

By e-mail to: violet.maziar@wada-ama.org, david.howman@wada-ama.org

Regarding: Netherlands reaction to draft 2012 Prohibited List International Standard
(a shared submission of four stakeholders)

Capelle aan den IJssel, 27 June 2011

Dear Mr. Howman and members of WADA's Prohibited List Expert Group,

Thank you very much for the invitation to review the draft 2012 Prohibited List International Standard. With this letter, I would like to provide you with the comments of four Dutch stakeholders, being:

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

On behalf of these four organisations I would like to ask you to treat this letter as a fourfold contribution to your consultation process.

As usual, we have used our continuous relationship with athletes, physicians, pharmacists, and scientists over the previous year to collate our remarks and comments.

Introduction

We thank you for the changes that were introduced in the Prohibited List last year; we feel the Prohibited List has increased in strength because of the changes that were introduced.

As in previous years, we would like to explain our view on the Prohibited List before commenting on specific sections of the 2012 draft. We feel it is important that a Prohibited List International Standard is compiled on the basis of the following characteristics:

- it minimises the impact on good-willing athletes, which means it is as short as possible, but as long as necessary;
- it minimises the requirements for good-willing physicians and other support personnel;
- it does not interfere with guidelines of good medical practice and focuses on the issue of doping in sports;
- it optimises the possibility to catch cheating athletes and their supporting personnel by prioritising on the criterion of performance enhancement;
- it is easily explainable to athletes, their support personnel and the general public, so these groups will not be alienated from anti-doping efforts in general.

By following these characteristics, we feel that the Prohibited List will be optimally focussed, practical, and understandable to all involved, strengthening the World Anti-Doping Program.

We would like to emphasise that these characteristics should not only lead to discussions on whether certain substances or groups of substances could be added or removed from the Prohibited List. Other possible solutions to strengthen anti-doping efforts include raising reporting thresholds, changing the rules on sanctioning for these substances, and/or limiting their prohibited status to certain sports known to have problems regarding this particular group of substances.

We kindly ask WADA to acknowledge our firm opinion in this regard, and to choose solutions that recognise the different views that exist rather than deciding in a manner which completely rejects the strongly held views of one or more Anti-Doping Organisations.

General comments

More transparency

We welcome the summary of modifications and the "Explanatory Note" that annually accompanies the release of a new Prohibited List International Standard. Yet, we feel that the process of drafting the Prohibited List and collating comments from stakeholders would benefit from even more transparency. Any change in the Prohibited List should be accompanied by an explanation why it was decided to make this change. This would help both the support of the Prohibited List and the educational efforts when introducing a new Prohibited List to the athletic community (including support personnel). In addition, we favour a process where both all stakeholder's comments and WADA's reaction to the proposals are made public. This way, it would also be better known publicly what the reactions of the different athlete's committees are, especially WADA's own athlete committee. We do our work to aid the athletes of the world, and it is especially their opinion that matters.

More clarity

Together with transparency, we feel that more clarity (and perhaps more guidance) is needed on certain substances that fall under the text "similar chemical structure or similar biological effect(s)". In the previous year, we have had three instances where WADA's interpretation of certain substances was different than we had thought initially, which makes it difficult to give clear and proper information to our "clients". Apparently, some sort of list exists in WADA's office that gives guidance on the issue whether certain substances, that are not specifically mentioned on the Prohibited List, are in fact prohibited or not. Perhaps more examples could be mentioned on the Prohibited List itself, or otherwise WADA could consider to make their interpretation public.

Working symposium

Finally, since the Code Revision process has started already, we also feel it is opportune to repeat our previous request to have a working symposium on the contents and principles of the Prohibited List in the near future. The proposed changes in the monitoring program show that the discussions on prohibiting substances in and/or out-of-competition continue, and this is just one example of an important issue that is best discussed at large, in stead of being tackled once a year in written reactions. Other topics could be the absence of potentially harmful performance enhancing substances such as thyroid hormones and nicotine and the presence of substances where these properties are doubtful (e.g. cannabinoids, narcotics, and alcohol).

We feel that such a symposium should be organised in time to be able to include the outcome in the process towards the Revision of the World Anti-Doping Code. A working symposium would provide a platform to find a common approach regarding all Prohibited List issues, especially the most controversial ones. This way, the Prohibited List International Standard could be supported by a much larger proportion of all stakeholders than in the current situation, which would seriously strengthen the World Anti-Doping Program.

S0

The proposed change ("i.e." into "e.g.") broadens the scope of this section so much, that one might argue that nutritional supplements and functional foods would become part of the definition of "non-approved substances" as well. In our view, this should not be the consequence of this section, and any possible misinterpretation should be avoided.

The main impact of section S0 is to prohibit pharmaceutical substances under development, like calstabin-ryanodine receptor complex stabilisers. In principle, the term "any pharmacological substance" limits the scope of this section to medicines only, but it should be totally clear that this is the case. The proposed text has the theoretical pitfall that a substance that is considered an official medicine in country A, but that simultaneously is regarded as a supplement in country B (and has been allowed on the market as a supplement in country B), will not be prohibited in any country.

