Therapeutic Use Exemptions (TUEs)
Regulations and Procedures

Information regarding the Prohibited List and Therapeutic Use Exemptions (TUEs)
Questions & Answers on 2014 Prohibited List

1. What noteworthy changes have been made to the 2014 List compared to the 2013 version?

IN – AND OUT-OF COMPETITION

- Use of International Non-proprietary Names (INN)
  
  With the assistance of the World Health Organisation, the nomenclature of some substances on the List has been updated to International Non-proprietary Names (INN). For ease, however, previous names have been maintained and no substance has been deleted.

- S1. Anabolic Agents
  
  To ensure clarification and accuracy, changes were made to the definitions of “exogenous” and “endogenous”

- S2. Peptide Hormones, Growth Factors and Related Substances
  
  As made clear through points S2.2, S2.3 and S2.4, Releasing factors are prohibited. Furthermore, other prohibited growth factors are listed separately.

- S5. Diuretics and other Masking Agents
  
  Vasopressing V2 antagonists (vaptans) were added as an example of a diuretic subclass.

- M1. Manipulation of Blood and Blood Components
  
  For the purpose of scientific accuracy, the term allogenic was introduced.

IN-COMPETITION

- S6. Stimulants
  
  Some drugs that metabolize to amphetamine or methamphetamine have been reclassified because improved analytical techniques permit the identification of the administered drug and corresponding metabolites; MDMA and MDA are reclassified because they are now recognized as less likely to be used as doping agents; cathinone and its analogues (e.g. mephedrone, methedrone, α-pyrrolidinovalerophenone) and trimetazidine have been added as examples to reflect emerging patterns of drug use.

IN PARTICULAR SPORTS

- P1. Alcohol
  
  In the interest of accuracy, changes were made to the wording describing the blood alcohol threshold. In addition, “Aeronautic” has been replaced by “Air Sports”, and “FITA” has been replaced by its new acronym “WA” (World Archery).

- P2. Beta-blockers
  
  “FITA” has been replaced by its new acronym “WA” (World Archery).
Monitoring Program

In order to detect potential patterns of abuse, mitragynine has been added to the Narcotics class of the Monitoring Program.

2. What is the status of methylhexaneamine (MHA)?

Methylhexaneamine (MHA), which sometimes is presented as dimethylamylamine, remains prohibited in competition as a specified stimulant under Section 6.b.

It has been considered a stimulant at least since WADA took over responsibility for the List in 2004. It was reclassified on the 2011 List to become a ‘specified substance’.

Methylhexaneamine was sold as a medicine up to the early 1970s and has medicinal properties, but to WADA’s knowledge it has not been sold as a medicine since then.

3. What is the link between geranium oil and methylhexaneamine (MHA)?

Recent scientific studies have clearly demonstrated that natural geranium oil does not contain methylhexaneamine (MHA), and the use of geranium oil cannot be considered as being the source of the presence of MHA or related metabolites in a urine sample collected for anti-doping purposes.

Methylhexaneamine (MHA) is a pharmacological substance classified as a stimulant that was commercialized up to the beginning of the seventies. MHA reappeared a few years ago as a constituent of dietary supplements sold freely on some markets or on the Internet.

MHA is prohibited as a stimulant under section S6.b of the 2013 List of Prohibited Substances and Methods.

Athletes should be aware that MHA has been made available under several names, one being geranium oil.

4. What is the status of clenbuterol?

Clenbuterol is a prohibited substance and there is no threshold under which this substance is not prohibited.

At present, and based on expert opinions, there is no plan to introduce a threshold level for clenbuterol.

It is possible that under certain circumstance the presence of a low level of clenbuterol in an athlete sample can be the result of food contamination. However, each case is different and all elements need to be taken into account, along with the context of the case.

Under the World Anti-Doping Code, result management of cases foresees the opportunity for an athlete to explain how a prohibited substance entered his/her body.

WADA is working closely with countries, International Federations and event organizers to help minimize the risk of contamination through the monitoring of meat to official hotels and restaurants. This is a government issue and not a WADA issue.
5. What is a ‘specified substance’?

A specified substance is a substance which allows, under defined conditions, for a greater reduction of a two-year sanction when an athlete tests positive for that particular substance.

