



Australian Government
Australian Sports Drug
Medical Advisory Committee

24 April 2009

Ms Cathy Taylor
President
Ice Skating Australia Inc
PO Box 3266
North Strathfield NSW 2137

Dear Ms Taylor,

Re: SUBMISSION OF THERAPEUTIC USE EXEMPTION (TUE) APPLICATIONS

I write with advice on behalf of the Australian Sports Drug Medical Advisory Committee (ASDMAC) in relation to Therapeutic Use Exemption (TUE) applications.

Since the implementation on 1 January 2009, of the new World Anti-Doping Code, ASDMAC process all Therapeutic Use Exemptions including TUE applications for asthma medications (previously known as an Abbreviated TUE).

ASDMAC wish to advise that ALL TUE applications submitted for consideration MUST be accompanied with a comprehensive medical history, and the results of all examinations (*example: ASTHMA, a lung function test by way of spirometry or bronchial provocation test*). Note Clause 7.6 of the *International Standard for Therapeutic Use Exemptions January 2009 (excerpt attached)* or visit http://www.wada-ama.org/rtecontent/document/TUE_Standard_2009_Final_031008.pdf

Any TUE application (see attached) received by ASDMAC that does not have a medical report or results of examinations cannot be processed and, unfortunately, will be returned to the athlete for resubmission with the required documents as mentioned.

Should you have any questions regarding the process of TUE Applications, feel free to visit the ASDMAC website at www.asdmac.gov.au where you can also download the most current TUE APPLICATION FORM.

We trust this information will assist your athletes with the specific requirement(s) for submission of a Therapeutic Use Exemption application.

Kind regards,


Jennifer Krevatin
ASDMAC Secretariat

Encl.



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Australian Sports Drug
Medical Advisory Committee

ASDMAC

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APP

Standard Application Form Therapeutic Use Exemption of a Prohibited Substance

Application Checklist (please complete before sending application)	
1. Athlete details complete	<input type="checkbox"/>
2. Athlete declaration signed	<input type="checkbox"/>
3. TUE details complete	<input type="checkbox"/>
4. Medical practitioner details complete	<input type="checkbox"/>
5. Medication details including all medications and treatments tried (generic names and doses)	<input type="checkbox"/>
6. Evidence confirming diagnosis attached	<input type="checkbox"/>
7. Medical practitioner declaration signed	<input type="checkbox"/>
8. Diagnosis evidence attached	<input type="checkbox"/>
a. Clinical history	
b. Examination and Investigations or specialist medical reports	
c. Copies of original reports or letters (where possible)	

The information collected on this form will be used by ASDMAC to consider approval to use a drug or doping method for therapeutic purposes whose use is otherwise prohibited under the anti-doping rules for sport. ASDMAC is authorised under the *Australian Sports Anti-Doping Authority Act 2006* ('the Act') and clause 5.01 of the National Anti-Doping scheme to provide such approvals. This information, and the results of the application, may be released to the following parties in the circumstances as described by the Act and Regulations:

- > The Australian Sports Anti-Doping Authority (ASADA);
- > The Australian Sports Commission (ASC);
- > A Sporting Administration Body (as defined by section 4 of the Act);
- > The World Anti-Doping Agency (WADA); and
- > Other National and International Anti-Doping Organisations

for the purposes of the implementation, co-ordination, administration, monitoring and enforcement of anti-doping programs in sport.

Incomplete applications can not be considered. Please attach and forward all relevant medical information that will assist the committee in its consideration of this request. For more information, visit the ASDMAC website <http://www.asdmac.gov.au/>.

ASDMAC (office use)	Application complete:	Yes	No:	Approved: <input type="checkbox"/>	Not Approved: <input type="checkbox"/>
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1. Athlete Information (please write clearly using block letters)		
Title Dr <input type="checkbox"/> Mr <input type="checkbox"/> Ms <input type="checkbox"/> Mrs <input type="checkbox"/> Miss <input type="checkbox"/>	Surname	Given Name(s)
Gender Male <input type="checkbox"/> Female <input type="checkbox"/>	Date of Birth (dd/mm/yyyy)	
Address		
Suburb	State	Postcode
Email		
Phone (h)	Mobile	
Sport	Discipline/position	
National Sporting Organisation		
Athlete with a disability (AWD) Yes <input type="checkbox"/> No <input type="checkbox"/>	If an AWD, please indicate disability	
Current level of competition: International <input type="checkbox"/> National <input type="checkbox"/> State <input type="checkbox"/> Club <input type="checkbox"/> Other <input type="checkbox"/>		
International Federation Registered Testing Pool Member*: Yes <input type="checkbox"/> No <input type="checkbox"/>		
ASADA Registered Testing Pool Member*: Yes <input type="checkbox"/> No <input type="checkbox"/>		
*If you are unsure of whether you are a member of your International Federation's or ASADA's Registered Testing Pool/s, please contact your National Sporting Organisation to check.		