- We recommend to explain more clearly that this section prohibits misuse of non-approved *therapeutical* substances only. A possibility would be to start the section with "Any pharmacological substance that is in the development for therapeutic use and which is not addressed...".
- Moreover, we would like to ask the List Committee to explain what prompted the proposed change. We do not see why broadening the scope of this section is necessary, and fear that this change could lead to more confusion.
- On a different note, and less important, the heading "Prohibited Substances" should be moved to a position above section S0, as this section deals with substances as well.

S1

The proposed changes in section S1-1 are supported.

We would like to make some comments on the status of clenbuterol, even though the prohibited status of this substance is beyond dispute. Recent doping cases in relation to the Chinese and Mexican meat industry have shown that this substance is a risk for non-doping athletes. In a recent national case, we have experienced what this situation can do to the personal life of an athlete. In the past, cases with endogenous nortestosterone have shown similar difficulties. The current rules of the World Anti-Doping Program allow for tackling such unexpected cases, but these procedures take several months, and the damage done to the athlete during these procedures (in terms of procedural costs, publicity, loss of employment and emotional stress) cannot be repaired.

- We would like to ask WADA, and particularly both the List Committee and the Laboratory Committee, to try and find a solution for potential unintentional Adverse Analytical Findings regarding steroids-in-meat. We feel that the World Anti-Doping Program should protect good-willing athletes at all times. A possible solution that could be implemented on relatively short notice might be to raise the reporting levels for certain substances for all WADA-accredited laboratories. Other possible solutions might be to introduce the possibility to report "atypical" findings below a certain threshold, or to

look for specific analytical approaches that may discern intentional use from unintentional use through food (presumably meat) consumption.

➤ Regarding the names of the different anabolic substances, we were advised by the Royal Dutch Pharmacists Association that sometimes an available IUPAC name is not mentioned (e.g. for oxandrolone the IUPAC name is 17 β -hydroxy-17 α -methyl-2-oxa-5 α -androstan-3-one). We recommend that all INN- and IUPAC-names are mentioned when available.

S2

In January 2011, we welcomed the removal of the methods of injecting "Platelet Rich Plasma" (PRP) or "Platelet Leukocyte Gel" (PLG) in therapeutic settings from this section. The Explanatory Note to the Prohibited List International Standard 2011 explains this status, but when the Prohibited List 2012 comes into effect this remark will no longer be easily available.

➤ Since the methods of injecting "Platelet Rich Plasma" (PRP) or "Platelet Leukocyte Gel" (PLG) involve prohibited growth factors (like IGF-1), we feel it is necessary to explain the permitted status of these methods in therapeutic settings in the Prohibited List itself, in order to avoid any confusion. This could for example be done in a similar way to the remarks regarding felypressin (in section S5) or imidazole and adrenaline (in section S6).

S3

Over the past few years, scientific literature has well established that inhaled β 2-agonists have no performance enhancing effect on endurance, strength and sprint performance in healthy athletes. In this light, it is strange to have different rules for salbutamol and salmeterol (and possibly formoterol) on one hand, and terbutaline, fenoterol and other similar substances on the other hand. In fact, this demarcation in the anti-doping rules is interfering in a physician's decision to prescribe certain medication; we have had several cases already where an athlete has been using a β 2-agonist for many years, and partly because of this optimal medication the required drop in lung function parameters during a provocation test was not reached. In such cases, the athlete is caught between the doping rules and their personal optimal medication regimen, but because of the current rules they often opt to switch their medication to salbutamol. This is a real-life example where anti-doping rules interfere too much in the physician-patient relationship, and with guidelines of good medical practice.

➤ We strongly urge WADA to allow the use of all inhaled β 2-agonists and to introduce a new threshold not just for formoterol, but also for terbutaline, fenoterol and other β 2-agonists.

S4

The move of the metabolic modulators from section M3 to this section is supported.

➤ A minor detail: the "5" preceding these modulators should be in bold.

S5

The listing of glycerol in this section continuous to prompt questions from both athletes and (medical) support personnel. It is a regular ingredient of food, medicines, and in addition it can be produced endogenously. A threshold value for this substance was announced in the Explanatory Note last year, but to our knowledge this has not yet been introduced.

➤ We strongly urge to introduce a threshold value for glycerol (this should preferably be done in a new version of TD2010MRPL). The fact that not all sorts of glycerol consumption are prohibited should be explained in either a specific note (much like the "50 mL per 6 hour" rule in section M2) or in the Explanatory Note document that will probably accompany the Prohibited List 2012.

M1

No comments.

M2

We are happy that the "50 mL per 6 hour" rule is now explicitly mentioned.

➤ A minor point: this is the only section where the word "prohibited" is repeated in each and every sentence. We suggest to leave the first sentence ("The following are prohibited") as is, and to remove the "prohibited remarks" in sentences 1, 2, and 3.

M3

The change in this section is supported. The current definition of gene doping is clear and precise.