The purpose is to recognize that it is possible for a substance to enter an athlete’s body inadvertently, and therefore allow a tribunal more flexibility when making a sanctioning decision.

Specified substances are not necessarily less serious agents for the purpose of doping than other prohibited substances, and nor do they relieve athletes of the strict liability rule that makes them responsible for all substances that enter his or her body.

However, there is a greater likelihood that these substances could be susceptible to a credible non-doping explanation, as outlined in section 10.4 of the World Anti-Doping Code. This greater likelihood is simply not credible for certain substances – such as steroids and human growth hormone – and this is why these are not classified as specified.

6. What is the status of colostrum?

Colostrum is not prohibited per se, however it contains certain quantities of IGF-1 and other growth factors which are prohibited and can influence the outcome of anti-doping tests. Therefore WADA does not recommend the ingestion of this product.

7. What is the status of platelet derived preparations (PRP)?

Despite the presence of some growth factors, platelet-derived preparations were removed from the List as current studies on PRP do not demonstrate any potential for performance enhancement beyond a potential therapeutic effect.

Note that individual growth factors are still prohibited when given separately as purified substances as described in S.2.5.

8. Is dialysis a Prohibited Method?

Yes, Hemodyalisis is prohibited under M1.1, as blood is taken out from the patient (in a closed circuit) and then reintroduced into the circulatory system. An athlete needing this treatment requires a TUE.

9. Is Plasmapheresis prohibited?

Plasmapheresis should be considered from 2 angles:

a. For the donor, plasmapheresis is prohibited under M1.1 because the donor’s own red blood cells (and other blood components) are being reintroduced into the circulatory system after the plasma has been separated.

b. For the recipient, plasmapheresis is not prohibited under M1.1 or M1.3 as the patient receives only plasma but does not receive whole blood or red blood cells. For the recipient plasmapheresis would only be prohibited under M2.2 if it is not legitimately received in the course of a hospital admission when the volume is more than 50 mL per 6 hour period.
10. Is Intravenous Laser Therapy prohibited?

Yes it is prohibited under M1.3 as “Any form of intravascular manipulation of blood…”

11. Why may there be a delay in determining the status of some substances on the Prohibited List?

The WADA Prohibited List endeavours to capture as many known substances and methods that satisfy any two of the following three criteria:

1. Potential to enhance or enhances sports performance
2. An actual or potential health risk to the athlete
3. Use violates the spirit of sport (outlined in the Code)

Substances or methods which mask the effect of prohibited substances are also prohibited. In addition, a substance which has not been approved for human use is likely to be prohibited as well.

Substances are grouped under the “S” categories, which are either:

i. Closed categories: all the prohibited substances are included by name in the category e.g. S6.a (Non-specified stimulants), S7 (Narcotics).

ii. Open categories with examples: composed of a non-exhaustive list of examples representing the most typical drugs in the group, based on their chemical structure and/or mechanism of action, e.g. S2 (Peptide hormones, growth factors & related substances), S6.b (Specified stimulants). Other substances in these categories are either captured by the name of a family of compounds (e.g. Corticotrophins) or by more general statements such as:

1. “other substances with similar chemical structure or similar biological effect(s)“.
2. “including but not limited to…”
3. “any other growth factor affecting ….”

iii. Open categories without examples: no particular substances are listed but they are captured if they belong to a particular pharmacological class e.g. S9 (Glucocorticosteroids) or if they meet a particular criteria e.g. S0, which refers to substances not approved for human therapeutic use [1].

This means that while the status of some substances is straight forward (e.g. for those that are specifically listed by name), this is not necessarily the case for substances that are not included by name on the List. For these substances, it is necessary to gather information on, for example, their chemical structure, pharmacological/biologic actions and whether they are approved for human therapeutic use anywhere in the world. This verification can take some time to complete, especially for non-approved drugs (e.g. designer drugs, new investigational drugs) for which little scientific information is publicly available. In such cases, WADA will not be able to immediately determine the status of that substance. It is in
the best interest of the athlete to refrain from taking any substance or use any method if its status is unknown or unclear.

This process of thoroughly collecting and analysing information on substances and methods is the way to practically manage the Prohibited List, as it encompasses thousands of substances and methods, and has the potential to capture many thousands more which have not yet caught the attention of the anti-doping movement.

