



Therapeutic Use Exemptions (TUEs) Regulations and Procedures

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**Information regarding FIVB Medical Regulations on
Therapeutic Use Exemptions (TUEs) and application
procedures**

I. Therapeutic Use Exemptions (TUEs) – changes for 2010

According to the 2010 WADA International Standard for TUEs (ISTUE) the following changes took effect from 1 January 2010:

- The “Asthma TUE” does not exist anymore for inhaled beta2-agonists. The use of salbutamol and salmeterol by inhalation now requires a “Declaration of Use” and a mandatory declaration on the Doping Control Form;

Please note: If the urinary concentration of Salbutamol is above 1,000 nanograms per millilitre, there will be a presumption that the substance was not taken by inhalation and the athlete will have to demonstrate through a controlled pharmacokinetic study that the level found in the urine was the result of therapeutic inhaled use;

- The use of glucocorticosteroids by non-systemic routes requires a “Declaration of Use” and a mandatory declaration on the Doping Control Form;
- The WADA online ADAMS system is mandatory for all types of declarations or applications as of 1 January 2010;
- Pseudoephedrine (originally on the WADA Prohibited List until 2003 when it was removed from the list) is again prohibited above 150 micrograms per milliliter.

Please find the 2010 Prohibited List here:

<http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/International-Standards/Prohibited-List/>

II. Therapeutic Use Exemptions (TUEs) - application procedures

Each Athlete with a documented medical condition requiring the use of a Prohibited Substance or a Prohibited Method competing in an FIVB competition must obtain a TUE from the FIVB regardless of whether the Athlete has previously received a TUE at the national level (Art. 4.4.2 FIVB Medical Regulations).

1. Application procedure for a Declaration of Use (DOU)

Only For: Inhaled beta2-agonists Salbutamol and Salmeterol & glucocorticosteroids by non-systemic routes

All Athletes competing in FIVB competitions (whether in one of the FIVB Registered Testing Pool or not) wanting to use Inhaled beta2-agonists Salbutamol and Salmeterol and/or glucocorticosteroids by non-systemic routes have to **declare** its use **via ADAMS**, an online Anti-Doping Administration System.

Should an Athlete not be in possession of an ADAMS account, please contact the FIVB at medical@fivb.org and an account will be established. Detailed instructions on how to establish a Declaration of Use in ADAMS can be found further in this document.

Further to the Declaration of Use (DOU) via ADAMS, it is mandatory that the Athlete states the use of these substances **also on the Doping Control Form** when tested.

2. Application procedure for a TUE request

All Athletes competing in FIVB competitions and for substances other than Inhaled beta2-agonists Salbutamol and Salmeterol and/or glucocorticosteroids by non-systemic routes requesting a Certificate of Therapeutic Use must:

Either and preferably:

a) Apply for a certificate of Therapeutic Use via ADAMS (especially where an Athlete's user accounts exists and/or the National Federation has been given an administrator account)

1. Fill in the required information via ADAMS and submit the TUE request via ADAMS – you will be able to attach medical files in the system;
2. You can follow the status of the application via ADAMS;
3. Once approved, you will be able to print out a hard copy ("TUE receipt").

Detailed instructions on how to apply for a TUE via ADAMS can be found further in this document.

Or: b) Apply for a certificate of Therapeutic Use via paper form

1. **fill in the FIVB Therapeutic Use Exemption form (M-8 Application Form)** which can be downloaded from the FIVB website:
http://www.fivb.org/EN/Volleyball/Forms/Medical/FIVB_VB_M-8.pdf
The FIVB Medical Commission will **not** accept requests made on any other forms, i.e. NADO forms;
2. **include an up to date medical file for all requests;**
3. **send the request** via fax or email, as well as the original request also via mail **to the FIVB Headquarters;**
4. wait to see whether or not the FIVB Medical Commission approves your request. The FIVB Medical Commission has 30 days for approval or denial from the day the FIVB receives the request. The certificate for Therapeutic Use will be sent to the Athlete's National Federation (NF) and shall be forwarded by the NF to the Athlete.

Please note that in case of a denial the athlete may request WADA for a review. Please be informed that a TUE will only be granted if certain conditions are fulfilled:

- that the athlete would experience significant health problems without taking the prohibited substance or method;
- that the therapeutic use of the substances would not produce significant enhancement of performance over and above the athlete's normal condition;
- that there is no reasonable therapeutic alternative to the use of otherwise prohibited substance or method;
- the necessity for the Use of the otherwise Prohibited Substance or Prohibited 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.

