# THE USE OF SUPPLEMENTS & THERAPEUTIC USE EXEMPTIONS

AS WE HAVE IN THE PAST, AND IN LIGHT OF THE FACT THAT WE HAVE RECEIVED TWO VERY INTERESTING QUESTIONS FROM OUR READERS, THIS EDITION OF THE IPOD ADDRESSES TWO IMPORTANT ISSUES BOTH OF WHICH CONTINUE TO BE AT THE FOREFRONT OF ANTI-DOPING EDUCATION.

e thank all IPOD readers for their questions and gladly offer the following answers. As always, ISSF encourages all IPOD readers to direct any anti-doping related questions they may have to doris@issf-sports.org so that they may be addressed and answered in future editions.

## **QUESTION 1**

THERE ARE SO MANY DIETARY SUPPLEMENTS ON THE MARKET. AM I AT RISK OF FAILING A DRUG TEST IF I USE SOME?

## ANSWER:

While it is easy to assume that an inadvertent anti-doping rule violation can only happen to someone else, in reality anyone that uses supplements is at risk, even after taking any recommended precautionary steps.

## Dietary and nutritional supplements

Dietary and nutritional supplements are defined as products containing "dietary ingredients" intended to supplement the diet. These include vitamins, minerals, amino acids, botanicals, herbs, and substances such as enzymes, organ tissues and glandulars, metabolites, and proteins

But, the reality is two-fold. First, there continues to be significant health risks associated with nutritional supplement use, and second, adverse analytical findings and antidoping rule violations continue occurring as a result of their use.

Many athletes question why supplements receive such negative reputations. It is because nutritional supplements may intentionally contain prohibited substances or may be inadvertently cross contaminated with prohibited substances.

In many countries, the manufacturing of dietary supplements is not appropriately regulated by the government. Indeed, there is little government regulation on the supplement industry. In some cases, supplement manufacturers mislabel their products by not accurately specifying the contents or the relative amounts of each ingredient per dose. In other cases, the ingredients on the inside of the bottle may not match those listed on the outside label or package. In many cases, the undeclared substances found in the supplement can include one that is prohibited under anti-doping regulations. Finally, it is not uncommon for supplements to be cross-contaminated with banned substances during the manufacturing process if the manufacturer produces other products that contain prohibited substances.

Studies have shown that as many as 20 percent of supplements available to athletes can contain ingredients that are not declared on the label. Not surprisingly, a significant number of positive tests have been attributed to the misuse of supplements.

## ISSF's position regarding supplement use

ISSF believes that the use of supplements is a dangerous risk for athletes and advises against it. While ISSF does not recommend the use of supplements, we do acknowledge that many athletes will choose to use them to support the nutritional demands of training and travelling.

But, be forewarned, ultimately, under the principle of strict liability, athletes are responsible for any prohibited substance that may be found in their sample. As such, taking a poorly labelled dietary supplement is not an adequate defence in a doping hearing in the event that the use of the supplement results in an anti-doping rule violation.

Therefore, any shooter who uses a supplement and then tests positive for a prohibited substance will have to deal with the consequences of an anti-doping rule violation being asserted, even if the use of the prohibited substance was inadvertent.

The simple fact is that the use of most supplements poses an unacceptable risk for athletes and their athletic career. Would it not just be safer and easier to eat a balanced diet?

# New World Anti-Doping Code (WADC) and ISSF Anti-Doping Rules provisions

In order to address those situations where an athlete inadvertently ingests a contaminated supplement that results in a positive test and that an anti-doping rule violation is then asserted against him or her, the new WADC and 2015 ISSF Anti-Doping Rules now both include a new leniency provision. This new Rule (Art 10.5.1.2) looks to protect those individuals who are really not trying to cheat by ensuring that they are not punished too severely when fairness requires.

Article 10.5.1.2 reads as follows: 10.5.1.2 Contaminated Products

In cases where the Athlete or other Person can establish No Significant Fault or Negligence and that the detected Prohibited Substance came from a Contaminated Product, then the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and at a maximum, two years Ineligibility, depending on the Athlete's or other Person's degree of Fault.

Article 10.5.2.1 now offers a new type of sanctioning flexibility in those particular cases where logic, reason and justice dictate that such leniency would be warranted.

