International Association of Athletics Federations

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M/24/03
Monaco, 3 July 2003

To: MEMBER FEDERATIONS
Copy: Council Members
Committee Chairpersons
Commission Chairpersons
Area Association Headquarters
RDCs / HPTCs

Dear General Secretary,

RE: THERAPEUTIC USE EXEMPTION

The purpose of this letter is to remind relevant parties of the need to follow IAAF procedures when applications are made for therapeutic use exemptions to take substances that are prohibited under IAAF Rules, in particular in relation to the forthcoming IAAF World Championships in Paris.

This letter applies to all first-time applications for therapeutic use exemptions and to all renewal applications for existing therapeutic use exemptions that have expired. Note that therapeutic use exemptions are only valid under IAAF Rules for one year and they must be renewed on their expiry. A change in medication shall require a new application to be filed.

Athletes who fail to make an application for an exemption or who fail to renew an existing exemption that has expired, and proceed to compete without a current exemption on file for the substance they are taking, are at risk of testing positive for a prohibited substance and of being sanctioned for a doping offence in accordance with IAAF Rules.

Note: Athletes applying for a therapeutic use exemption for the use of beta-2-agonists, as well as athletes holding a current exemption for the use of beta-2-agonists on file, should pay particular attention to the detailed information required under the IAAF's beta-2-agonists exemption procedure (see below).

Application Form for Therapeutic Use Exemptions

In accordance with Chapter 5 of the IAAF Procedural Guidelines for Doping Control, all requests for therapeutic exemptions must be made by means of written application. A copy

of the IAAF Application Form is attached and can be downloaded in PDF format from the IAAF website at: www.iaaf.org>Downloads>Publications.

The Application Form should be sent to the IAAF:

- by mail: 17, Rue Princesse Florestine, BP 359, MC-98007, Monaco; or
- by confidential fax: 377 93 50 83 95.

Careful attention should be paid to ensuring that all relevant medical documents are provided in support of an application. A failure to do so may delay a proper review of the application being made.

Application Forms in connection with therapeutic use exemptions for the forthcoming World Championships should be submitted to the IAAF **no later than 10 August 2003**.

Application for Exemptions to Use Beta-2-Agonists

In response to a generally recognised increase in the use of beta-2-agonists by athletes, the IAAF Council has endorsed a recommendation from the IAAF Medical Committee to require more detailed information from applicants who seek an exemption for the use of beta-2-agonists for asthma and/or exercise-induced broncho-constriction.

The required information can be summarised in 3 categories as follows:

1. Detailed Medical Records
2. Spirometry Test Results
3. Provocation Test Results

A copy of the IAAF's Beta-2-Agonists Exemption Procedure setting out in detail the information that is required is attached and can also be viewed on the IAAF website: www.iaaf.org>Downloads>Publications.

To whom does this procedure apply?

The beta-2-exemption procedure applies to:

1. all first-time applications for exemptions to use beta-2-agonists; and

2. all renewal applications for exemptions where the previous 12 months authorisation has expired (or will expire prior to the World Championships).

Athletes who have a current valid exemption for the use of beta-2-agonists on file are only required to provide the IAAF with a copy of their detailed medical records. These will be reviewed by the IAAF who may require the athletes concerned to undergo further testing, if necessary.

Where must applications be sent?

The IAAF Procedural Guidelines provide that applications for exemptions to use beta- 2-agonists may be sent to the IAAF or to the relevant body of an athlete's National Federation. It is strongly recommended that applications from international athletes be filed (together with all supporting documents) directly to the IAAF. In the event that a National Federation receives an application from an athlete whom it knows to be competing internationally, or whom it knows may compete internationally, this application should be forwarded immediately (together with all supporting documents) to the IAAF.

What is the time limit for applications for the Paris World Championships?

The deadline for the receipt of applications and renewal applications for exemptions to use beta-2-agonists at the World Championships (and for the receipt of detailed medical records only from athletes with a current exemption on file) is **10 August 2003**.

Further questions/Help

If there are any further questions arising from this letter or regarding the relevant procedures for applications for therapeutic use exemptions, please contact the IAAF Anti-Doping Department for further information on: 377 93 10 88 89/79 (tel) or 377 93 50 83 95 (fax) or beta2exemptions@iaaf.org (e-mail).

Yours sincerely,

István Gyulai
General Secretary

IAAF BETA-2-AGONISTS EXEMPTION PROCEDURE

Under IAAF Rules, the administration of the beta-2-agonists salbutamol, formoterol, salmeterol or terbutaline may be permitted by inhalation where prescribed for therapeutic purposes by properly qualified medical personnel and where prior clearance has been given for such administration.