[1] The full SO category description is “Any pharmacological substance which is not addressed by any of the subsequent sections of the List and with no current approval by any governmental regulatory health authority for human therapeutic use (e.g. drugs under pre-clinical or clinical development or discontinued, designer drugs, substances approved only for veterinary use) is prohibited at all times.”

12. Can I test positive for ingesting glycerol found in foodstuffs and toiletries?

Glycerol is prohibited as a plasma expander. The consumption of quantities of glycerol far beyond those commonly found in e.g. foods, beverages, personal care products, medicinal tablets tuffs, cough syrup is required to produce an Adverse Analytical Finding. Therefore, its prohibition is not intended to prevent the ingestion of this substance in the amounts commonly found in foodstuffs and toiletries, as such small quantities will not cause an athlete to test positive for this Prohibited Substance.

2014 Prohibited List
Useful links

1. The 2014 Prohibited List

2. Summary of Major Modifications and Explanatory Notes
Questions & Answers on Therapeutic Use Exemptions

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

   Athletes, like all others, may have illnesses or conditions that require them to take particular medications. If the medication an athlete is required to take to treat an illness or condition happens to fall under the Prohibited List, a Therapeutic Use Exemption (TUE) may give that athlete the authorization to take the needed medicine.

2. **What are the criteria for granting a TUE?**

   The criteria are:
   - The athlete would experience significant health problems without taking the prohibited substance or method
   - The therapeutic use of the substance would not produce significant enhancement of performance, and
   - There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance or method.

3. **Who grants TUEs?**

   Under the World Anti-Doping Code, WADA has issued an International Standard for TUEs. The standard states that all International Federations (IFs) and National Anti-Doping Organizations (NADOs) must have a process in place whereby athletes with documented medical conditions can request a TUE, and have such request appropriately dealt with by a panel of independent physicians called a Therapeutic Use Exemption Committee (TUEC). IFs and NADOs, through their TUECs, are then responsible for granting or declining such applications.

4. **Where should an athlete submit a TUE Application?**

   If you are an international level athlete or if you are entered in an international event for which a TUE issued by your International Federation (IF) is required, you must submit your TUE Application to your IF, which is responsible for accepting applications and granting TUEs. If you are a national level athlete you must submit your TUE Application to your National Anti-Doping Organization (NADO).

   **Athletes must not submit TUE Applications to more than one organization.**

   **WADA does not accept TUE Applications from athletes.**

   **Special protocols for TUE Applications may be in effect during Major Events**

   If you are entered in a Major Event, you are advised to inquire of your IF or NADO whether there is any variation in the TUE submission protocol for the Event. Major Events include those organized by international multi-sport organizations that function as the ruling body for any continental, regional, or other international event (e.g. IOC, IPC, FISU).
5. What is WADA’s role regarding TUEs?

WADA’s role in the TUE process is two-pronged. First, the Agency, through its TUE Committee (TUEC), has the right to monitor and review any TUE granted by a federation or anti-doping organization and, pursuant to such review, to reverse any decision. Second, an athlete who submits a TUE Application to a federation or anti-doping organization and is denied a TUE, can ask WADA to review the decision. If WADA determines that the denial of the TUE did not comply with the International Standard for TUEs, the Agency can reverse the decision.

6. How can an athlete apply for a TUE?

The process for an athlete to apply for a TUE is fairly simple. Each athlete must:

- Contact his or her International Federation (IF) or National Anti-Doping Organization (NADO) (whichever applies) and ask for the TUE Application process. Applications are usually submitted through ADAMS or using a paper form.

- Have his or her physician fill out the TUE Application form and produce the required supporting documentation and forward it to the IF or NADO (whichever applies). Athletes should remember that according to the International Standard for TUEs, the TUE Application should be submitted at least 30 days before participating in an event.

- Tips on applying for a TUE

  - Complete the form through ADAMS, or by typing (if possible) or hand written in block capital letters. If the form is not legible, it is deemed incomplete and will be returned to the athlete.

  - If faxing the form, ensure that you include all the required documentation and keep a copy of the request as well as a record of the transmission or acknowledgement of receipt.

7. What happens if an athlete 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 athlete needs to comply with all the treatment conditions outlined in the TUE Application.

