

# WORLD ATHLETICS ELIGIBILITY REGULATIONS FOR TRANSGENDER ATHLETES

*(Effective as from 1 October 2019)*

The World Athletics Eligibility Regulations for Transgender Athletes (Transgender Regulations) will come into effect on 1 October 2019 and replace the IAAF Regulations Governing Eligibility of Athletes who Have Undergone Sex Reassignment to Compete in Women's Competition.

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## 1. Introduction

- 1.1 The term '**Transgender**' is used in these Regulations to refer to individuals whose gender identity (i.e. how they identify) is different from the sex designated to them at birth, whether they are pre- or post-puberty, and whether or not they have undergone any form of medical intervention.
- 1.2 World Athletics, as the international federation responsible for the global governance and regulation of the sport of Athletics, has adopted these Regulations further to Constitution Article 4.1j and Competition Rule 141 in order to facilitate the participation of Transgender athletes at the international level of the sport in the category of competition that is consistent with their gender identity, in accordance with the following imperatives:
  - 1.2.1 World Athletics needs to establish conditions for participation in the sport of Athletics, including eligibility categories, that (a) protect the health and safety of participants; and (b) guarantee fair and meaningful competition that displays and rewards the fundamental values and meaning of the sport:
    - (a) World Athletics wants its athletes to be incentivised to make the huge commitments required to excel in the sport, and so to inspire new generations to join the sport and aspire to the same excellence. It does not want to risk discouraging those aspirations by permitting competition that is not fair and meaningful.
    - (b) Most relevantly for present purposes, because of the significant advantages in size, strength and power enjoyed (on average) by men over women from puberty onwards, due in large part to much higher levels of androgenic hormones, and the impact that such advantages can have on sporting performance, it is necessary to have separate competition categories for males and females in order to preserve the safety, fairness and integrity of the sport, for the benefit of all of its participants and stakeholders.
  - 1.2.2 World Athletics wishes to be as inclusive as possible, to impose only necessary and proportionate restrictions on eligibility, and to provide a clear path to participation in the sport for all:
    - (a) World Athletics recognises that Transgender athletes may wish to compete in Athletics in accordance with their gender identity. World Athletics wishes to encourage and facilitate such participation, on conditions that go only so far as is necessary to protect the safety of all participants and to deliver on the promise of fair and meaningful competition offered by the division of the sport into male and female categories of competition.
    - (b) The eligibility conditions established in these Regulations are driven solely by the desire to guarantee fairness and safety within the sport. In no way are they intended as any kind of judgement on or questioning of the gender identity or the dignity of any Transgender athlete.
  - 1.2.3 The need to respect and preserve the dignity and privacy of Transgender athletes, and to avoid improper discrimination and stigmatisation on grounds of gender identity, is paramount. All cases arising under these Regulations must

be handled and resolved in a fair, consistent and confidential manner, recognising the sensitive nature of such matters.

- 1.3 These Regulations reflect a broad medical, scientific and legal consensus as to the approach required to achieve the imperatives identified above, and are based on the principles of:
- 1.3.1 the IAAF Regulations Governing Eligibility of Athletes who Have Undergone Sex Reassignment to Compete in Women's Competition (1<sup>st</sup> of May 2011);<sup>1</sup>
  - 1.3.2 the IOC Consensus Meeting on Sex Reassignment and Hyperandrogenism (2015);<sup>2</sup> and
  - 1.3.3 the subsequent discussions and exchanges between medical experts, sports physicians, legal counsel, human rights experts, and transgender representatives.
- 1.4 These Regulations will come into effect on 1 October 2019 and will apply both to cases arising prior to that date and to cases arising after that date. They are binding on and must be complied with by athletes, National Federations, Areas, Athlete Representatives, Member Federation Officials, and all other Applicable Persons. These Regulations will be subject to periodic review to take account of any relevant scientific or medical developments and may be amended from time to time by World Athletics, with such amendments to take effect from the date specified by World Athletics when it issues the amendments.
- 1.5 Since the Regulations are intended to operate globally, regulating the conditions for participation in international-level events, they are to be interpreted and applied not by reference to national or local laws, but rather as an independent and autonomous text, and in a manner that protects and advances the imperatives identified above.
- 1.6 In the event an issue arises that is not foreseen in these Regulations, it will be addressed by World Athletics in a manner that protects and promotes the imperatives identified above.
- 1.7 The words and phrases used in these Regulations that are defined terms (denoted by initial capital letters) shall have the meanings specified in the Constitution, or (in respect of the following words and phrases) the following meanings:

**Competition Rules** means the rules of competition of World Athletics, as amended from time to time.

**Expert Panel** means a panel with appropriate knowledge and expertise, appointed by World Athletics to perform the functions set out in these Regulations (see Appendix II).

**International Competitions** means the competitions in the World Athletics Series (as described in the Rules), the Athletics programme on the Olympic Games and the other

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<sup>1</sup> See <https://www.iaaf.org/about-iaaf/documents/health-science>.

<sup>2</sup> See <https://stillmed.olympic.org/media/Document%20Library/OlympicOrg/IOC/Who-We-Are/Commissions/Medical-and-Scientific-Commission/EN-IOC-Consensus-Meeting-on-Sex-Reassignment-and-Hyperandrogenism.pdf>.

competitions organised by or on the behalf of World Athletics or as specified in the Competition Rules and Regulations (Rule #1)

**Medical Manager** means a person who is appointed by World Athletics to act on its behalf in matters arising under these Regulations.