Now, if an athlete was to inadvertently use a contaminated supplement and that this resulted in an anti-doping rule violation, the athlete would have to show both that he/she had no significant fault or negligence in the matter (i.e.: that he/she was not cheating or trying to cheat and that he / she had taken considerable measure to inquire about the ingredients in the supplement before using it). Then the whole of the circumstances surrounding the case would be taken into consideration by the deciding Panel when evaluating the evidence on file and this could allow the sanction to be reduced down to a simple warning.

To be clear, the anti-doping rule violation would always be asserted, as the athlete



would always hold a certain fault, but the mandatory sanction could be greatly reduced.

Even with this new regulatory provision, meeting the burden of proving that this Rule should apply to him or her remains an onerous task for an athlete to accomplish in the course of a hearing and procedures related thereto. Therefore, ISSF believes that you are best to avoid this altogether by not using supplements.

As ISSF acknowledges that many athlete will nonetheless seek out supplements to complement their diet ISSF offers the following advice:

### Understand the risk

As indicated above, supplements may intentionally contain prohibited substances (which may or may not be clearly indicated on their label or list of ingredients) or may be inadvertently contaminated with prohibited substances. Some supplement manufacturers also mislabel their products by not accurately specifying the contents or the relative amounts of each ingredient per dose. Lastly, is not uncommon for supplements to be crosscontaminated with banned substances during the manufacturing process if the manufacturer produces other products that contain prohibited substances.

So, notwithstanding the new provisions of the Rules which seek to provide greater leniency for anti-doping rule violations caused by contaminated supplements, the reality is that there continues to be significant unregulated risks associated with supplement use.

## Evaluate the risk

All athletes have a personal responsibility to evaluate all the risks associated with supplements before using them.

ISSF reminds you all that:

- Supplements which advertise "muscle building" or "fat burning" capabilities are the most likely to contain a prohibited substances, such as anabolic agents or stimulants:
- The terms "herbal" and "natural" do not necessarily mean that the product is safe; and
- Although pure vitamins and minerals are not prohibited on their own, athletes are advised to use reputable brands and avoid those combined with other substances.

The risks associated with supplementation are clear – the responsibility for evaluating these risks ultimately rests with you.

## Minimize the risk

All athletes who will choose to use supplements should take these precautions PRIOR to using the supplement in order to minimize their risk.

Although an anti-doping rule violation will still be asserted even if the athlete can show the supplement was contaminated, proof that the utmost caution was observed will certainly be taken into consideration when the sanction is imposed and it may be reduced down to a simple warning.

These precautions may help demonstrate that you were not significantly at fault if an anti-doping rule violation occurs as a result of supplement use.

- Conduct online searches and make direct enquiries to the manufacturer when possible to obtain a written guarantee that the product is free of any substances on the WADA Prohibited List.
- Ask if the manufacturer makes any products that do contain prohibited substances at the plant where the supplement is produced. If prohibited substances are present in a manufacturing plant, the risk of crosscontamination with the supplement is very high – do not use that product.
- Ask if the manufacturer is prepared to stand behind its product. If they are not you should not use that product.
- Have proof showing the sensible and obvious precautions you took before taking the supplement to address the various risk factors associated with its use and,
- Always declare the use of the supplement on your doping control form at the time of testing.

#### Assume the risk

Never forget... finger pointing will not help you. Seeking advice from your nutritionist or other health professionals regarding dietary supplement use may help reduce, but cannot eliminate, the risk of inadvertent doping. If the use for a supplement recommended by a third party (your doctor, your parent, your nutritionist) results in an anti-doping rule violation, you cannot point fingers at them.

Athletes are responsible for everything they ingest and cannot blame others, even in the event of an unintentional adverse analytical finding.

The following passage from a Court of Arbitration for Sport opinion (CAS) advisory opinion FIFA and WADA (CAS 2005/C/976 & 986, 21 April 2006, refers to and explains this "duty of utmost caution" to which all athletes must be held. It reads at par. 73

"The WADC imposes on the athlete a duty of utmost caution to avoid that a prohibited substance enters his or her body. Case law of CAS and of other sanctioning bodies has confirmed these duties, and identified a number of obligations which an athlete has to observe, e.g., to be aware of the actual list of prohibited substances, to closely follow the guidelines and instructions with respect to health care and nutrition of the national and international sports federations, the NOC's and the national anti-doping organisation, not to take any drugs, not to take any medication or nutritional supplements without consulting with a competent medical professional, not to accept any medication or even food from unreliable sources (including on-line orders by internet), to go to places where there is an increased risk of contamination (even unintentional) with prohibited substances (e.g. passive smoking of marijuana). Further case law is likely to continue to identify other situations where there is an increased risk of contamination and, thus, constantly specify and intensify the athlete's duty of care. The Panel underlines that this standard is rigorous, and must be rigorous, especially in the interest of all other competitors in a fair competition..."

