (e.g. Beclometasone, betamethasone, budesonide, cortisone, fluticasone, methylprednisolone, prednisolone, prednisone, etc.)

- <u>Until 31.12.2021</u>: Glucocorticoids 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 (=NO TUE required)
- As from 01.01.2022: all injectable routes of administration of glucocorticoids during the In-Competition period. Examples of injectable routes of administration include: intravenous, intramuscular, periarticular, intra-articular, peritendinous, intratendinous, epidural, intrathecal, intrabursal, intralesional (e.g. intrakeloid), intradermal, and subcutaneous.
- **Topical use of glucocorticosteroids (NO TUE required = no change)** GCS preparations when used topically (auricular, buccal, dermatological, gingival, nasal, ophthalmic and perianal) are not prohibited and do not require a TUE.

### PROHIBITED METHODS: PROHIBITED AT ALL TIMES

M1 - MANIPULATION OF BLOOD AND BLOOD COMPONENTS

M2 - CHEMICAL AND PHYSICAL MANIPULATION

(e.g. Intravenous infusions and/or injections of more 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.

M3 - GENE AND CELL DOPING





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#### **REMINDER:**

#### 1) What is a *Therapeutic Use Exemption (TUE)*? (Art.4.4 of the Anti-Doping Code/ADC)

You, like all people, may have illnesses or conditions that require you to take particular medication/substance or undergo certain procedures/methods. If the medication or the method 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 a substance or use a method.

#### 2) What are the criteria for obtaining a TUE?

The criteria are:

- 1. The *Prohibited Substance* or *Prohibited Method* in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence;
- 2. The <u>Therapeutic</u> Use of the Prohibited Substance or Prohibited Method will not, on the balance of probabilities, 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 medical condition.
- 3. The *Prohibited Substance* or *Prohibited Method* is an indicated treatment for the medical condition, and there is no reasonable permitted <u>Therapeutic</u> alternative.
- 4. 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 FIM Prize events (FIM Cups & Trophies)

According to article 4.4.2 of the FIM Anti-Doping Code, if you compete in FIM World Championship or FIM Prize events (FIM Cups & Trophies), you shall submit to the FIM Anti-Doping Coordinator (evelyne.magnin@fim.ch) a **TUE** application using the appropriate FIM TUE application form.

The application form must be LEGIBLE, in either <u>English or French and</u> <u>submitted</u> no later than 30 days before your participation at the event. A <u>TUE application form</u> can be downloaded from the <u>FIM website</u>:

The TUE application shall include a complete medical file including clinical information, tests, 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 to enable the FIM TUE Committee (TUEC) to reach a decision in accordance with WADA's documents entitled "Medical Information to Support the Decisions of TUECs/TUE Physician Guidelines" available <u>here</u>

#### 4) FIM TUE Committee (TUEC)

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>here</u> and, if the exemption is granted, will send to you the "<u>Certificate of 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 or urgent treatment of a medical condition was necessary; or
- b. There was insufficient time, opportunity or other exceptional circumstances that prevented you from submitting (or the TUEC to consider) an application for the TUE prior to sample collection; or
- c. Due to national level prioritization of certain sports, your National Anti-Doping Organization did not permit or require you to apply for a prospective TUE (see Article 5.1 of the <u>the International Standard for</u> <u>Therapeutic Use Exemptions (ISTUE)</u>





- d. If an Anti-Doping Organization chooses to collect a sample from you who are not an International-level Rider or National Rider and you are using a prohibited substance or prohibited method for therapeutic reasons, the Anti-Doping Organization must permit you to apply for a retroactive TUE; or
- e) You used out-of-competition, for therapeutic reasons, a prohibited substance that is only prohibited In-Competition.

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 4.2 of the Anti-Doping Code, in case an application for a retroactive TUE is necessary following Sample collection.

## 6) If you compete in a National event or International events other than FIM events)

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 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 or NADO 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 Anti-Doping Coordinator (evelyne.magnin@fim.ch) to recognize that TUE, in accordance with Article 7 of <u>the ISTUE</u> 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 4.4.3.1 of the ISTUE. 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. 4.4.7.2 & 4.4.7.3 (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. 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 in a reasonable time, given the circumstances of 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.

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#### For riders applying to a National Anti-Doping Organisation:

You may appeal the NADO decision to an independent appeal body in your 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 <u>here</u> and FIM web site <u>here</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,

All bear

Dr David McManus FIM Medical Director

Evelyne Magnin FIM ANTI-DOPING COORDINATOR

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