2019 WADA Prohibited List stakeholder consultation: review Dutch stakeholders

July 10, 2018

We would like to thank the Prohibited List Expert Group (LiEG) for giving us the opportunity to review the DRAFT 2019 Prohibited List International Standard.

Also, we would like to thank the LiEG for the 2017 WADA monitoring program figures provided by email on 13 June 2018.

Unfortunately, we have not received a letter from the LiEG explaining the rationale for the decisions made for the 2018 Prohibited List. In the last two years this letter was provided. It proved to be very helpful to understand the decision-making process and to endorse the final decisions made. We would like to ask the LiEG to reinstall this 'two year tradition'.

Fourfold contribution

In line with previous years our contribution is composed by the four Dutch stakeholders, being:

- Ministry of Health, Welfare and Sport
- Netherlands Olympic Committee*Netherlands Sports Confederation (NOC*NSF)
- NOC*NSF Athletes' Commission
- Anti-Doping Authority Netherlands

On behalf of these four stakeholders we would like to ask you to treat our review as a fourfold contribution to your consultation process.

Review criteria

We use the following criteria to review the DRAFT 2019 Prohibited List.

The proposed changes to the Prohibited List should:

- Be based on a transparent decision-making process
- Be easily explainable to the sports community
- Have strong focus on catching real cheats
- Protect the benevolent athletes
- Have minimal interference with good medical practice

We feel these criteria help us to focus on the interests of our most important target group: the true athletes. They should benefit the most from the amendments we put into practice.

General comments

Add thyroid hormones

In the 2016 Stakeholder Feedback, the LiEG claims there is no evidence of widespread misuse of thyroid hormones in sport. However, we received indications from medical professionals in the Netherlands that thyroid hormones are currently being misused by elite athletes. Colleagues from Great Britain and the United States made similar claims in recent years.

With (1) the theoretical power to cause weight loss, (2) the concomitant power to release energy substrates, and (3) the well-known and longstanding abuse in the world of bodybuilding and fitness ***(e.g. McKillop, Scott Med J, 32(2):39, 1987 and Auge & Auge, Subst Use Misuse, 34(2):217, 1999)***, we feel there is sufficient evidence that thyroid hormones are currently being misused to enhance athletic performance in elite sports. This belief has only be strengthened over the past year because of several informal discussions we have had with people in the world of elite sport, which made clear that thyroid hormone use amongst elite athletes is higher than one would expect from a medical point of view. Also, it is clear that the abuse of thyroid hormones leads to potential health risks for heart, skeletal muscle, bones, and metabolic pathways. For recent reviews on all of these effects please see *Senese et al.* ***(Frontiers in Physiology, doi: 10.3389/fphys.2014.00475)*** **or** ***Coppola et al. (World J Hepatol 2014 March 27; 6(3): 114-129)***.

On 13 December 2016 Dr Audrey Kinahan, Chair of the LiEG, wrote:

"WADA is supporting the preparation of a critical review of thyroid hormones in sport and anticipates it will be ready for publication in the very near future."

Since then, as far as we know, this critical review has never been published. Hence, we ask the LiEG to give more clarity about the current status of this review.

Consequently, in the absence of this critical review, we see no other option than to stress the importance of adding thyroxine (T4), triiodothyronine (T3), Thyroid Stimulating Hormone (TSH) and Thyrotropin-Releasing Hormone (TRH) to the 2019 Prohibited List.

Abrogate the category *Substances & methods prohibited in-competition*

We propose to create a single Prohibited List, including only substances and methods prohibited at all times. Creating such a list will improve clarity on what is allowed and what is not. Also, it will prevent the unethical misuse of stimulants, narcotics and glucocorticoids during training and recovery.

We propose to create a single Prohibited List by:

- Prohibiting the substances from class S6 both in- and out-of-competition. In order to prevent an increase in unintentional doping violations, we ask the LiEG to consider reporting thresholds for specified substances.
- Allowing the use substances from classes S7 and S9 only for those legitimately received in the course of hospital treatments, surgical procedures or clinical diagnostic investigations. Athletes who legitimately received a prohibited substance from one of these classes receive a start ban and may not enter competition for a fixed number of days.
- Allowing the use of substances from class S8 both in- and out-of-competition.

Specific comments

S1.

- The International Non-proprietary Name (INN) of ostarine is enobosarm. Please consider changing the name to enobosarm.

S2.

- The International Non-proprietary Name (INN) of hexarelin is examoralin. Please consider changing the name to examoralin.