#### Final words

It is well-known that all athletes searching for a competitive edge often look to a supplement or special combination of nutrients to find it. However, research has shown that there are no quick-fix supplements for improving sports performance. Consuming a wide variety of foods and staying well hydrated are the basic cornerstones to reaching athletic potential.

Notwithstanding the new article 10.5.2.1 of the ISSF Anti-Doping Rules, which will not be applied freely and only within strict parameters, ultimately, based on the fundamental principle of strict liability, athletes are responsible for any prohibited substance that may be found in their urine sample. If athletes who chose to use vitamin, homeopathic or dietary supplements end up testing positive for a prohibited substance, this can result in a violation being declared regardless of how the prohibited substance got into their body. The bottom line remains that all athletes are responsible for everything they ingest even in the event of an inadvertent and unintentional adverse analytical finding caused by a contaminated supplement.

## **QUESTION 2**

I READ THAT AN ATHLETE WAS RECENTLY SUSPENDED FOR FAILING A DRUG TEST EVEN IF HE WAS TAKING MEDICATION PRESCRIBED TO HIM BY HIS DOCTOR TO TREAT A VALID MEDICAL CONDITION. IF SOMETHING HAS BEEN PRESCRIBED TO ME BY MY DOCTOR, IT IS SAFE TO USE IT, RIGHT?

## ANSWER:

Wrong. Just because your doctor has prescribed a medication for you to use whilst competing this does not mean you can freely use it. If the medication is on the Prohibited List, you cannot use it until you have applied for and been granted a Therapeutic Use Exemption whether by the ISSF (for all international-level athletes) or by your National Anti-Doping Organization (for all national-level athletes).

Sadly, there are still far too many antidoping rule violations that occur as a result of an athlete not applying for a Therapeutic Use Exemption when such an exemption could have and would have been granted.

All athletes hold the important responsibility of applying - at least 30 days before they plan to compete - for a TUE for any substance that they need to use and should be allowed to use because in their case it offers no performance enhancement. If an athlete does not apply for a TUE, and tests positive for the use of a substance for which a TUE would have been granted, he or she will still be subject



to the consequences under the ISSF Anti-Doping Rules and will, in most circumstances, be sanctioned.

The Rules regarding TUEs apply to all athletes, in all sports throughout the world. All athletes are subject to them.

The system is strict – but it is also fair and flexible when reason dictates it to be so. Certainly, when an athlete is prescribed a medication to treat a valid medical condition and when the dosage at which that substance is prescribed does not confer him or her a performance enhancing benefit, and where they are not other alternatives to treat his or her condition than the use of a substance on the Prohibit List, a TUE should be granted.

# The International Standard for Therapeutic Use Exemptions

The International Standard for Therapeutic Use Exemptions (ISTUE) was created with the understanding that, due to illness or medical condition, an athlete may require the Use of medications or treatments on the World Anti-Doping Agency's (WADA's) Prohibited List.

No one can argue that athletes may have illnesses or conditions that require them to take particular medications. If the medication an athlete is required to take to treat an illness or condition happens to fall under the Prohibited List, a Therapeutic Use Exemption (TUE) may give that athlete the authorization to take the needed medicine.

The purpose of the ISTUE is to ensure that the process of granting TUEs is harmonized across sports and countries.

The presence of a Prohibited Substance or its Metabolites or Markers, and/or the use or attempted use, possession or administration or attempted administration of a Prohibited Substance or Prohibited Method shall not be considered an anti-doping rule violation (ADRV) if it is consistent with the provisions of a Therapeutic Use Exemption (TUE) granted in accordance with the ISTUE (ISSF Anti-Doping Rules article 4.4.1).

A TUE is granted to an athlete under narrow, well-defined conditions. The TUE enables the athlete to take the necessary medication while competing in sport events or competitions, without resulting in a doping offence or asserted anti-doping rule violation.

