



HA REGULATIONS

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What is hyperandrogenism?

Hyperandrogenism (HA) is a term used to describe the excessive production of androgenic hormones in females. The androgenic hormone of specific interest for the purposes of the new Regulations is the performance enhancing hormone, testosterone.

What is the rationale for the IAAF seeking to regulate the eligibility of females with HA?

The IAAF's role as the international governing body for the sport of Athletics is first and foremost to guarantee the fairness and integrity of the competitions that are organised under its Rules. Men typically achieve better performances in sport because they benefit from higher levels of androgens than women and this is predominantly why, for reasons of fairness, competition in Athletics is divided into separate men's and women's classifications. By extension, since it is known today that there are rare cases of females with HA competing in women's competitions, in order to be able to guarantee the fairness of such competitions for all female competitors, the new Regulations stipulate that no female with HA shall be eligible to compete in a women's competition if she has functional androgen levels (testosterone) that are in the male range.

Moreover, from the athlete's health perspective, there is a scientific consensus as regards the importance of determining the presence (and source) of high levels of androgens in females. The early diagnosis of HA is considered critical to an effective therapeutic strategy¹.

How has the IAAF gone about preparing the new Regulations?

Eighteen months ago, the IAAF set up a working group of experts to review its existing gender policies and to come up with a suitably adapted approach for regulating the eligibility for female competition of (i) females with HA and (ii) females who have undergone male-to-female sex reassignment. The IAAF expert group worked over this period in close co-operation with the IOC Medical Commission and with other recognised leading experts in the field (science, law, ethics, sport, athletes, women's groups and intersex organisations).

A full list of the international meetings in which the IAAF working group participated is as follows:

2009

December IAAF Expert Working Group, Monaco

2010

January IOC/IAF DSD Meeting, Miami

May IAAF Expert Working Group, Monaco

September IOC/IAAF Working Session, Stockholm

October IOC HA Expert Working Group, Lausanne

2011

February IOC/IAAF Working Session, Monaco

April IAAF Council Meeting, Daegu

¹ American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the diagnosis and treatment of hyperandrogenic disorders. *Endocrine Practice* 2001; Vol 7(no. 2)

On 5 April 2011, the IOC Executive Board took a decision to introduce regulations governing the eligibility of females with HA to compete in women's competitions at the London 2012 Olympic and Paralympic Games and at the same time recommended to international sports federations to introduce regulations adapted to the specificities of their individual sports. The IAAF Council adopted the new Regulations in the sport of Athletics a week later on 12 April 2011.

What will become of the IAAF's existing Gender Verification Policy?

The IAAF's existing Gender Verification Policy will be abandoned upon the entry into force of the new Regulations (1 May 2011). Henceforth, under IAAF Rules, if an athlete is recognised as a female in law, she is eligible to compete in women's competition in Athletics provided that she complies with IAAF Rules and Regulations.

To which athletes do these new Regulations apply?

The new Regulations are mandatory for all athletes who compete or who seek to compete in International Competitions (as defined in IAAF Rules). No athlete with HA shall be eligible to compete in an International Competition until her case has been evaluated in accordance with the Regulations. Outside of International Competitions, the Regulations are recommended for implementation at national level but they are not mandatory.

What do the new Regulations provide?

In summary, once a potential case is known, the Regulations provide first for a medical assessment of the athlete (to be conducted at different levels – initial clinical assessment, preliminary endocrine assessment or full examination at a specialist reference centre - depending on the circumstances of the case) the purpose of which assessment is to ensure that all information is obtained that may be of potential relevance to a determination of the athlete's eligibility to compete in women's competition. This information is referred in confidence and on an anonymous basis to an Expert Medical Panel who will make a recommendation to the IAAF as regards the eligibility of the athlete concerned. The final decision on an athlete's eligibility lies with the IAAF taking into account the recommendation that has been made.

A flowchart designed to outline clearly how the process works is attached to these Notes.

How will potential cases of females with HA be identified in the first place?

First, any athlete who has previously been diagnosed with HA and who seeks to compete in an International Competition shall be required to notify the IAAF Medical Manager in confidence so that her case may be evaluated in accordance with the Regulations.

The IAAF Medical Manager may also initiate a confidential investigation into an athlete's case if he has reasonable grounds for believing that a case of HA may exist. Reasonable grounds for belief may be derived from any reliable source, including an athlete approaching the IAAF or her National Federation for clarification on an associated medical condition, the results from a routine pre-participation examination, the results from a routine drug test showing an abnormal profile within the athlete's Athlete Biological Passport or confidential information that is received by the IAAF Medical Delegate or IAAF Medical Manager. All cases managed under the Regulations will be treated by the IAAF in strict confidence.