**Regulations** means these Transgender Regulations, as amended from time to time.

**Transgender** has the meaning given to that term in clause 1.1.

**Transgender Female Eligibility Conditions** has the meaning given to that term in clause 3.2.

**World Record** has the meaning given to that term in the Competition Rules.

## 2. Application

- 2.1 These Regulations establish the conditions enabling Transgender athletes to compete in International Competition, or to be eligible to set a World Record in a competition that is not an International Competition, in the competition category that is consistent with their gender identity. Further guidance on certain medical aspects can be found in Appendix I.
- 2.2 A Transgender athlete who wishes to participate in an International Competition, or to be eligible to set a World Record in a competition that is not an International Competition, agrees, as a condition to such participation:
  - 2.2.1 to comply in full with these Regulations;
  - 2.2.2 to cooperate promptly and in good faith with the Medical Manager and the Expert Panel in the discharge of their respective responsibilities under these Regulations, including providing them with all of the information and evidence they request to assess his/her compliance and/or monitor his/her continuing compliance with the eligibility conditions referred to in these Regulations;
  - 2.2.3 (to the fullest extent permitted and required under applicable data protection and other laws of the Principality of Monaco) to the collection, processing, disclosure and use of information (including his/her sensitive personal information) as required to implement and apply these Regulations effectively and efficiently;
  - 2.2.4 to follow exclusively the procedures set out in clause 7 to challenge these Regulations and/or to appeal decisions made under these Regulations, and not to bring any proceedings in any court or other forum that are inconsistent with that clause; and
  - 2.2.5 to provide written confirmation of his/her agreement with clauses 2.2.1 to 2.2.4 upon request by World Athletics.
- 2.3 An athlete may revoke at any time, with or without giving reasons, the consent that he/she has granted in accordance with clause 2.2. In that event, the athlete will be deemed to have withdrawn any claim to satisfy the eligibility conditions for Transgender athletes set out in clause 3.

- 2.4 Every person and entity under the jurisdiction of World Athletics (including any person who brings him/herself within the jurisdiction of World Athletics by providing information to World Athletics pursuant to clause 5.4 of these Regulations):
- 2.4.1 is bound by and must comply in full with these Regulations, including in particular only providing accurate and complete information, and not providing any information in bad faith or for any improper purpose; and
  - 2.4.2 must cooperate promptly and in good faith with the Medical Manager and the Expert Panel in the discharge of their respective responsibilities under these Regulations.
- 2.5 Each Member Federation must cooperate with and support World Athletics in the application and enforcement of these Regulations, and to observe strictly the confidentiality obligations set out below.
- 2.6 It is recommended that each Member Federation adopts its own regulations to determine the eligibility of Transgender athletes to compete in events taking place under its own jurisdiction. At the level of national championships (or similar), it is recommended that these Regulations be followed. At lower levels, however, less stringent eligibility requirements may be imposed, where appropriate. For the avoidance of doubt, however, anything that the Member Federation does, or does not do, at national level will not affect the eligibility of Transgender athletes to compete in International Competition. That will instead be determined exclusively by reference to these Regulations.

### **3. Eligibility Conditions For Transgender Athletes**

#### **3A. Eligibility conditions for Transgender male athletes**

- 3.1 To be eligible to participate in the male category of competition at an International Competition, or to set a World Record in the male category of competition in any competition that is not an International Competition, a Transgender male athlete must provide a written and signed declaration, in a form satisfactory to the Medical Manager, that his gender identity is male. As soon as reasonably practicable following receipt of such declaration, the Medical Manager will issue a written certification of that athlete's eligibility to compete in the male category of competition in International Competition and to set a World Record in the male category in a competition that is not an International Competition.
- 3.1.1 To ensure that certification is received in good time, the athlete should provide the declaration to the Medical Manager at least six weeks in advance of the first International Competition in which he wishes to participate in the male category of competition.

#### **3B. Eligibility conditions for Transgender female athletes**

- 3.2 To be eligible to participate in the female category of competition at an International Competition, or to set a World Record in the female category of competition in any competition that is not an International Competition, a Transgender female athlete must meet the following requirements (together, the **Transgender Female Eligibility Conditions**) to the satisfaction of an Expert Panel, in accordance with clause 4:

- 3.2.1 she must provide a written and signed declaration, in a form satisfactory to the Medical Manager, that her gender identity is female;
- 3.2.2 she must demonstrate to the satisfaction of the Expert Panel (on the balance of probabilities), in accordance with clause 4, that the concentration of testosterone in her serum has been less than 5 nmol/L<sup>3</sup> continuously for a period of at least 12 months; and
- 3.2.3 she must keep her serum testosterone concentration below 5 nmol/L for so long as she wishes to maintain her eligibility to compete in the female category of competition.

