



Australian Government

Australian Sports Drug
Medical Advisory Committee

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Asthma Therapeutic Use Exemption FACT SHEET

The Australian Sports Drug Medical Advisory Committee (ASDMAC) processes Therapeutic Use Exemptions (TUE). These exemptions give permission to athletes who, for medical (therapeutic) reasons, need to use medications or methods that are prohibited in sport.

Asthma Therapeutic Use Exemptions

The World Anti-Doping Agency's (WADA) 2011 List of Prohibited Substances includes a change of status to the therapeutic use of inhaled Beta-2 agonists, **salbutamol (e.g. ventolin) and salmeterol (e.g. seretide and serevent)**:

- Therapeutic use of inhaled salbutamol (maximum 1600 micrograms per day) and salmeterol will be permitted in sport as of 1 January 2011. No Therapeutic Use Exemption (TUE) application is necessary. WADA have also removed the need for a declaration of use for these substances. Athletes are free to use salbutamol and salmeterol in and out of competition in their chosen sport.
- **CONDITION:** Salbutamol will still be prohibited for urinary concentrations 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 their urine was the result of therapeutic inhaled use. Athletes are advised not to overuse their salbutamol inhalers.
- **Prohibited Beta-2 agonists** including formoterol and terbutaline will still require an in-advance TUE and meet the WADA's specific criteria of a positive bronchial provocation test (BPT) or positive bronchodilator test (BDT) as per the 'Suggested Medical File Requirements' described below (available on the WADA website).
- **ALL** athletes and athletes in an International Federation Registered Testing Pool (RTP), the Australian Sports Anti-Doping Authority's (ASADA) RTP and athletes in the ASADA Domestic Testing Pool (DTP) must have an **in-advance TUE to inhale prohibited Beta-2 agonists**.

For an athlete with well documented asthma who undertakes one or more bronchial provocation tests (BPT) which are negative, there is a possibility that a TUE may be approved if a comprehensive medical file is submitted together with all details of the negative BPT(s).

Suggested Medical File Requirements for Prohibited Beta-2 agonists TUE

1. History

- the athlete's age of onset
- symptoms
- trigger factors, for example exercise or allergies
- associated allergic or a topic conditions
- history of any hospitalisation, including accident and emergency presentations(if any)
- all current medication, and any previous asthma medications trailed
- previous requirements for oral glucocorticosteroids
- relevant family history

2. Examination

- Clinical examination with particular reference to respiratory system

Fact Sheet updated January 2011

3. Previous Investigations

- Relevant tests including skin prick, RAST etc.
- Any spirometry
- Any previous bronchial provocation tests regardless of age

4. Current evidence of asthma

One positive result is required, but if a bronchial provocation test is negative, athletes can submit the application with the medical file and negative test for consideration.

The evidence must include either:

- Reversible airway obstruction:
 - evidence of airway obstruction with a 12% increase in FEV1 after the administration of an inhaled Beta-2 agonist, or
- Bronchial Provocation tests
 - Mannitol – 15% fall in FEV1
 - Hypertonic Saline – 15% fall in FEV1
 - EVH – 10% fall in FEV1
 - Exercise Challenge tests – 10% fall in FEV1
 - Methacholine – 20% fall in FEV1

Helpful Hints

- Ensure the athlete ceases inhaled steroids and long acting Beta-2 agonists before the test (a minimum of 24 hours is suggested) and short acting Beta-2 agonists for at least 8 hours prior to the test. The longer an athlete is off the medication, the more likely that he/she will return a positive BDT or BPT.
- If an athlete is unsure whether they are in an RTP or the DTP should contact their National Sporting Organisation.

You must supply **appropriate and separate medical evidence** with your application.

Applications will be returned if there is insufficient supporting medical evidence.