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 Certificate. Do **carry the certificate** all the time with you, show it to the Doping Control Officer upon notification to provide a sample and declare all medication and substances you are taking in the Doping Control Form.



**How to apply for
Therapeutic Use Exemptions (TUEs)
and/or
declare Declarations of Use (DOUs) on
ADAMS
(organizations/athletes)**

*Extracted from ADAMS User Guide - Athletes Version 2.2 and readapted to International
Standard for Therapeutic Use Exemptions – changes 2010*



Therapeutic Use Exemption (TUE) Documents

A TUE is a form used by athletes to ask an Anti-Doping Organization (ADO) permission to use a prohibited substance.

You may create, fill and submit the following forms using ADAMS:

- TUE
- Declaration of Use

These forms are described in the following sections.

Please note that you may no longer create Abbreviated TUEs or Asthma TUEs in ADAMS.

As an athlete you can create the various types of TUE yourself, but you may also opt for asking your custodian organization to enter the TUE on your behalf. You may also ask a designated Athlete Doctor in ADAMS with access to your medical file to create and submit, or complete the medical information for you. In this case you should send a formal request to your custodian organization.

Declaration of Use (DoU)

[quoted from the STANDARD FOR TUE 2009]:

It is acknowledged that some substances included on the List of Prohibited substances are used to treat medical conditions frequently encountered in the athlete population. For monitoring purposes, these substances, for which the route of administration is not prohibited, will require a simple declaration of use.

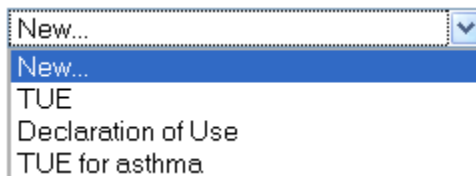
The declaration should mention the diagnosis, the name of the substance, the dose undertaken, the name and the contact details of the physician

In addition, the athlete must declare the use of the substance in question on the Doping Control Form.

Athlete users can create a Declaration of Use form themselves by selecting this form from the dropdown menu in the athlete tree section. Athlete users can view all DoU's from their athlete tree.

Creating a Declaration of Use

1. Go the file tree section.



2. Select **Declaration of Use** from the **New** drop down list.
3. Complete all required fields (with *): see the [Fields descriptions](#) below for more details.



Mandatory information is indicated with a red asterisk.

STEP 1: INFORMATION ABOUT YOUR SPORT

Specify the sport for which you require a Declaration of Use. Specify the event if it is relevant or required by your sporting organization. Select the Sporting Organization to which you declare. Unless specified otherwise by your sporting organization if you are a national level athlete you declare to your National Antidoping Organization (NADO) and if you are an international-level athlete you declare to your International Federation.

Sport Discipline*	
<input type="text" value="Ice Hockey Ice Hockey"/>	
Sporting Organization*	Registered Testing Pools
<input type="text"/>	<input type="text"/>

STEP 2: INFORMATION ABOUT YOUR PHYSICIAN

Last Name*		First Name*		Qualification & Medical Specialty	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Address					
<input type="text"/>					
Country*	Region	City*	Postal code/Zip		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Telephone Work*	Telephone Home	Telephone Mobile	Telephone Fax		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Email					
<input type="text"/>					

STEP 3: MEDICAL INFORMATION

If an appropriate diagnosis is not listed, select "Other, please specify" in the Diagnosis list and describe your condition in the "Diagnosis description" box.

Diagnosis	Diagnosis description
<input type="text" value="Other, please specify"/>	<input type="text"/>
Medical Exam / Test Performed	
<input type="text"/>	
Additional Information	
<input type="text"/>	

STEP 4: SPECIFY THE MEDICATION YOU ARE TO TAKE

If you do not know the generic name of the substance, or it does not appear in the list, please specify it in the "Comments" box. The prescribed dosage (e.g. 375 mg) is required. You may enter more than one substance by clicking the "Add Substance" button, and you may remove a substance by clicking the small "x" that appears in the top right-hand corner of the substance box.