### **3C. Provisions applicable to all Transgender athletes**

- 3.3 For the avoidance of doubt, no athlete will be forced to undergo any medical assessment and/or treatment. It is the athlete's responsibility, in close consultation with his/her medical team, to decide on the advisability of proceeding with any assessment and/or treatment.
- 3.4 For the further avoidance of doubt, the following are not required in order for a Transgender athlete to compete at an International Competition, or to be eligible to set a World Record in a competition that is not an International Competition, in the category of competition that is consistent with his/her gender identity (because such requirements are not relevant to the imperatives identified above):
  - 3.4.1 legal recognition of the athlete's gender identity as the athlete's sex; or
  - 3.4.2 surgical anatomical changes.
- 3.5 Once a Transgender athlete has satisfied the relevant eligibility requirements and has started participating in International Competition in the category of competition consistent with his/her gender identity, he/she may not then switch back to participating in the other gender category in International Competition unless and until (a) at least four years have passed since the first International Competition in which he/she participated as a Transgender athlete; and (b) he/she satisfies all of the conditions for eligibility to compete in the other gender category.
- 3.6 For the avoidance of doubt, the eligibility conditions for Transgender athletes set out in this clause 3 operate without prejudice to the other eligibility requirements that are applicable to all athletes (Transgender or otherwise) under the rules of World Athletics, which must also be satisfied at all relevant times. In particular, nothing in these Regulations is intended to undermine or affect in any way any of the requirements of the World Anti-Doping Code, of the WADA International Standards (including the

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<sup>3</sup> For purposes of these Regulations, all measurements of serum testosterone must be conducted by means of liquid chromatography coupled with mass spectrometry. The decision limit of 5 nmol/L is a conservative one and is based on (among other things) Handelsman et al, *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews 2018 Oct 1;39(5):803-829. doi: 10.1210/er.2018-00020 and references cited within that paper. The decision limit also takes into consideration that, for clinical purposes, the Endocrine Society Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons recommends that transgender females should have serum testosterone levels of less than 50 ng/dL (i.e. approximately 1.7 nmol/L) (Hembree et al, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, J Clin Endocrinol Metab, November 2017, 102(11):1–35. doi: 10.1210/jc.2017-01658).

International Standard for Therapeutic Use Exemptions), or of the World Athletics Anti-Doping Rules. Nothing in these Regulations permits, excuses or justifies non-compliance with any of those requirements, including any requirement for an athlete to obtain a Therapeutic Use Exemption for the use of substances on the WADA Prohibited List, such as testosterone, spironolactone, or GnRH agonists.<sup>4</sup>

#### **4. Assessment By The Expert Panel**

- 4.1 A Transgender female athlete who wishes to compete in the female category of competition at an International Competition (or to be eligible to set a World Record in the female category in a competition that is not an International Competition) must file the appropriate declaration with the Medical Manager, along with a comprehensive medical history and such other evidence as is required to demonstrate her satisfaction of the Transgender Female Eligibility Conditions, including evidence addressing any of the factors set out at clause 4.4 that are applicable to her case. The athlete is responsible for ensuring that the information provided is accurate and complete, and that nothing relevant to the Expert Panel's assessment of the case is withheld. The athlete must also provide the appropriate consents and waivers (in a form satisfactory to the Medical Manager) to enable her physician(s) to disclose to the Medical Manager and the Expert Panel any information that the Expert Panel deems necessary to its assessment.
  - 4.1.1 Subject always to clause 4.6 of these Regulations, to ensure that certification is received in good time, the athlete should (assuming that the 12-month period has already been complied with) provide the declaration to the Medical Manager at least six weeks in advance of the first International Competition in which she wishes to participate in the female category of competition.
- 4.2 The Medical Manager will review the submission and, after communicating with the athlete and/or the athlete's physician to remedy any obvious deficiencies, will refer the file (in anonymised form) to the Expert Panel for assessment in accordance with the following provisions of this clause 4.
- 4.3 The Expert Panel will assess cases referred to it by the Medical Manager to determine whether the Transgender Female Eligibility Conditions have been met (or, if not, then what else the athlete must do to satisfy those conditions). It may make such enquiries or investigations as it considers necessary to carry out the required assessment effectively, including requesting further information from the athlete or the athlete's physician and/or obtaining additional expert opinion(s).
- 4.4 In making its assessment, which will be based on the guidance set out in Appendix I to these Regulations, the Expert Panel will take into account all relevant and reliable evidence, including:
  - 4.4.1 any reassignment surgeries the athlete has undertaken, including the date(s) of any such procedures and whether they took place before or after puberty;
  - 4.4.2 any other relevant treatment the athlete has received (including any pre- or post-reassignment treatment), including the dosage and frequency of such treatment;

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<sup>4</sup> See, further the WADA Transgender Athletes TUE Physician Guidelines, available at [www.wada-ama.org](http://www.wada-ama.org).



- 4.4.3 the levels of testosterone in the athlete's serum during the relevant 12-month period, as well as the current level of testosterone in the athlete's serum; and
- 4.4.4 the results of any pre- or post-reassignment monitoring.
- 4.5 If the Expert Panel has any concerns about the adequacy of the evidence provided by the athlete on any particular point, it must give the athlete a fair opportunity to try to address those concerns before it comes to its final decision.
- 4.6 The Expert Panel will complete its assessment as soon as is reasonably practicable in all of the circumstances of the case. However, in no circumstance will World Athletics or any member of the Expert Panel be liable for any detriment allegedly suffered by the athlete or anyone else as a result of the length of time taken by the Expert Panel to complete its assessment.
- 4.7 Once it has completed its assessment, the Expert Panel will send its decision in writing to the Medical Manager.
  - 4.7.1 If the Expert Panel decides that the Transgender Female Eligibility Conditions have not (yet) been met, it must explain in writing the reasons for its decision. Where applicable, it should also specify what else the athlete may do in order to satisfy those conditions (including, for example, maintaining the concentration of testosterone in her serum at less than 5 nmol/L for a longer period; monitoring; reporting; and further reviews).
  - 4.7.2 If the Expert Panel decides that the Transgender Female Eligibility Conditions have been met, the Medical Manager will issue a written certification of that athlete's eligibility to compete in the female category of competition in International Competition (and to set a World Record in the female category in a competition that is not an International Competition). That eligibility will be subject in every case to the athlete's continuing satisfaction of the Transgender Female Eligibility Conditions, including continuously maintaining her serum testosterone at a concentration of less than 5 nmol/L. The Expert Panel may specify particular means of demonstrating such continuing compliance. In any event, the athlete must produce, on request, evidence satisfactory to the Medical Manager of such continuing compliance.
- 4.8 The Expert Panel's decision will be final and binding on all parties. It may only be challenged by way of appeal in accordance with clause 7.

