

Strasbourg, 31 July 2006

T-DO (2006) 29

Anti-Doping Convention (T-DO)

Meeting of the Advisory Group on Science (T-DO SCI) Strasbourg, 11 July 2006

Meeting report

1. Opening of the meeting

Michael PETROU (Cyprus), Chair of the Advisory Group, welcomed the participants (see List of participants in Appendix 1).

The representatives of WADA, as well as the Holy See, Luxembourg, the Netherlands and Switzerland, apologised for their absence.

2. Adoption of the agenda

The agenda was adopted as set out in Appendix 2.

3. Examination of the Draft List of Prohibited Substances for 2007 and recommendations to WADA

The Chair recalled that the present draft of the Prohibited List for 2007 had been circulated as document T-DO (2006) 22. This document includes the draft list as well as the list of modifications.

S1. Anabolic agents

Additional investigation in the event of a T/E ratio higher than four

Many delegates expressed their concern regarding the high cost of isotopic ratio analysis and stated that these analyses, and the additional investigation in cases of T/E ratio higher than four, constituted a significant additional workload, not only for the accredited laboratories, but also for the Anti-Doping Organisations.

Frans DELBEKE (Belgium – Flemish Community) explained that the World Association of Anti-Doping Scientists (WAADS) conducted a survey on the results of T/E analysis. 25 out of 33 accredited laboratories replied, representing 130,018 samples. 3265 of these samples produced an adverse analytical finding in 2005. Among these, 955 (29%) of the AAF had $4 < T/E < 6$. These samples had therefore to be confirmed either by IRMS or by reviewing the results of any previous test(s) or

conducting subsequent test(s). Only 3 of the 955 samples have been confirmed (2 by IRMS and 1 by follow-up study), but not all laboratories have IRMS and also the outcomes of follow-up or previous tests are not always known by the laboratories. However, only 2 of the 789 samples analysed by IRMS contained testosterone or its precursors.

With regard to cases with T/E >10 which had been analysed with IRMS, the same survey provided the following results:

10>T/E>15: 11 confirmed, 14 not confirmed

15<T/E<20: 7 confirmed, 2 not confirmed

T/E >20: 26 confirmed, 1 not confirmed

Many experts expressed the desire to be provided with more data and information on the rationale behind this threshold of 4:1. Moreover, given that reservations have been expressed on the validity of the IRMS method, scientific background for its use would also be appreciated.

The Group:

- ***recommended that WADA maintains the threshold of (T/E) requesting additional investigations at 4 in 2007;***
- ***expressed its concerns regarding the relevance of this value with regard to the necessary workload and the limited efficiency;***
- ***urged WADA to gather and publish data:***
 - a) ***on positive results identified for the different classes of T/E values, from both the laboratories and the NADOs;***
 - b) ***on the current research on the detection method for exogenous testosterone;***
 - c) ***on the cost of the decision to lower the threshold requesting additional investigation from 6 to 4;***
 - d) ***on other information (intelligence of suspected misuse, deterrence effect of these analyses) which may be useful for deciding to keep this threshold on the list;***
- ***declared its intention to review its position for the List 2008, in light of the data available;***
- ***recommended that WADA continues to support research on analytical methods to detect exogenous testosterone;***
- ***requested the secretariat of the Monitoring Group to distribute surveys or questionnaires among the States parties in order to provide the expected information before the discussion on the List 2008, in the event that WADA cannot commit itself to releasing it;***
- ***drew the WADA secretariat's attention to the formatting of the title "Other Anabolic Agents, including, but not limited to:", which should be numbered with a "2."***

S3 Beta – 2 Agonists

The Group discussed the addition of procatenol to the list of exceptions that require an Abbreviated Therapeutic Use Exemption when administered only by inhalation, and found it logical.

The Group:

- ***agreed with the addition of procatenol as proposed by WADA.***

S5 Diuretics and other masking agents

Cecilia RODRIGUEZ (Spain) stated that the problems related to the lack of references to the thresholds in the List, will increase with the footnote which makes reference to the thresholds and sub-threshold without mentioning them explicitly. The problem of threshold which are not enacted in official documents (but, for example, are in circular letters of recommendation as is the case of GCS) may open the door to appeals in countries where the List has to be published as a legal provision.