What is the role of the Expert Medical Panel in the process?

The Expert Medical Panel plays an important role in two stages of the process. First, upon referral of a potential case by the IAAF, it is for the Expert Medical Panel to determine, based on the preliminary medical information available, whether to refer an athlete for a full examination and diagnosis at a specialist reference centre. Secondly, following diagnosis at the specialist reference centre, if an athlete with HA states an intention to continue competing in Athletics, it falls to the Expert Medical Panel to review all potentially relevant information in the athlete's case and to make a recommendation to the IAAF whether the athlete is eligible to compete in women's competition according to the criteria specified in the Regulations.

Who is on the Expert Medical Panel?

The IAAF has appointed a pool of independent international medical experts who are specialised in the field of HA (the full list is set out in Appendix 1 of the Regulations). In the event of a potential case, the IAAF Medical Manager shall appoint an Expert Medical Panel to sit on the case which will usually be composed of a Chairman and two other experts. The Expert Medical Panel conducts itself at all times under strict confidentiality and without knowing the identity of the athlete concerned.

Where are the specialist reference centres located?

The IAAF has so far arranged for specialist reference centres to be set up in the US, Brazil, Sweden, France, Japan and Australia. The IAAF continues to search for a reference centre with the relevant specialist expertise in Africa.

Can an athlete compete pending the outcome of a decision on eligibility in her case?

If the Expert Medical Panel refers a case for full examination and diagnosis by a specialist reference centre, it may at the same time make a recommendation that the athlete is provisionally eligible to compete in women's competition pending the outcome of the examination. The athlete shall be notified in such event, however, that, following diagnosis and further review of her case by the Expert Medical Panel, if she is found not to be eligible under the Regulations, then any results that she has obtained during the period of provisional eligibility shall be annulled.

What are the criteria for determining an athlete's eligibility under the Regulations?

The Expert Medical Panel shall recommend that a female athlete is eligible to compete in women's competition if (i) she has androgen levels outside of the male range or (ii) she has androgen levels within the male range but can establish that she derives no advantage from such levels. Androgen levels for these purposes are measured by the concentration of Total Testosterone in serum. The normal male range of Total Testosterone is $\geq 10\text{nmol/L}$.

What if an athlete is found by the Expert Medical Panel not to meet the specified criteria for eligibility?

In such a case, the Expert Medical Panel may specify conditions under which it would be acceptable for the athlete to compete. These conditions may necessitate the athlete undergoing treatment by her personal physician to normalise her androgen levels and, in such a case, it would be the athlete's responsibility, in close consultation with her medical

team, to decide on the advisability of proceeding with such treatment. If an athlete does decide to undergo treatment as a means to continue participating in women's competition, before returning to such competition, her case would be referred back to the Expert Medical Panel to satisfy itself that the conditions previously imposed had been met. The IAAF would then be responsible for monitoring the athlete's compliance with the conditions on an on-going basis by conducting regular testing of the athlete, including on an unannounced basis.

Will the IAAF be involved in carrying out medical diagnosis of an athlete and/or prescribing treatment?

No. Diagnosis will always be carried out by medical experts at specialist reference centres that are independent of the IAAF and treatment, if any, will be prescribed by the athlete's supervising physician. The IAAF will not be involved in either process. The IAAF's role is strictly limited to deciding on the eligibility of such athletes to compete in its women's competitions.

Will athletes be obliged to undergo medical assessment and/or treatment?

No. Although there is a consensus within the scientific community that early diagnosis and treatment of females with HA is critical to an effective therapeutic strategy, athletes cannot be forced to undergo medical assessment and/or treatment. However, if an athlete declines, fails or refuses to undergo assessment or is otherwise not compliant with the Regulations, she shall not be eligible to compete in women's competition.

Who will pay for the medical assessment and treatment?

The IAAF will pay for athletes to attend a full examination and diagnosis at the nearest specialist reference centre to which they are located. If an athlete requires on-going treatment following such diagnosis, however, this would be the athlete's financial responsibility.

Is Athletics the only sport to have such regulations concerning female athletes with HA?

For the time being, the IAAF is the only sport to have such regulations in place. It is nevertheless anticipated, following the IOC's specific recommendations to international federations on the subject last month (see above), that other sports are likely to follow suit in the near future.

Will the Regulations be kept under review?

Yes. In approving adoption of the new Regulations last month, the IAAF Council specifically commented upon the need to keep them under regular review, notably, in line with any future developments made in the science in this area. The Regulations should therefore be seen as a 'living' document that will be subject to review and updating from time to time as may be necessary.