## **5. Monitoring/Investigating Compliance**

- 5.1 The Medical Manager may monitor an athlete's compliance with the Transgender Female Eligibility Conditions at any time, with or without notice, whether by random or targeted testing of the athlete's serum testosterone levels (and the athlete agrees to provide whereabouts information and blood samples for this purpose, and also agrees that any samples or whereabouts information that she provides for anti-doping purposes and/or any anti-doping data relating to her may also be used for this purpose) or by any other appropriate means.
- 5.2 In addition to the general power to monitor continuing compliance with the Transgender Female Eligibility Conditions, the Medical Manager may investigate, at any time:

- 5.2.1 whether an athlete who has not filed a declaration under these Regulations is a Transgender athlete who needs to establish his/her eligibility to compete in a particular competition category in accordance with these Regulations;
- 5.2.2 whether (because of a subsequent change in circumstances, subsequent learning or experience, or otherwise) it is necessary to require a Transgender athlete who has previously been determined to satisfy the Transgender Female Eligibility Conditions to undergo further assessment by the Expert Panel to determine whether she still satisfies those conditions; and/or
- 5.2.3 any circumstances that indicate potential non-compliance with these Regulations;

and in such cases the athlete in question must cooperate fully and in good faith with that investigation, including by providing blood samples upon request. Where necessary to safeguard the fairness and/or integrity of competition and/or the safety of the competitors, the Medical Manager (acting on behalf of World Athletics) may provisionally suspend the athlete from competing in International Competition (and from being eligible to set a World Record in the female category in any competition that is not an International Competition) pending resolution of the matter, provided that in such cases all reasonable endeavours should be used to complete the investigation as expeditiously as possible. Any such provisional suspension may be appealed in accordance with clause 7.2.1.

- 5.3 Only the Medical Manager may initiate an investigation under clause 5.2, and he/she should only do so in good faith and on reasonable grounds based on information derived from reliable sources, such as (for example) the affected athlete him/herself, the Member Federation to which the affected athlete is affiliated, results from a routine pre-participation health examination, or data as to serum testosterone levels and/or other data obtained from analysis of samples collected for anti-doping purposes.
- 5.4 The dignity of every individual must be respected. All forms of abuse and/or harassment are prohibited. In particular (but without limitation):
  - 5.4.1 Any person or entity (including, without limitation, any other athlete, official or Member Federation) that provides information to the Medical Manager for consideration under these Regulations is under a strict obligation:
    - (a) to ensure that the information is accurate and complete; and
    - (b) not to provide any information in bad faith, to harass, stigmatise or otherwise injure an athlete, or for any other improper purpose.
  - 5.4.2 No stigmatisation or improper discrimination on grounds of gender identity will be tolerated. In particular (but without limitation), persecution or campaigns against athletes simply on the basis that their appearance does not conform to gender stereotypes are unacceptable. Any such conduct will be considered a serious breach of these Regulations.
- 5.5 Where the Medical Manager or the Expert Panel determines that a Transgender female athlete who has previously been declared eligible to compete in the female category of competition in International Competition has failed to maintain her serum testosterone level at a concentration of less than 5 nmol/L, she may not compete in the female category of competition in International Competition (and will not be eligible to set a World Record in the female category in a competition that is not an International

Competition) until such time as she demonstrates to the satisfaction of the Expert Panel that she has maintained her serum testosterone below 5 nmol/L for a new continuous period of at least 12 months.

- 5.6 If it is determined at any time that a Transgender female athlete has competed in the female category of competition at an International Competition while having serum testosterone levels of 5 nmol/L or more, or that she set a World Record in the female category at a competition that is not an International Competition while having serum testosterone levels of 5 nmol/L or more, then (without prejudice to any other action that may be taken, but subject to clause 5.7) the Medical Manager, as per the World Athletics Chief Executive Officer's delegation of authority, may in its absolute discretion disqualify the individual results obtained by the athlete at that competition, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other rewards awarded to the athlete based on those results.
- 5.7 In cases arising under clause 5.5 or clause 5.6, the athlete will be given an opportunity to provide any explanations or comments she sees fit before any action is taken. If the Medical Manager (following consultation with the chair of the Expert Panel, if necessary) is satisfied that the athlete's failure to maintain her circulating levels of blood testosterone below 5 nmol/L was temporary and inadvertent, he will not impose any period of ineligibility pursuant to clause 5.5 or disqualify any results pursuant to clause 5.6.