She also reported possible problems which may occur in the future with the entry into force of the Unesco Convention and the adoption of the List by Unesco and the Monitoring Group of the Council of Europe.

Stanislas FROSSARD (Secretariat of the CoE) took note of the issues, and recommended that these issues be discussed within the Advisory Group on Legal Issues, whose next meeting will take place on 31 August 2006. He also stated that the note mentioning the substances which are subjected to analytical thresholds (in other standards) will be added to the List submitted to the Monitoring Group.

The Group thoroughly discussed the alpha-reductase inhibitors (e.g. finasteride and dutasteride). Taking note of a study on finasteride by Geyer et al¹ (from the Institute of Biochemistry, German Sport University, Cologne, Germany), the Group decided after this discussion to keep the alpha-reductase inhibitors on the List. Considering the risk of error and accidental use without TUE, the Group decided to recommend their inclusion on the list of "Specified Substances".

The Group discussed the comment "*A Therapeutic Use Exemption (for diuretics) is not valid if an Athlete's urine contains a diuretic in association with threshold or sub-threshold levels of a Prohibited Substance(s)*" and considered the case of the detection of a diuretic in a sample with a level of 19-norandrosterone below the level of 2 ng/ml, which is natural. The Group however concluded that in such cases, the identification of exogenous origin of such substances could be detected and that a TUE for diuretic would be valid. The Group therefore decided not to recommend amendment of the note.

The Group:

- *recommended that WADA includes finasteride and dutasteride on the list of Specified Substances;*
- *requested the Advisory Group on Legal Issues to prepare a draft decision to clarify the relation between the list adopted by the Monitoring Group and the list adopted under the Unesco Convention, in order to prevent conflict.*

M1 Enhancement of oxygen transfer

The group discussed the wording of this category of methods.

The Group:

- *suggested replacing "use" by "administration" in point a.:*
 - a. *Blood doping, including the administration of autologous, homologous or heterologous blood or red blood cell products of any origin.*

¹ Geyer, H., Gorius, I., Mareck, U., Thevis, M., Schanzer, W. (2006) Investigation about the effects and the detection of finasteride.

M2 Chemical and physical manipulation

The Group discussed the interpretation of the meaning of “legitimate acute medical treatment”.

Klaus MÜLLER (Germany) explained that as long as the infusion is decided on the basis of diagnosis, following the consideration of a patient’s situation, it will be considered as a “legitimate acute medical treatment”. However, in cases where a whole team systematically receives infusion after competition, it would not be seen as “legitimate acute medical treatment”.

Michael Petrou mentioned the case of discipline of athletes in sports with weight categories, where it sometimes occurs that athletes receive intravenous infusions in order to compensate for dehydration and/or nutritional deficiency caused by extreme weight loss practices, and raised the question whether such practices should not be prohibited more explicitly.

S6 Stimulants

Frans Delbeke commented on pseudoephedrine, and stated that since this substance has been removed from the List he has observed many cases of pseudoephedrine misuse. He mentioned the case of an athlete who admitted the ingestion of 320 mg in one day. Misuse of this stimulant appears to be quite common in cycling. A high level of cathin is often detected in the samples of these athletes, which suggests that the presence of cathin may be a metabolite of pseudoephedrine. He stated that he would suggest the reintroduction of pseudoephedrine on the List, with an analytical detection threshold at 25 µg/ml

Luis HORTA (Portugal) and Günter GMEINER (Austria) also reported that they had taken note of numerous cases of misuse of pseudoephedrine, in certain sports. Luis Horta also referred to a recently published article by Hodges et al², which underlined the potential performance enhancing properties of pseudoephedrine.

Katia COLLOMP (France) suggested that WADA should promote comparative studies on the physiological effects of the different types of ephedrine, as well as their dosage.

Klaus Müller underlined that this issue highlights the more general problem of the implications of removing a substance from an open list. He underlined the sensitivity of the decision to remove a substance and the importance of providing very accurate results or studies before taking such a decision.

Hans COOMAN (Belgium), also proposed to put stimulants on the List of Prohibited Substances in and out-of-competition. The rationale for this is that athletes, in certain sport, use stimulants for training or recreational purposes.