Once a TUE has been granted by an International Federation (IF) 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 an athlete do if WADA reverses the original decision granting him/her a TUE?

You or your granting authority can appeal to the Court of Arbitration for Sport (CAS) for a final decision.
9. What should an athlete 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, 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.

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 your test will be recorded as negative.

11. What can an athlete do if his/her TUE is denied by the granting authority?

Under Article 10.0 of the ISTUE, if your TUE is denied by the granting authority (International Federation [IF] or National Anti-Doping Organization [NADO]), you may ask WADA to review the decision, provided you are either:

- An athlete belonging to an International Registered Testing Pool (IRTP);
- An athlete belonging to a National Registered Testing Pool (NRTP); or
- An athlete competing in an IF-sanctioned international 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 10.0 of the ISTUE;

b) You will be asked to pay WADA an administrative fee of US$500. 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 within 30 days 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).
12. What can an athlete do if WADA upholds the granting authority's decision not to grant the TUE?

For athletes applying to an International Federation: You can then appeal the IF decision to CAS for a final decision.

For athletes applying to a National Anti-Doping Organization: You can then appeal the NADO decision to an independent review body in your country. If this body grants you the TUE, WADA could appeal this decision to CAS for a final decision.

13. Will the information on the athlete's TUE Application remain confidential?

Athletes concerned about confidentiality should note that all the information contained in their TUE Application will be kept strictly confidential as medical data. All members of the TUECs are required to sign confidentiality agreements and if they require advice from other scientific experts on a particular case, the name of the athlete will not be used when circulating the application outside the TUEC.

14. Where can an athlete find out more about TUEs?

The procedures for applying for and granting a TUE are outlined in the International Standard for TUEs, published by WADA. You may also contact your IF or NADO for more information.

15 Are athletes still required to file a declaration of use?

As of January 1, 2011, it is no longer necessary for athletes to file a declaration or use.

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

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

Therapeutic Use Exemptions

Useful Links

1. International Standard

2. FIVB Medical Regulations – Chapter 4

For any further information, contact: medical@fivb.org
Or visit: http://www.fivb.org/EN/Medical/
ADAMS TUE quick reference card for the athletes

How to enter a TUE in ADAMS?

1. Request username and password from your ADO for you and/or your doctor
   Send an email to your International Federation (IF) or National Anti-Doping Organization (NADO) depending on your RTP level. The message must include your doctor name and contact details including email address

2. Log into ADAMS on the Internet
   • Make sure that your pop-up blocker is disabled
   • Go to http://adams.wada-ama.org
   • Enter your new username and password
   • Click [login]
   • When you log in for the first time, an information form will appear.
     o Read the statement
     o Type your password to indicate your acknowledgment
     o Click [Accept]

3. Update your Profile and set your Preferences
   • Click [My Profile] for updating your profile if required
   • To set your Preferences click on your name displayed at the right top in the header on the Home page
   • Adjust your Password, select your Language, indicate whether you want to receive notifications on your email address (as set in your profile) if desired
   • Click [Save] to save your modifications
4. Open your TUE form

- Expand the **New** drop down and select **TUE**:

- Complete the mandatory fields (with *)
  - RTP information
  - physician details
  - diagnosis
  - medication
  - attachment (Medical file)

- Save, review your information
- The save option is a draft only available to you.
- You will not be able to modify any data once you submit your application.
- Your IF and NADO will only see your TUE application once you submit your application.
- Click **Submit Application**
Helpdesk Access

WADA has arranged for a Helpdesk to be available to answer any user queries. The Helpdesk, located in Québec, Canada, is available from Monday to Friday (9:00 – 17:00 EST) and outside business hours through voice mail and e-mail adams@wada-ama.org

From North America dial: (866) 922-3267 (1-866-92-ADAMS)

From outside North America you may reach the Helpdesk by dialing: +1 (514) 904-8800

To reset your password or any information pertaining to your record please directly contact your organization ADAMS administrator (Contact details are on your Security tab).

For further information: http://www.wada-ama.org/en/science-medicine/tue/
M-8 Application Form
Therapeutic Use Exemption

Before taking into consideration this demand the FIVB requires the athlete’s medical file.