Specific name of drug	Prohibited Substance*	Dosage*	<input type="button" value="Add Substance"/>
<input type="text"/>	<input type="text"/>	<input type="text" value="0"/>	
Frequency of Administration	Route of Administration*	Expected Duration of Treatment	Starting Dates of Medication
<input type="text" value="as needed"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Medical Information			
Conditions and Comments			
<input type="text"/>			
<input type="button" value="Add Medication"/>			

STEP 5: ADD MEDICAL INFORMATION

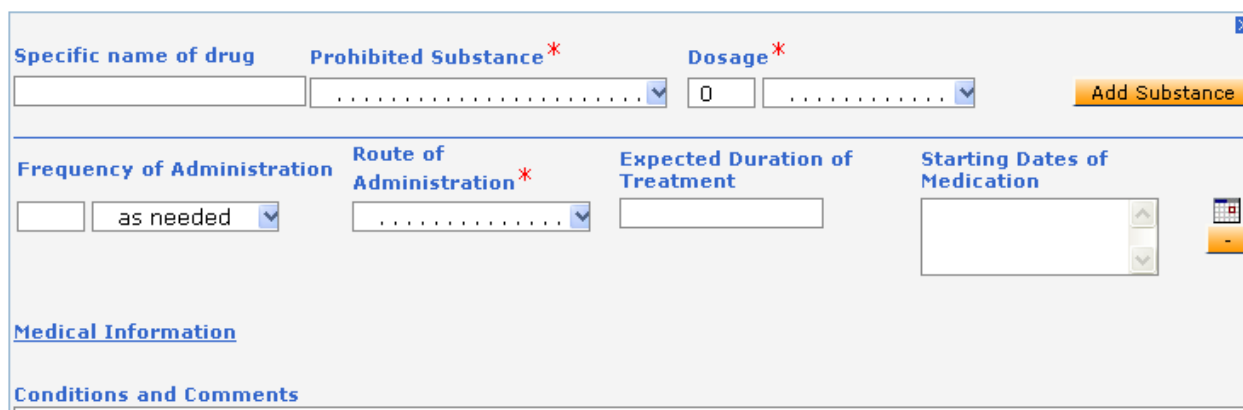
Attach your scanned documents. If this is truly not possible, you may send your medical file by other means to your sporting organization.

Document Title	Document
<input type="text"/>	<input type="text" value="Browse..."/>
Document Description	
<input type="text"/>	

STEP 6: SUBMIT YOUR APPLICATION

You may submit your declaration by clicking the "Declare" button. If you would like to save it to complete later, simply click "Save". Once declared, your sporting organization will automatically receive notification that your declaration has been entered.

- I. Verify your *sport/discipline*
- II. Select the *Sporting Organization* from the pick list. Enter the first 3 letters and press on the magnifying glass. This is the organization to which you are submitting the DoU.
- III. Only specify the event under *Competition name* if it is relevant
- IV. The *Registered Testing Pools* dropdown lists all RTP's you belong to as an athlete. Select the relevant one for the DoU.
- V. Information about your *physician*: fill in the Medical Practitioner's Last Name, First Name, Qualification & Medical Specialty, Address, Country, Region, Telephone and email address. Provide at least one telephone number. [Your sporting organization has the option to make certain fields mandatory – first/last name, country, city, telephone work]
- VI. *Medical information*:
 - a) Pick a diagnosis in the Diagnosis pick list (the most common diagnosis are listed.) If your diagnosis is not in the list pick **"Other, please specify"** and enter the diagnosis in the **Diagnosis description** field.
 - b) Enter the Medical exams/tests performed and any additional information
- VII. Specify the *medication*:
 - c) Fill in the Specific name of drug, frequency of administration
 - d) Select the relevant Prohibited Substance from the dropdown list
 - e) Fill in the dosage and select the unit
 - f) Select the route of administration
 - g) Optionally enter the expected duration of treatment and starting date(s) of medication using the Calendar [the calendar icon is for selecting a single date to add to the list and the '-' button for removing a date]
 - h) Under Conditions and comments indicate any



The screenshot shows a web form for entering medication information. It has several sections:

- Top Section:**
 - Specific name of drug:** A text input field.
 - Prohibited Substance*:** A dropdown menu with a magnifying glass icon.
 - Dosage*:** A text input field followed by a dropdown menu for units.
 - Add Substance:** A yellow button.
- Second Section:**
 - Frequency of Administration:** A dropdown menu with 'as needed' selected.
 - Route of Administration*:** A dropdown menu.
 - Expected Duration of Treatment:** A text input field.
 - Starting Dates of Medication:** A calendar icon and a list of dates with up/down arrows.
- Third Section:** **Medical Information** (a link).
- Fourth Section:** **Conditions and Comments** (a link).