The Group:

- ***recommended that WADA puts pseudoephedrine back on the Prohibited List, as a “Specified Substance” and urged WADA, if this is done, to draw the attention of the sport community on this change in the List.***
- ***recommended that WADA includes the stimulants in the List of Prohibited Substances at All Times (in and out-of-competition).***
- ***recommended that WADA removes the second part of the last paragraph on stimulants, in order to make the following sentence: “A stimulant not expressly mentioned as an example under this section should be considered as a specified substance”.***

² Hodges, K., Hancock, S., Currell, K., Hamilton, B., and Jeukendrup, A.E. (2006) Pseudoephedrine enhances performance in 1500-m runners, *Medicine & Science in Sports & Exercise*, 38 (2), pp 329-333.

S9 Cannabinoids

Classification of cannabinoids in “Substances Prohibited in Particular Sports”

Michael STOW (United Kingdom) expressed the position of his States which is in favour of removing cannabinoids from the List.

Hans Cooman expressed the position of Belgium which would be in favour of including cannabinoids in substances prohibited in particular sport.

Michael Petrou stated that cannabinoids are placed on the List based on their capacity to indirectly enhance performance for some athletes by reducing pre-competition anxiety and promoting euphoric mood state. And also that he considers the inclusion of Cannabinoids in the List of Substances Prohibited in Competition as justified.

The Group also mentioned the number of AAF related to cannabinoids, the slow extraction of the substance which makes it difficult to distinguish recent and less recent consumption, the political issues underlying the presence of cannabinoids on the list and agreed that the right place to challenge this old and much disputed issue would be the World Anti-Doping Conference in 2007 if the criteria for including Substances and Methods on the Prohibited List are changed.

The Group:

- ***took note of the proposal of the delegates from Belgium to move the cannabinoids to the category P3 (substances prohibited in particular sports) and the position of the UK to remove them from the List.***

S9 Glucocorticosteroids

The delegates from Belgium criticised the current solution which had little sense, given that athletes who wish to misuse Glucocorticosteroids can allege dermatological problems or use a TUE. The threshold of 30 ng/ml also appeared to be much too high.

Representatives of France and Portugal recognised that the present situation is unsatisfactory.

Cecilia Rodriguez complained about the lack of description of the substances covered by this class, as well as the lack of provision defining the detection threshold (except a recommendation letter to the laboratories).

The Group:

- ***asked WADA to keep the Glucocorticosteroids on the List;***
- ***recommended that WADA considers:***
 - ***including an open list of substances as examples;***
 - ***lowering the reporting level;***
- ***expressed its concerns regarding the present misuse of Glucocorticosteroids.***

P1 Alcohol

The Group:

- ***recommended that WADA states that the threshold values mentioned are related to blood analysis.***

Specified Substances

The Group:

- *recommended that WADA completes the line on Beta-2 agonists with “except clenbuterol and salbutamol above 1000 ng/ml”.*
- *recommended the inclusion of Pseudoephedrine*
- *recommended the inclusion of finasteride and dutasteride*

4. Artificially-induced hypoxic conditions

Michael Petrou explained that this item was placed on the revised version of the Agenda after it was received from WADA consultation from its Ethical Issues Review Panel. In order to launch the discussion with background information on previously adopted decisions, Stanislas Frossard presented the previous declaration adopted by the Monitoring Group on this issue.

Declaration on the use of altitude rooms/hyperbaric chambers adopted by the Monitoring Group at its 11th Meeting on 30 – 31 March 2000 in Strasbourg:

As forbidding these techniques is not the best solution, the Group suggests warning those concerned of the risks of these processes:

High-altitude training is permitted for athletes, and it cannot be banned for specific reasons: some nations/athletes are normally located at high altitudes. Artificial environments mimicking the main consequence of high altitude (lowering of the partial pressure of oxygen, i.e. the percentage of oxygen in the inspired air) could theoretically be banned, because they are unnatural, and can be controlled.

Contrary to natural high altitude, artificial means (hypoxic chambers) are not limited to conditions corresponding to several thousand meters above sea level: their pressure or oxygen content can theoretically be expanded to unnatural, dangerous or even lethal measures.