I apply for approval from FIVB for the therapeutic use of a prohibited substance on the WADA List of Prohibited Substances and Prohibited Methods, and according to the FIVB Medical Regulations that is subject to the Therapeutic Use Exemption application process.

1. Athlete Information (please print and complete ALL sections)

Surname: ____________________________
Given Names: ____________________________

Male ☐ Female ☐

Date of Birth (d/m/y): ____________________________

Country: ____________________________

ZIP and City: ____________________________

Address: ____________________________

Tel. Home: ____________________________

Tel. Work: ____________________________

E-mail: ____________________________

Mobile: ____________________________

Fax: ____________________________

National Federation ____________________________

Position: ____________________________

Discipline: ____________________________

Please tick the appropriate box:

☐ I am part of the FIVB Registered Testing Pool for Beach Volleyball or Volleyball

☐ I am part of a National Anti-Doping Organization Testing Pool

☐ I am participating in a FIVB or continental Event for which a TUE granted pursuant to the FIVB Medical Regulations is required

– Name of FIVB or continental Event: ____________________________

If athlete with disability, indicate disability: ____________________________

2. Notifying medical practitioner

Name, qualifications and medical specialty (for example Dr. AB Cook, MD FRACP, Gastro-enterologist): ____________________________

Address: ____________________________

ZIP and City: ____________________________

Tel. Home: ____________________________

Tel. Work: ____________________________

Mobile: ____________________________

Email: ____________________________

1 International Events for which a certificate of Therapeutic Use from FIVB is required are defined as being those events where the FIVB or its Confederations are “the ruling body for the Event or appoint the technical officials for the Event”. FIVB Events are listed on the FIVB website: www.fivb.org
3. Medical Information
Diagnosis with sufficient medical information:

Medical examination (s)/test (s) performed:

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<th>Medication</th>
<th>Prohibited Substance(s)</th>
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Anticipated duration of this medication plan:

Additional information:

Previous TUE applications:
- [ ] Yes
- [ ] No
  - For which substance?
  - To whom?
  - When?

Decision:
- [ ] Approved
- [ ] Not approved

4. Medical practitioner’s declaration
I, ___________________________, certify the above-mentioned substance(s) for the above named athlete have been/are to be administered as the correct treatment for the above named medical condition. I further certify that the use of alternative medications not on the Prohibited List would be unsatisfactory for the treatment of the above named medical condition.

Specify reasons:

Signature and stamp of Medical Practitioner: ________________________________

Evidence confirming the diagnosis must be attached and forwarded with this application. The medical evidence should include a comprehensive medical history and the results of all relevant examinations, laboratory investigations and imaging studies. Copies of the original reports or letters should be included when possible. Evidence should be as objective as possible in the clinical circumstances and in the case of non-demonstrable conditions independent supporting medical opinion will assist this application.
5. Athlete’s declaration

I __________________________ certify that the information under 1. is accurate and that I am requesting approval to use a Substance or Method from the WADA Prohibited List. I authorize the release of personal medical information to the FIVB and other responsible Anti-Doping Organization (ADO) as well as to WADA authorized staff, to the WADA TUEC (Therapeutic Use Exemption Committee) and to other ADO TUECs and authorized staff that may have a right to this information under the provisions of the Code.

I understand that my information will only be used for evaluating my TUE request and in the context of possible anti-doping violation investigations and procedures. I understand that if I ever wish to (1) obtain more information about the use of my information; (2) exercise my right of access and correction or (3) revoke the right of these organizations to obtain my health information, I must notify my medical practitioner and FIVB in writing of that fact. I understand and agree that it may be necessary for TUE-related information submitted prior to revoking my consent to be retained for the sole purpose of establishing a possible anti-doping rule violation, where this is required by the Code.

I understand that if I believe that my personal information is not used in conformity with this consent and the International Standard for the Protection of Privacy and Personal Information I can file a complaint exclusively to WADA or CAS.

Signature of the athlete:  
__________________________________________

Date:  
__________________________________________

Parent’s/Guardian’s Signature:  
__________________________________________

(If the athlete is a minor or has a disability preventing him/her to sign this form, a parent or guardian shall sign together with or on behalf of the athlete).

Incomplete and/or illegible Applications will be returned and will need to be resubmitted!

FEDERATION INTERNATIONALE DE VOLLEYBALL

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