4. Submit your DoU by clicking on the **Declare** button. Once submitted, the sporting organization automatically receives a notification of your DoU submission. You may also use the **Save** button to complete your DoU later.



Access to a Saved Declaration of Use

Athlete users

Athletes can view all Declaration of Uses created for them regardless of the status. There are three status values: Not Declared, Declared and Cancelled.

They can only edit a Declaration of Use if the status is "Not Declared".

If the status of the Declaration of Use is "Declared" the athlete can only "Cancel" it.

Athlete doctor users

Athlete doctors can view all Declaration of Uses for the athletes for which they have been granted access in ADAMS, regardless of the status.

They can only edit a Declaration of Use they or the athlete created, if the status is "Not Declared".

Organizations with access to the athlete

1. If the organization created the Declaration of Use:

- They can edit the Declaration of Use if it is "Not Declared".
- When the Declaration of Use is "Declared", they can edit all the fields except the Medical Information Section fields.
- When the Declaration of Use is "Cancelled" they can only view the Declaration of Use.

2. If the organization did not create the Declaration of Use:

- They can only view the Declaration of Use if it is "Declared" or "Cancelled"

3. WADA

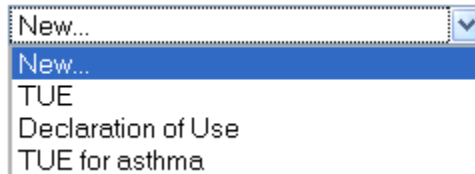
- WADA users with access to the athlete can view all Declaration of Use's regardless of status.
- If WADA created the Declaration of Use then it follows the same rules as other organizations.

TUE (TUE)

TUEs are used for substances that are not pre-approved by an ADO or WADA.

Applying for a TUE

1. Go the file tree section.
2. Select **TUE** from the **New** drop down list.



3. Complete all required fields (with *): see the Fields descriptions below for more details



Athlete TUE

Save

Submit Application

Mandatory information is indicated with a red asterisk.

STEP 1: INFORMATION ABOUT YOUR SPORT

Specify the sport for which you require a Therapeutic Use Exemption (TUE). Specify the event if it is relevant or required by your sporting organization. Select the Sporting Organization to which you are applying for this TUE. Unless specified otherwise by your sporting organization if you are a national level athlete you apply to your National Antidoping Organization (NADO) and if you are an international-level athlete you apply to your International Federation. You must specify the Registered Testing Pool you belong to.

Sport Discipline* Ice Hockey Ice Hockey	Next competition and date
Sporting Organization*	Registered Testing Pools

STEP 2: INFORMATION ABOUT YOUR PHYSICIAN

Last Name*	First Name*	Qualification & Medical Specialty	
Address			
Country*	Region	City*	Postal code/Zip
Telephone Work*	Telephone Home	Telephone Mobile	Telephone Fax
Email			

STEP 3: MEDICAL INFORMATION

If an appropriate diagnosis is not listed, select "Other, please specify" in the Diagnosis list and describe your condition in the "Diagnosis description" box.

Diagnosis* Other, please specify	Diagnosis description*
Medical Exam / Test Performed	
Additional Information	

STEP 4: SPECIFY THE MEDICATION YOU ARE TO TAKE

If you do not know the generic name of the substance, or it does not appear in the list, please specify it in the "Comments" box. The prescribed dosage (e.g. 375 mg) is required. You may enter more than one substance by clicking the "Add Substance" button, and you may remove a substance by clicking the small "X" that appears in the top right-hand corner of the substance box.

Specific name of drug	Prohibited Substance*	Dosage* 0	Add Substance
Frequency of Administration as needed	Route of Administration*	Expiry Date	
Medical Information Conditions and Comments			
Add Medication			

STEP 5: ADD MEDICAL INFORMATION

Attach your scanned documents. If this is truly not possible, you may send your medical file by other means to your sporting organization.

Document Title	Document Browse...
Document Description	

STEP 6: SUBMIT YOUR APPLICATION

You may submit your application by clicking the "Submit Application" button. If you would like to save it to complete later, simply click "Save". Once submitted, your sporting organization will automatically receive notification that you are applying for a TUE. You can log into ADAMS at any time and see the status of your application by selecting the TUE from your athlete tree on the left side of the screen.