## **6. Disciplinary Proceedings**

### **6.1 Where:**

- 6.1.1 an athlete competes in an International Competition in a category of competition for which he/she has not satisfied the eligibility conditions set out in these Regulations;
- 6.1.2 a Transgender athlete who has been determined to be eligible to compete in the female category of competition in an International Competition, and has not renounced that eligibility, fails to cooperate fully and in good faith with the efforts of the Medical Manager to determine her continuing compliance with the Transgender Female Eligibility Conditions;
- 6.1.3 a coach, trainer, agent or other person or entity has been complicit in a breach of or non-compliance with these Regulations by an athlete;
- 6.1.4 a person or entity breaches clause 5.4; and/or
- 6.1.5 there has been any other breach of or non-compliance with these Regulations;

World Athletics may take disciplinary action against such person/entity in accordance with its Integrity Code of Conduct.

- 6.2 In such disciplinary proceedings, an athlete may not challenge the validity of these Regulations or of any decision made under these Regulations. Instead such challenge may only be brought by way of challenge or appeal in accordance with clause 7.

- 6.3 In such disciplinary proceedings, the sanctions that may be imposed, depending on all of the circumstances of the case, will include (without limitation):

- 6.3.1 a caution, reprimand and/or warning as to future conduct;

- 6.3.2 the disqualification of individual results obtained by the athlete at International Competition, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other rewards awarded to the athlete based on those results;
- 6.3.3 a specified period of ineligibility to participate in International Competition;
- 6.3.4 a fine; and/or
- 6.3.5 if the breach involves more than two members of a national representative team of a Member Federation, or if there are multiple breaches involving such a team, appropriate sanctions on the team and/or the Member Federation (e.g., disqualification of team results; imposition of a period of future ineligibility to participate in International Competition; a fine).

## **7. Dispute Resolution**

- 7.1 The validity of these Regulations may only be challenged by way of ordinary proceedings filed before the CAS and/or as part of an appeal to the CAS made pursuant to clause 7.2.
- 7.2 The following decisions (and only the following decisions) made under these Regulations may be appealed to the CAS, in accordance with this clause 7:
  - 7.2.1 a decision by the Medical Manager to suspend an athlete provisionally from competition pursuant to clause 5.2 may be appealed by the athlete, in which case World Athletics will be the respondent to the appeal;
  - 7.2.2 a decision by the Medical Manager or the Expert Panel that the athlete may not compete in the category of competition in International Competition that is consistent with his/her gender identity may be appealed by the athlete, in which case World Athletics will be the respondent to the appeal; and
  - 7.2.3 a decision by the Expert Panel that the athlete may compete in the category of competition in International Competition that is consistent with his/her gender identity may be appealed by World Athletics, in which case the athlete will be the respondent to the appeal.
- 7.3 Any such challenge or appeal will be conducted in the English language and will be governed by the Constitution, rules and regulations (in particular these Regulations), with the laws of Monaco applying subsidiarily, and in the case of any conflict between any of the above instruments and the CAS Code of Sports-Related Arbitration currently in force, the above instruments will take precedence. The CAS will hear and determine the challenge/appeal definitively in accordance with the CAS Code of Sports-Related Arbitration provided that in any appeal the athlete will have fifteen days from the filing of the Statement of Appeal to file his/her Appeal Brief, and World Athletics will have thirty days from its receipt of the Appeal Brief to file its Answer. Pending that determination, the Regulations under challenge and/or the decision under appeal (as applicable) will remain in full force and effect unless the CAS orders otherwise.
- 7.4 The decision of the CAS will be final and binding on all parties, and no right of appeal or other challenge will lie from that decision on any ground, except as set out in Chapter 12 of the Swiss Federal Code on Private International Law.

## **8. Confidentiality**

- 8.1 All cases arising under these Regulations, and in particular all athlete information provided to World Athletics under these Regulations, and all results of examinations and assessments conducted under these Regulations, will be dealt with in strict confidence at all times. All medical information and data relating to an athlete will be treated as sensitive personal information and the Medical Manager will ensure at all times that it is processed as such in accordance with applicable data protection and privacy laws. Such information will not be used for any purpose not contemplated in these Regulations and will not be disclosed to any third party save (a) as is strictly necessary for the effective application and enforcement of these Regulations; or (b) as is required by law.
- 8.2 World Athletics will not comment publicly on the specific facts of a pending case (as opposed to general descriptions of the process and science involved) except in response to public comments attributed to the athlete or the athlete's representatives.
- 8.3 Each member of the Expert Panel must sign an appropriate conflict of interest declaration and confidentiality undertaking in relation to his/her work as a member of the panel.

## **9. Costs**

- 9.1 The costs of any medical assessment, examination, treatment, monitoring, reporting, and any other costs involved in complying with the Regulations will be borne by the relevant athlete. The standing costs of the Expert Panel will be borne by World Athletics.

## **10. Mutual Recognition**

- 10.1 Where a Transgender athlete from another sport wishes to participate in the sport of athletics, World Athletics may elect to recognise and give effect to the eligibility decision of the international federation of the other sport with respect to that athlete, provided that it is consistent with the principles set out in these Regulations, and subject to ongoing compliance by the athlete with the requirements of these Regulations.

## **11. Limitation Of Liability**

- 11.1 In no circumstances will World Athletics, any member of the Expert Panel, or any of World Athletics' employees, officers, agents, representatives and other persons involved in the administration of these Regulations be liable in any way in relation to acts done or omitted to be done in good faith in connection with the administration of these Regulations.