In response to a generally recognised increase in the use of beta-2-agonists by athletes, the IAAF Council has recently endorsed a recommendation from the IAAF Medical Committee to require more detailed information from applicants who seek an exemption for the use of beta-2-agonists for asthma and/or exercise-induced broncho-constriction.

The IAAF will now require applicants to provide an accompanying letter to their exemption applications, signed by a Respiratory Specialist or a National Federation Team Physician, including the following documentation:

1. Detailed Medical Records

Medical records should include:

- A precise diagnosis of the individual's condition requiring the use of beta-2-agonists.

- All relevant information concerning the individual concerned and his condition:
  - age of onset
  - symptoms suggesting airway obstruction following exercise, upper respiratory infection at rest and at night and/or during the pollen season.
  - identified triggering factors
  - past history of atopic disorders and/or childhood asthma
  - past physical examinations
  - results of skin prick tests or RAST to document the presence of allergic hypersensitivity.

- Any specific information concerning the individual's coughing during or post-exercise, dyspnoea, shortness of breath, wheezing, chest tightness or excess sputum.

- Details of all consultations with physicians qualified in the treatment of asthma and details of any attendance in hospital emergency departments for treatment or admission to hospital for treatment of acute exacerbation of asthma.

- Details of the individual's currently prescribed medication and any other medication prescribed in the last 6 months. Details of medication in the 3 months prior to provocation tests (see below) must also be notified.

2. Resting Spirometry Test Results

Athletes must present the results of a Spirometry Test (resting) together with the following data: FEV_1, FVC, FEV_1 / FVC presented both as an actual and % predicted value. Graphic evidence (spirometry of flow volume tracings) must also be submitted.

3. Provocation Test Results

Athletes must also present a positive test result from one of the following recognised provocation tests:

a) Bronchodilator test:

A positive test result shall be defined as:

- a 15 % or greater increase in FEV_1 calculated as a percentage of the baseline FEV_1

OR

- a 12 % or greater increase in FEV_1 on predicted FEV_1

in either case, after the administration of an inhaled permitted beta-2-agonist. Graphic evidence (spirometry of flow volume tracings) must be submitted in support of the result.

b) Bronchial provocation test:

A Bronchial provocation test will take the form of an exercise test in the laboratory or in the field or a eucapnic voluntary hyperpnoea test (EVH).

A positive test result will be obtained if Airway Hyper-Responsiveness (AHR) is confirmed with a fall of 10% or more in FEV_1 in the post-test period. Graphic evidence (spirometry of flow volume tracings) must be submitted in support of the result.

c) Bronchial provocation test with inhaled methacholine:

A positive test result will be obtained if AHR is confirmed with:

- a PC_{20} FEV_1 equal to or less than 2 mg/ml;

OR

- a PD_{20} FEV_1 equal to or less than a cumulative dose of 1 micromol or 200 micrograms or 20 breath units in steroid-naïve subjects.

In the case of individuals on daily inhaled corticosteroid treatment of more than 3 months duration, a positive test result will be obtained if AHR is confirmed with:

- a PC_{20} FEV_1 equal to or less than 13.2 mg/ml;

OR

- a PD_{20} FEV_1 equal to or less than a cumulative dose of 6.6 micromol, or equal to or less than 1320 micrograms or 130 breath units.

d) Broncho-constrictor test:

A positive test result for a Broncho-constriction test is defined as a fall of 15 % or more in FEV_1 after the subject inhaling a hypertonic aerosol (4,5 % saline commonly used).

Note: Peak Expiratory Flow Rate (PEFR) measurements will not be accepted.

Abbreviations

FEV_1 = Forced expired volume in one second.

FVC = Forced Vital Capacity

MEF25-75 = Mid-expiratory Flow from 25% to 75%.

FEV_1 / FVC = Ratio of FEV_1 to FVC expressed as a percentage.

PC_{20} FEV_1 = Is the provocative concentration of methacholine causing a 20% fall in FEV_1

PD_{20} FEV_1 = Is the provocative dose of methacholine causing a 20% fall in FEV_1

References:

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7. Sterk PJ, Fabri LM, Quanjer PH, et al. Airway responsiveness: Standardized challenge testing with pharmacological, physical and sensitizing stimuli in adults. Eur Respir J, 1993 ; 6 (Suppl 16) :53-83.