Save

Submit Application

- I. Verify your *sport/discipline*
- II. Select the *Sporting Organization* from the pick list. Enter the first 3 letters and press on the magnifying glass. This is the organization to which you are submitting the TUE.
- III. Only specify the event under *Next competition and date* if it is relevant
- IV. The *Registered Testing Pools* dropdown lists all RTP's you belong to as an athlete. Select the relevant one for the TUE.
- V. Information about your *physician*: fill in the Medical Practitioner's Last Name, First Name, Qualification & Medical Specialty, Address, Country, Region, Telephone and email address. Provide at least one telephone number. [Your sporting organization has the option to make certain fields mandatory – first/last name, country, city, telephone work]
- VI. *Medical information*:
 - a) Pick a diagnosis in the Diagnosis pick list (the most common diagnosis are listed.) If your diagnosis is not in the list pick "**Other, please specify**" and enter the diagnosis in the **Diagnosis description** field.
 - b) Enter the Medical exams/test performed and any additional information.
- VII. Specify the *medication*:
 - a) Fill in the Specific name of drug, frequency of administration.
 - b) Fill in the relevant Prohibited Substance. Fill in at least 3 characters of the prohibited substance name and search for the relevant substance from a database by clicking on the magnifying glass.
 - c) Fill in the dosage and select the unit
 - d) Select the route of administration
 - e) Enter an expiry date (expiry dates are per medication)
 - f) Under Conditions and comments indicate any
- VIII. You may attach any file or scanned document containing your medical information: enter a title and description for the document, click the Browse button and select the file to be attached.
- IX. Fill in any other available information.
 4. Submit your TUE electronically by clicking on the **Submit Application** button. Once submitted, the sporting organization automatically receives a notification of your TUE submission. You may also use the **Save** button to complete your TUE later.
 5. You can use the **Generate Application Form** button to print out a completed hard copy of your application after you have submitted electronically.



[As long as the status is not Approved, Rejected or Cancelled]

6. At any time you can view the status of your application by selecting the TUE from your athlete tree on the left side of the screen. [Edit is only possible as long as the status of your TUE is Not Submitted or Incomplete].
7. When the TUE has had its status changed to Approved, you will be offered the option to generate a **TUE Receipt hard copy**.



TUE No./Numéro de AUT
T-253576

CERTIFICATE OF APPROVAL FOR THERAPEUTIC USE
CERTIFICAT D'AUTORISATION D'USAGE À DES FINS THÉRAPEUTIQUES

Athlete Details/Renseignements sur l'athlète

Surname/Nom de famille	Given Name/Prénom	
BIRDI	Karam	
Date of Birth/Date de naissance	Sport/Sport	Discipline/Discipline
12-Apr-1977	Aquatics	Swimming

Clicking the Generate TUE Receipt button will invoke a PDF file within the work area of the system. This can be printed by clicking the PDF Printer icon.



Appendix 1

Therapeutic Use Exemptions
TUE

Please complete all sections in capital letters or typing

1. Athlete Information

TUE Fields

- a) **Sport/Discipline:** this field is copied from the athlete sport identity tab. If it is empty please review the sport/discipline tab of the athlete
- b) Next competition and date: To be filled if the TUE is for a specific event
- c) **Sporting organization:** the organization to which the TUE is submitted
- d) Information about your Physician: Information about the doctor prescribing the medication.
- e) **Medical Information:** Diagnosis information
 - i. Diagnosis: List of most frequently used diagnosis. If the athlete is not listed select “other please specify” and enter details in the Diagnostic description field (mandatory in this case).
 - ii. Diagnostic description: in case you selected the “other please specify” this field must give an accurate description of the diagnosis.
 - iii. Medical Exam/Test Performed: list medical tests and exams performed for the diagnosis
 - iv. Additional information: any additional information about the medical condition
- f) **Medical Information:**
 - v. Specific name of drug: medication name
 - vi. Frequency of administration: frequency of administration of the medication
 - vii. Dates of administration: dates of applying the drug
 - viii. Prohibited substance: name of the prohibited substance, as per the WADA prohibited list, included in the medication. You can add as many prohibited substance as you need.
 - To pick a substance: enter the first 3 letters and press the magnifying class. The system will list the corresponding substance for you to choose from.
 - ix. Dosage: dosage of the prohibited substance
 - x. Route of administration: medication route of administration. This field must be filled only after you have entered the prohibited substance as it may vary based on the substance.
 - xi. Condition and Comments: any comments about the medication you would like to add.
 - xii. Add medication: you can add as many medications as you need

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).