## **APPENDIX I: MEDICAL GUIDELINES**

### **Contents**

- 1. General background medical information**
- 2. Guidance on monitoring serum testosterone levels in transgender female athletes for eligibility purposes**
- 3. Guidance on the method for measuring serum testosterone levels for eligibility purposes**

The application of the Regulations will necessarily be highly individualised and specific to the circumstances of the particular case. These medical guidelines are only intended to provide some general guidance on certain medical aspects of the Regulations, to assist with their application in practice. All information detailed in this Appendix I is based on existing literature applicable to such cases and World Athletics or any of its representatives cannot be liable in any way for any results obtained by the procedures adopted.

### **1. General Background Medical Information**

- 1.1 Gender identity refers to an individual's self-perceived gender. This may be different to the individual's sexual anatomy, chromosomal, gonadal or hormonal sex, gender role or sex recorded at birth.
- 1.2 Because some children who present as transgender will not in fact do so as adults, early medical treatment carries significant risk. The issue is problematic because individuals who wish to avail themselves of transgender treatment will find it easier at a younger age, prior to the need to reverse opposite sex characteristics developed in puberty. A paradigm to address the tension is to use GnRH analogs (or progestins) that delay puberty in a reversible fashion until a longer-term plan is in place. GnRH analogs would be started at the first visible signs of puberty or approximately Tanner 2. Note that pre-pubertal children do not require any medical intervention.

#### **Diagnosis**

- 1.3 Diagnosis of transgender identity is usually straightforward among adults. Whether or not a given individual with a transgender identity wants to address the incongruence is a very personal decision and may be influenced by a variety of factors.
- 1.4 In order to avoid a psychiatric condition confounding the situation to such a degree that gender identity is not clear, a mental health provider is normally included on the medical management team to confirm the absence of such a confounder and to assist with transition-related stress (which can be significant).

#### **Medical treatment**

- 1.5 For transgender individuals who seek medical intervention, the most effective treatment strategy is generally to change the individual's appearance to align with gender identity.
- 1.6 The mainstay of medical treatment is hormone therapy. Many transgender individuals will also seek gender-affirming surgical interventions, with choices influenced by (among other things) access to care, technical aspects of the specific surgeries, and personal elements that must be customised to the specific patient.

- 1.7 Hormone treatment of transgender individuals follows conventional hormone paradigms, with the same concerns and effects as are seen when using the same hormones for other purposes.
- 1.8 As referenced at clause 3.6 of the Regulations, it is also important for transgender athletes to consider whether any medical treatment sought requires them to obtain a Therapeutic Use Exemption for the use of a substance on the WADA Prohibited List (such as testosterone, spironolactone or GnRH agonists). Further information can be found in the WADA Transgender Athletes TUE Physician Guidelines, available at [www.wada-ama.org](http://www.wada-ama.org).

#### Transgender male treatment strategy and typical regimens

- 1.9 Typically, hormone treatment for transgender men consists of administration of testosterone to bring the serum testosterone level up from the female range to the male range. The doses required are similar to those used for treatment of hypogonadal males. Testosterone is administered parenterally (either intramuscularly or subcutaneously) or transdermally (via gel, solution or patch).
- 1.10 A typical testosterone regimen is as follows:

#### Parenteral

- Testosterone esters (enanthate, cypionate, mixed): 50 – 250 mg IM or SC every 1-3 weeks
- Testosterone undecanoate: 750 or 1000 mg every 8-12 or 10-14 weeks

#### Transdermal

- Testosterone gel, cream or solution: 50 – 100 mg/day
- Testosterone transdermal patch: 2.5 – 7.5 mg/day

- 1.11 Most transgender men who seek medical intervention will also want chest reconstruction surgery (mastectomy). However, most transgender men will not seek genital reconstruction surgeries (phalloplasty or metoidioplasty) because of the high rate of complications, the cost (in countries where it is not part of general healthcare), and the potential for multiple surgeries (Kailas et al, Endocr Pract. 2017; 23).
- 1.12 Transgender treatment guidelines have expressed concern of possible malignancy risk in female reproductive tissues exposed to androgens for long periods. This is one reason why transgender men have commonly elected to have hysterectomy and oophorectomy early in treatment. However, because there are no data demonstrating the cancer risk, there has been a downward trend in the frequency of such surgeries.

#### Transgender female treatment strategy and typical regimens

- 1.13 For transgender women, the strategy is to decrease serum testosterone levels from the male range to the female range (i.e., from around 7.7 to 29.4 nmol/L down to 0.06 to 1.68 nmol/L (95% two-sided confidence limit)). Although more invasive than medicine alone, the easiest way to achieve the goal is with a gonad-removing surgery (orchidectomy, which may or may not be part of a genital reconstruction surgery, i.e. vaginoplasty), followed by estrogen replacement therapy appropriate for age to feminise and to protect bone health over time.