On the other hand, the real benefit in performance enhancement will certainly depend on further conditions: while enhanced performances have been observed under specific circumstances, they may lack under other ones.

Different technical concepts play an additional role: hypobaric chambers similar to high geographical altitude provide low air pressure and lower oxygen content per inhaled volume simultaneously, whereas other chambers lower only the oxygen content (lower percentage than the normal 20%). The physiological consequences or risks of those different conditions, as well as the influence on performance, may differ.

In general, these considerations must assume technical perfection. Serious risks could occur, if the predetermined, physiologically justified parameters could not be technically guaranteed.

But the possibility of obtaining similar effects by natural (although more expensive and more time-consuming) means, should be discouraged for at least unreasonably extended use, but these methods should not be prohibited for the meantime.

Stanislas Frossard also summarised the relevant discussion of the Advisory Group held in April 2005:

Many participants to the meeting expressed the need for safety standards for the commercialised hypoxic equipments, as well as the need for adequate education, so that those “training methods” do not pose a safety hazard. Some ethical concerns were also discussed (health risks, and in particular mental health risks, equity between countries, risk of abuse or misuse, medical supervision ...).

Following the presentations and extensive discussions, the Advisory Group on Science did not recommend including artificial altitude training methods as a prohibited doping method. As such methods are artificial, they may raise some ethical issues. Such methods, designed to lower oxygen content in blood, mimic natural high altitude conditions. If such methods should be used, it should only be under controlled parameters (altitude, duration, exposure) and under medical supervision.

The Group recognised that these methods have a performance enhancing potential and underlined some health risks (i.e. inappropriate use and quality/safety of equipment). The Group expressed ethical concerns related to the fact that the method is artificial.

The WADA Ethical Committee, in its recently released new contribution on the analysis of the compliance of these methods with the spirit of sport, concluded that hypoxic chambers may be seen as not complying with the spirit of sport, as defined in the introduction of the Code.

Luis Horta expressed his doubts with regard to the criteria of passivity of the athlete which has been developed by the ethical committee, as this would also challenge methods like electro stimulation, air conditioning, baths, etc.

Many experts took the floor to raise concerns about the inclusion of these methods on the List. At present, there are 3 criteria for allowing the inclusion of prohibited substances and methods on the List, but do not make this inclusion compulsory.

Warning letters from groups of scientists, although they do not represent the scientific community in general, should also be taken into consideration.

Richard L. HILDERBRAND (USA) reported that many of the physicians attending the recent American College of Sport Medicine meeting made comments against WADA controlling hypoxic chambers.

The Group, however, underlined that being against prohibition should not be interpreted as promoting this kind of method.

The Group:

- *took note that there is, at present, no support to prohibit the hypoxic chambers through their inclusion on the prohibited list;*
- *considered that, at present, all arguments are not in favour of prohibition;*
- *expressed concerns about the negative consequences of the use of the methods and invited WADA, the sport organisations and the public authorities to express warnings against the risks of hypoxic chambers and to reconsider the issue at a later date, where appropriate;*
- *asked the secretariat to invite the Bioethics Committee to give an additional independent opinion from experts on the ethical criteria (compliance of hypoxic chambers with the spirit of sport as defined in the Code).*

5. Other matters

The secretariat informed delegates that the report of the previous meeting had been released and apologised that its adoption had not been put on the agenda of the Advisory Group, as it was unclear at the time of the adoption of the agenda whether the report would be available in both languages. This report will be submitted directly to the Monitoring Group in November. However, comments from participants can be sent to the Secretariat and will be taken into consideration with the approval of the Chair of the Group.

6. Next meeting

The next meeting of the Group will take place in spring 2007. The exact date may have to be coordinated with the other Advisory Groups and will therefore be released at the Monitoring Group meeting.

7. Close of the meeting

The Chair thanked all participants and closed the meeting.

Appendix 1

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Appendix 2

Agenda

1. Opening of the meeting
2. Adoption of the agenda T-DO (2006) 23 rev
4. Examination of the Draft List of prohibited substances and recommendations to WADA
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4. Artificially-induced hypoxic conditions T-DO (2006) Inf 8
5. Other matters
6. Next meeting
7. Close of the meeting