2. Athlete application, authority and declaration	
<p>I _____ declare that the information I have provided on and with this application form is accurate and complete. I am requesting that ASDMAC provide me with an approval to use a substance or method that is prohibited by the rules of my sport. I consent to my personal information being disclosed to, and used by relevant persons, bodies and agencies as appropriate for the consideration of this application and the implementation, co-ordination, administration, monitoring and enforcement of the therapeutic use exemptions under the relevant national and international anti-doping programs of my sport. I understand that these bodies may include the Australian Sports Anti-Doping Authority, Commonwealth Minister for Sport, Sporting Administration Bodies as defined under section 4 of the ASADA Act including, but not limited to, the Australian Sports Commission, the World Anti-Doping Agency, other national and international anti-doping agencies and organisations, and the relevant national and international sporting administration organisations of my sport.</p>	
Athlete's Signature:	Date:
Parent's / Guardian's signature: (athletes under 18 yrs of age)	Date:

3. TUE Details

Is this application for a retroactive TUE?*

Yes

No

*A retroactive TUE is for treatment involving a prohibited substance or method that has already commenced. A retroactive TUE can only be sought when:

- Emergency treatment or treatment of an acute medical condition was necessary;
- "Exceptional circumstances" means that there was insufficient time for ASDMAC to consider the application
- A Beta-2 Agonist has been detected in your doping control sample (drug test) and notified to you by ASADA or another Anti-Doping Organisation

If the retroactive request is for a substance/method detected as a result of doping control, please state:-

date of sample collection: _____; substance/method detected: _____

Have you previously had, or do you currently have, any TUEs?

Yes

No

If yes, please attach any current or relevant TUEs to this application.

Have you previously had any TUE applications rejected?

Yes

No

If yes, please fill out the following information in relation to those applications:

Date	Anti-Doping Organisation/TUE Committee	Substance

4. Notifying medical practitioner (please write clearly using block letters)

Surname

Given Name(s)

Specialty and qualifications

Address

Suburb

State

Postcode

Email

Phone (w)

Mobile

5. Medication/Treatment details (please write clearly using block letters)				
Medication/Treatment	Prohibited Substances/Method	Dose & Frequency	Route of Administration	Duration
Diagnosis:*				
If a permitted substance or method is available to treat the medical condition, provide clinical justification for the requested use of the prohibited substance or method:				
Full details of all medications or treatments that have been trialled:				
Additional Comments:				

* Evidence confirming the diagnosis MUST be attached and forwarded with this application. The medical evidence should include clinical history, examination, investigations or specialist medical reports. 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. Any additional investigations, examinations or imaging studies requested by ASDMAC will be undertaken at the expense of the applicant or his/her National Sporting Organisation.

6. Medical practitioner's declaration
<p>I, _____ declare the abovementioned medication/s for the above named athlete has been/are to be administered as the correct treatment for the above named medical condition. I further certify that the use of alternative medications or methods not on the Prohibited List would be unsatisfactory for the treatment of the above medical condition.</p> <p>Signature of Medical Practitioner: _____ Date: _____</p>

7.2 The TUE application form(s), as set out in Annex 2, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.

7.3 The TUE application form(s) may be translated into other language(s) by *Anti-Doping Organizations*, but English or French must remain on the application form(s).

7.4 An *Athlete* may not apply to more than one *Anti-Doping Organization* for a TUE. The application must identify the *Athlete's* sport and, where appropriate, discipline and specific position or role.

7.5 The application must list any previous and/or current requests for permission to use an otherwise *Prohibited Substance* or *Prohibited Method*, the body to whom that request was made, and the decision of that body.

7.6 The application must include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis and treatment, as well as duration of validity, should follow the WADA "Medical Information to Support the Decisions of TUECs". For asthma, the specific requirement(s) set out in Annex 1 must be fulfilled.

7.7 Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* before approval will be undertaken at the expense of the applicant or his/her national sport governing body.

7.8 The application must include a statement by an appropriately qualified physician attesting to the necessity of the otherwise *Prohibited Substance* or *Prohibited Method* in the treatment of the *Athlete* and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.

7.9 The dose, frequency, route and duration of administration of the otherwise *Prohibited Substance* or *Prohibited Method* in question must be specified. In case of change, a new application should be submitted.

7.10 In normal circumstances, decisions of the TUEC should be completed within thirty (30) days of receipt of all relevant documentation and will be conveyed in writing to the *Athlete* by the relevant *Anti-Doping Organization*. In case of a TUE application made in a reasonable time limit prior to an *Event* the TUEC should use its best endeavors to complete the TUE process before the start of the *Event*. Where a TUE has been granted to an *Athlete* in the *Anti-Doping Organization Registered Testing Pool*, the *Athlete* and WADA will be provided promptly with an approval which includes information pertaining to the duration of the exemption and any conditions associated with the TUE.

7.11 a. Upon receiving a request by an *Athlete* for review, the WADA TUEC will, as specified in Article 4.4 of the *Code*, be able to reverse a decision on a

ANNEX 1:

Minimal requirements for the medical file to be used for the TUE process in the case of asthma and its clinical variants

The file must reflect current best medical practice to include:

- 1) A complete medical history
- 2) A comprehensive report of the clinical examination with specific focus on the respiratory system
- 3) A report of spirometry with the measure of the Forced Expiratory Volume in 1 second (FEV1)
- 4) If airway obstruction is present, the spirometry will be repeated after inhalation of a short acting Beta-2 Agonist to demonstrate the reversibility of bronchoconstriction
- 5) In the absence of reversible airway obstruction, a bronchial provocation test is required to establish the presence of airway hyper-responsiveness
- 6) Exact name, speciality, address (including telephone, e-mail, fax) of examining physician.