- 1.14 For transgender women treated medically, the typical hormone treatment consists of estrogen supplementation and an androgen-lowering or -blocking agent.
- 1.15 Multiple estrogen options exist. The most popular are 17 beta estradiol and conjugated estrogens (although these are not used in Europe). Depending on the individual, doses may be double to quadruple those typically given to post-menopausal women. The doses sometimes need to be higher still for individuals with testes present in order to achieve serum testosterone levels in the female range.
- 1.16 There are reports that the thrombogenicity of estrogens can be mitigated if oral administration is avoided. Although the data are not conclusive, transdermal and injectable estrogens are recommended in some countries. While transdermal estradiol is easy to monitor, injectable estradiol is more difficult to monitor than oral estrogens. The strongest data regarding estrogens relate to increased thrombogenicity with oral ethinyl estradiol specifically. Therefore, current guidelines discourage its use in favor of the other agents available.
- 1.17 One anti-androgen is spironolactone, used because of its long-term safety profile arising from its 50-year history as a potassium-sparing diuretic to treat hypertension. Higher doses are used than are required for blood pressure control, with doses of approximately 200 mg/day not unusual and doses as high as 400 mg/day sometimes observed (in divided doses if needed for the patient to tolerate).
- 1.18 Another commonly used anti-androgen is cyproterone acetate. Cyproterone acetate is more expensive in some countries than spironolactone, and it is not available at all in some countries. Recently, cyproterone acetate has been associated with slight elevations in prolactin levels not observed with other androgen-lowering agents.
- 1.19 A third anti-androgen is depot GnRH agonist therapy, used for transgender children following the regimens typical for precocious puberty. However, GnRH agonist therapy can be very effective in lowering serum testosterone levels for adult transgender women as well. There are no long-term safety data for GnRH therapy in such patients. Its use is further limited by being substantially more expensive than either spironolactone or cyproterone acetate, as well as being administered parenterally, whereas the other two are administered orally.
- 1.20 Some transgender women may also use the androgen-blocking drug finasteride, a 5 $\alpha$ -reductase inhibitor that (among other things) is intended to mitigate male-pattern baldness.
- 1.21 A typical regimen for transgender women is as follows:

### ***Estrogens***

#### **Transdermal**

- Estradiol transdermal patch: 0.025 – 0.2 mg/day (new patch placed 1-2 times per week)
- Estradiol gel: 1 – 2 mg/day

#### **Parenteral**

- Estradiol valerate or cypionate: 2 – 30 mg IM every 1-2 weeks
- Polyestradiol phosphate: 80 mg every 3-4 weeks



### Oral

- Estradiol: 2.0 – 8.0 mg/day
- Conjugated estrogens: 2.5 – 10.0 mg/day

### **Testosterone lowering or blocking agents**

- Spironolactone: 100 – 400 mg/day
- Cyproterone acetate: 25 – 50 mg/day
- GnRH agonist: 3.75 – 11.25 mg SC monthly (longer interval regimens are common too)
- Finasteride: 1 – 5 mg/day

- 1.22 Many transgender women will supplement medical treatment with gender-affirming surgeries such as (1) facial feminisation surgeries (especially sought by transgender women transitioning later in life after having been exposed to male androgen levels for a longer time period); (2) breast augmentation surgery; and (3) genital reconstruction surgery. Although society has tended to focus on genital surgery as the defining gender-affirming surgery, transgender individuals demonstrate great heterogeneity in surgical choices. Notably, less surgery may be sought than previously expected, and a higher priority than commonly appreciated may be placed on visible surgeries like facial feminisation procedures and breast augmentation rather than on genital surgeries (Kailas et al, Endocr Pract. 2017; 23).

### **Monitoring of medical treatment**

#### Transgender male monitoring

- 1.23 One concern about testosterone therapy is an increase in haematocrit (with a possible increased thrombosis risk). This risk is greatest with excessive testosterone dosage. Patients may also be advised to be aware of mood changes.
- 1.24 The typical monitoring regime includes indicated clinical examination, including blood pressure and laboratory testing, every 3 months when making changes to the regimen and then every 6-12 months thereafter. Usual monitoring includes measurement of serum testosterone (to determine success of therapy), haematocrit, and lipid profile.
- 1.25 Malignancy screening must include all body parts present regardless of whether or not they are associated with one sex or another (for example, Pap smears and mammograms for transgender men who still have cervix and breasts, respectively).

#### Transgender female monitoring

- 1.26 The biggest concern for estrogen therapy is an increased thrombosis risk, which can lead to deep venous thromboses, pulmonary embolism, or stroke. There are no data for other estrogen-dependent health concerns, although many practitioners monitor classic estrogen-sensitive laboratory values including prolactin.
- 1.27 Anti-androgen therapy of any sort may result in decreased libido. Spironolactone is a potassium-sparing diuretic, which means that sensitive individuals may have unacceptable rises in their potassium levels.

- 1.28 Usual monitoring of transgender female hormone regimens includes measurement of serum testosterone (to determine success of therapy), estrogen level (estradiol), prolactin, potassium (if spironolactone is used). The typical monitoring regime includes indicated clinical examination and laboratory testing every 3 months when making changes to the regimen, and then every 6-12 months thereafter.
- 1.29 Malignancy screening must include all body parts present regardless of whether or not they are associated with one sex or another (including prostate cancer surveillance even for transgender women who have had genital reconstruction surgery).