- The International Non-proprietary Name (INN) of ghrelin is lenomoralin. Please consider changing the name to lenomoralin.

- We think it is necessary to explain the permitted status of cyanocobalamin (vitamin B12) and Platelet Derived Plasma preparations in the Prohibited List itself. This could for example be done in a similar way to the remark regarding the permitted status of clonidine in class S6 and cannabidiol in class S8.

- The text *"Additional growth factors or […] regenerative capacity or fiber type switching"* should be part of the enumeration of growth factors. Now it is incorrectly listed as a separate item. Please consider revising.

S3.

- We know the LiEG is undertaking further studies to better distinguish beta-2 agonist inhaled usage from oral usage. However, we did not hear about the outcomes of these studies yet. Therefore, we ask the LiEG again to make the incorporation and sharing of these study results a priority.

- For inhaled salbutamol the maximum is 1600 micrograms over 24 hours in divided doses not to exceed 800 micrograms over 12 hours starting from any dose. However, since a maximum of 800 micrograms over 12 hours will never exceed 1600 micrograms over 24 hours, we suggest to make it more simple and state: "*Inhaled salbutamol: maximum 800 micrograms over 12 hours starting from any dose*."

- The Prohibited List states: "*The presence in urine of salbutamol in excess of 1000 ng/mL or formoterol in excess of 40 ng/mL is not consistent with therapeutic use of the substance and will be considered as an Adverse Analytical Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of a therapeutic dose (by inhalation) up to the maximum dose indicated above."*

  Especially over the last year it became obvious that the practical framework for performing such a controlled pharmacokinetic study is not clear enough. We therefore propose to make this framework more clear and suggest WADA to publish an additional guideline document for performing controlled pharmacokinetic studies.

S4.

- We propose to allow the use of clomifene for women. We believe there are no potential performance or AAS post-cycle benefits for women to use it. At the same time, we receive multiple questions from women who suffer from fertility challenges. They need a TUE to start their clomifene therapy. Moreover, once the athlete starts the therapy, the substance can still be detected up to a year later, leading to numerous potential

moments on which the athlete can be confronted with the fertility challenges again during and after doping controls.

M1.

- We believe athletes have the right to donate blood plasma. But since this method involves the reinfusion of red blood cells, it is prohibited according to the current rules. This means that all athletes who perform their sport under the WADC - approximately 4.5 million people in the Netherlands – are not able to perform this noble and potentially lifesaving act. Also, no TUE can be granted since plasma donation does not meet at least one TUE criterion: athletes will not experience significant health problems if they abstain from this method. Furthermore, donating blood plasma is not considered to be performance enhancing and does barely influence the accuracy of the Athlete Biological Passport. Therefore, we feel this prohibition does not meet the criterion of proportionality and we suggest the LiEG to make an exemption to the current rules and explicitly allow blood plasma donation for all athletes.

- It seems odd to mention prohibited substances in the prohibited methods section. Therefore, we suggest to relocate M1.2. to S2.1.6.:

  1.6 ***Agents artificially enhancing the uptake, transport or delivery of oxygen****, e.g.*
  perfluorochemicals, efaproxiral *(RSR13) and* ***modified haemoglobin products*** *(e.g haemoglobin-based blood substitutes and microencapsulated haemoglobin products, excluding supplemental oxygen by inhalation)*

S7.

- The abuse of narcotics is limited and if these substances are abused, it constitutes medical malpractice more than doping use. Furthermore, in order to get a TUE, Registered Testing Pool athletes need to declare exactly which narcotics in what dosage will be given to them prior to the surgery. This often causes practical challenges for the athlete, the doctor as well as the TUE Committee. We therefore suggest a more practical policy for the use of narcotics and allow their use in the course of hospital treatment, surgical procedures and clinical diagnostic investigations. This policy is in line with the policy on intravenous infusions in section M2.2.

S8

- The LiEG allows the use of cannabidiol (CBD) since last year. However CBD is extracted from cannabis plants and therefore CBD products will contain varying concentrations of THC, which is still prohibited. The LiEG warns for this risk but does not provide a practical guideline for the athletes. It has led to the situation that CBD is allowed in theory, but not in practice. It also generated difficulties for athletes to obtain a TUE. They cannot get a TUE for CBD medication because CBD itself is already allowed. They also cannot get a TUE for THC because THC is not the active ingredient they need to treat their medical condition. Hence, we ask the LiEG to communicate clear guidelines on the use of CBD or to consider a re-ban in order to give the athletes more clarity.