S6

The new note regarding adrenaline is more clear and is supported.

➤ For the sake of clarity, we think it is better to include nicotine in the *-note, as the Monitoring Program itself clearly states that nicotine will be monitored as well.

➤ Text-wise, the word "are" in the **-text on local administration of adrenaline should probably be "is".

S7

To our knowledge, the abuse of this category of substances is very, very limited and if they are abused, it constitutes medical malpractice more than doping use (i.e. it is not a case where an unfair competitive edge is being sought). Frankly, we only encounter this section in relation to (questions about) abundant poppy seed use or TUE-applications regarding surgery and concomitant painkillers.

➤ Following the general characteristics we described earlier, we feel that this section is less important than other sections on the Prohibited List and that its practical influence should be lessened even further. We suggest that a remark could be made that the use of narcotics is allowed during surgical interventions, much like the felypressin remark in section S5 and the adrenaline remark in section S6.

S8

Whether cannabis use in sports should be prohibited and sanctioned by means of anti-doping rules will probably always remain a controversy. We would like to repeat our remarks of other years, that the use of a substance that is most likely to have a negative impact on athletic performance should not be part of the anti-doping program, especially when its use has been out-of-competition.

➤ We would like to ask WADA to try and find a solution that recognises our view (which we know is shared by many other stakeholders) as well as other views that exist in the world regarding the issue of "cannabinoids and doping". This might be arranged by

changes in the Prohibited List or in other WADA documents, e.g. raising the reporting threshold or changing the sanction regimen in case of a first cannabis offence. From a principal point of view, we feel it is unfair to sanction athletes on the basis of presence of a long-lasting metabolite in an athlete's sample when this particular substance is only prohibited in-competition. The work from Brenneissen et al. (Anal Bioanal Chem (2010) 396:2493–2502) gives examples on how to solve this fundamental issue in the case of cannabinoids.

S9 / P1

No comments.

P2

Last year, we contacted the WCBS to find out whether the discipline of Pool Billiards was intended to be included in the description "Billiards and Snooker (WCBS)" or not. They confirmed, after consulting WADA, that beta-blockers are indeed prohibited in the discipline of Pool Billiards as well.

➤ In order to avoid any possible confusion we suggest that the words "Billiards and Snooker" should be changed into either "Billiards sports" or "Billiards (all disciplines)".

In the "Summary of major modifications" you also invited us to comment on the prohibition of beta-blockers in general. We feel it is a particular class of substances that could serve as a perfect example on how to compile a Prohibited List that is focussed, practical, and understandable. The group of beta-blockers is one of the (unfortunately very few) examples where scientific research has shown that their (ab)use is indeed performance enhancing in certain sports, in this case in sports where top level performance is largely determined by concentration in combination with fine motor control. Together with their potentially health deteriorating effects, they qualify as doping substances in sports like pistol shooting and archery. Their effects in sports like motorcycling and automobile sports are likely to be smaller already; their prohibition in sports like wrestling, sailing and skiing/snowboarding is rather puzzling because the effect of beta-blockers on performances in these sports is likely to be (very) marginal.

In our introduction we explained that in our view the Prohibited List should be as short as possible, but as long as necessary. The wish for a more focussed list clashes at times with the general wish of harmonisation in anti-doping regulations, but we feel that in this section (regarding beta-blockers) the first argument outweighs the second. If WADA would have the final say in determining which sports activities would be listed in this section, we anticipate that the list of sports would be more logical. An easy example would be that if Bobsleigh and Skeleton remain listed, Luge should be added as well.

➤ We would like to ask WADA to decide on the type of sports where beta-blockers, and perhaps other substances, are prohibited, after consultation of the respective International Federations. In our opinion, this would lead to a more logical, and thus better explainable, Prohibited List.

The 2012 Monitoring Program

Four new additions are proposed, and as always we support the increase of knowledge by gathering new data. But we would like to emphasise beforehand that the presence of a certain substance in an athlete's sample does not constitute abuse. The new information that will be gathered on glucocorticosteroid use will likely respark discussions on whether this section should be banned out-of-competition as well, or perhaps even whether the difference between in-competition and out-of-competition should be maintained at all on

the Prohibited List. This, however, is an example of a change that is better discussed at a working symposium on Prohibited List issues, as we suggested in our general comments. Regarding glucocorticosteroids (and other substances being monitored), a certain prevalence will provide little information unless it can be compared with its prevalence in other cohorts, such as sub-elite athletes or age-matched controls.

Concluding remarks

We would be more than happy to assist if the work of the Expert Group can be helped by explaining our proposals in more depth or by providing alternative proposals or more data.

With sincere greetings and the best wishes in your efforts to compile the final version of the 2012 Prohibited List,

Also on behalf of the Ministry of Health, Welfare, and Sports, the Netherlands Olympic Committee*Netherlands Sports Confederation (NOC*NSF), and the NOC*NSF Athletes' Commission,

Anti-Doping Authority the Netherlands

Herman Ram
CEO