## References

1.30 The following (non-exhaustive) references may be of interest:

- Fung et al, *Differential Effects of Cyproterone Acetate vs Spironolactone on Serum High-Density Lipoprotein and Prolactin Concentrations in the Hormonal Treatment of Transgender Women*, J Sex Med 2016; 13: 1765e1772.
- Hembree et al, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, J Clin Endocrinol Metab, November 2017, 102(11):1–35.
- Irwig, *Testosterone therapy for transgender men*, Lancet Diabetes Endocrinol. 2017; Apr;5(4):301-311.
- Kailas et al, *Prevalence And Types Of Gender-Affirming Surgery Among A Sample Of Transgender Endocrinology Patients Prior To State Expansion Of Insurance Coverage*, Endocr Pract. 2017; 23.
- Mamoojee, Yaasir et al, *Transgender hormone therapy: understanding international variation in practice*, The Lancet Diabetes & Endocrinology, Volume 5, Issue 4, p243-246, April 2017.
- Saraswat et al, *Evidence Supporting the Biologic Nature of Gender Identity*, Endocr Pract. 2015; 21: 199-204.
- World Professional Association for Transgender Health, Standards of Care, available at [www.wpath.org](http://www.wpath.org).
- [www.uptodate.com/contents/transgender-men-evaluation-and-management](http://www.uptodate.com/contents/transgender-men-evaluation-and-management)
- [www.uptodate.com/contents/transgender-women-evaluation-and-management](http://www.uptodate.com/contents/transgender-women-evaluation-and-management)

## 2. Guidance On Monitoring Serum Testosterone Levels In Transgender Female Athletes For Eligibility Purposes

- 2.1 As discussed above, for transgender women there are a number of different treatment strategies to decrease serum testosterone from the male range to the female range (the most definitive being gonad-removing surgery). The typical clinical monitoring regime is detailed above.
- 2.2 For eligibility purposes, under the Regulations World Athletics may monitor an athlete's compliance with the Transgender Female Eligibility Conditions at any time, with or

without notice, whether by random or targeted testing of the athlete's serum testosterone levels, or by any other appropriate means.

2.3 Monitoring programmes will necessarily be highly individualised and specific to the circumstances of the particular case and should be established with the support of an endocrinologist/gynaecologist or an hormone prescribing physician experienced in the field. Particular factors to consider might include:

- Whether the athlete is pre- or post-puberty.
- Whether the athlete has undergone orchidectomy.
- The type of medical treatment used by the athlete. For example, an orchidectomised athlete may require only a limited amount of monitoring. Athletes using daily estrogen medications (oral, transdermal) that have short-term testosterone suppressive effects may require unannounced testing from time to time, whereas depot estradiol implants require less surveillance due to their longer duration of action. Similarly, athletes using daily oral spironolactone or cyproterone acetate in the form of oral daily capsules will likely need to be monitored more closely than athletes using depot gonadotropin-releasing hormone (GnRH) agonists administered every 1-3 months.
- The physiological demands of the sport and the likely performance-enhancing effect of testosterone.
- Other information collected during the course of establishing and maintaining eligibility (for example, any evidence of medication non-compliance, previous loss of eligibility, or other risk factors).

2.4 In some cases, the laboratory data obtained from an athlete's routine clinical follow-up might provide an acceptable or sufficient level of monitoring. In other cases, additional monitoring may be required.

### **3. Guidance On The Method For Measuring Serum Testosterone Levels For Eligibility Purposes**

3.1 For purposes of the Regulations, all measurements of serum testosterone levels must be conducted by means of liquid chromatography coupled with mass spectrometry (e.g. LC-MS/MS or LC-HRMS), which provides much better specificity than traditional immunoassay methods.

3.2 The method used must be validated by the laboratory carrying out the test and must also be accredited to the ISO/IEC-17025 or 15189 international standards by a recognised accreditation body that is a full member of the International Laboratory Accreditation Cooperation (ILAC). These requirements may be met by clinical laboratories as well as by WADA-accredited laboratories.

3.3 The method used must comply with assay performance criteria, including a measurement uncertainty (estimated during method validation at testosterone concentration levels close to the threshold of 5 nmol/L) of not more than 20%.

3.4 The performance of the method must be monitored through participation of the performing laboratory in appropriate proficiency testing (PT) and/or external quality assessment scheme (EQAS) round(s).

3.5 Serum samples should be collected using standardised sample collection procedures (for example, those used for anti-doping purposes). Such procedures might include the following:

- It is recommended that samples are collected in the morning (as testosterone concentration in serum decreases during the day).
- Venous blood should be collected, with the athlete remaining in a normal seated position with feet on the floor for at least ten minutes prior to providing the sample. Samples should not be collected within two hours of any physical exertion.
- A collection tube containing a clotting agent and a gel separator should be used e.g. BD Vacutainer SST-II Advance (a single sample only will be sufficient, but World Athletics may decide to collect a reserve sample as well, at its discretion).
- The sample should be transported to the laboratory in a refrigerated state. The sample should not be allowed to freeze, and temperature should preferably be maintained between 2-12°C (ideally around 4°C). A temperature data logger should be used to record the temperature of the sample during transport.
- The sample should arrive at the laboratory within 48 hours of sample collection. The sample should be centrifuged as soon as possible on arrival and stored frozen if it cannot be analysed immediately.

## **APPENDIX II: LIST OF INTERNATIONAL MEDICAL EXPERTS**

The Medical Experts referred to below, who are independent of the IAAF, have been appointed by the Council on the recommendation of the Chief Executive. Their term of appointment is four years, commencing on 1 October 2019. These Medical Experts are IAAF Officials and must comply with the Constitution and all Rules and Regulations of the IAAF, including the Integrity Code of Conduct.

<b>Name</b>	<b>Area of Expertise</b>
Prof. Guy G. T'Sjoen (BEL)	Endocrinology
Prof. Angelica Lindén Hirschberg (SWE)	Gynaecology/endocrinology
Prof. Joshua Safer (USA)	Endocrinology
Prof. David Handelsman (AUS)	Andrology
Prof. John Arcelus (GBR)	Psychiatry