The athlete must have a well-documented medical condition, backed up by reliable, relevant and sufficient medical data (ISTUE Article 6.2) that demonstrates he or she meets the criteria for grant of a TUE. This mandatory documentation supports the athlete's TUE application to his or her relevant Anti-Doping Organization (whether the ISSF or his or her NADO).

## Criteria for Granting a TUE

An athlete may be granted a TUE if (and only if) he or she can show that each of the following conditions is met:

**a.** The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the athlete would experience a significant

impairment to health if the Prohibited Substance or Prohibited Method were to be withheld (ISTUE Article 4.1(a)).

- **b.** The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the athlete's normal state of health following the treatment of the acute or chronic medical condition (ISTUE Article 4.1(b)).
- Although there may be some enhancement
  of individual performance as a result of the
  efficacy of the treatment, nevertheless,
  such enhancement must not exceed the
  level of performance of the athlete prior to
  the onset of his or her medical condition.
- **c.** There is no reasonable Therapeutic alternative to the use of the Prohibited Substance or Prohibited Method (ISTUE Article 4.1(c)).
- Three points should be noted in relation to reasonable therapeutic alternatives:
  - i. Only valid and referenced medications are to be considered as alternatives.
  - ii. The definition of what is valid and referenced may vary from one country to another. These differences should be taken into account. For example, a medication may be registered in one country and not in another, or approval may be pending, etc.
  - iii. There may be instances where it is not medically appropriate to try the alternatives before using the medication containing the Prohibited Substance. In these cases, the physician is to state why.
- **d.** The necessity for the Use of the Prohibited Substance or Prohibited Method is not due, wholly or in part, to prior Use (without a TUE) of a substance or method that was prohibited at the time of such use (ISTUE Article 4.1 d).

## **Submission Timing and Deadlines**

An athlete who needs a TUE should apply as soon as possible.

## • For substances prohibited In-Competition

The athlete should apply for a TUE at least 30 days before his/her next Competition, unless it is an emergency or exceptional situation (ISTUE Articles 4.3 and 6.1). If the athlete knows he or she will be taking a substance on a long-term basis, even if it is only prohibited In-Competition, he or she should still apply as soon as possible to the appropriate ADO.

## • For substances prohibited at all times:

The TUE application must be submitted as soon as the medical condition requiring the use of a Prohibited Substance or Prohibited Methods is diagnosed. If the condition is diagnosed before the athlete becomes subject to anti-doping rules prohibiting the use of Prohibited Substances and Prohibited Methods, he or she should submit a TUE application as soon as he/she becomes subject to those rules, unless he

or she is one of those athletes competing only at national level or below who is permitted by his or her NADO to apply (if necessary) for a retroactive TUE (ISTUE 4.3(c)).

## When does a TUE become effective?

The TUE is effective upon receipt of notification from the relevant anti-doping organization (either the ISSF or the NADO) that the athlete's TUE has been granted.

It must be underlined that athletes using the Prohibited Substance or Prohibited Method prior to receiving notification of TUE authorization do so at their own risk. Such use would constitute an anti-doping rule violation in the event of denial of the TUE by the TUEC.

Therefore until a TUE has been granted, and the athlete has been so informed, he or she should NOT use any substance that is on the Prohibited List.

## Where can you get a TUE application form?

Every athlete should be aware of the existence of TUEs and or the necessity of applying for TUEs. TUE applications can be downloaded from the ISSF website, from the WADA website and from each athlete's relevant NADO or RADO.

## Final words

There is no reason for clean athletes to be sanctioned for failing to apply for a TUE that would have been granted. This is not the purpose of anti-doping in sport.

But, where an athlete fails to do so, the Rules are clear: ignorance is not a defence.

In order to ensure that everyone is competing clean and without any advantages, the lack of a TUE remains an anti-doping rule violation and the athlete in question will likely still be sanctioned.

If you are an athlete, please, apply for a TUE in a timely manner and ensure that your TUE application is properly filled out and contains all the necessary medical information.

If you are a team doctor or part of the athlete's support personnel, please, educate yourself on the process and inform all your athletes about the possibility for the athlete to apply for TUE and the importance of them applying for TUEs.

Let us work together to avoid anti-doping rule violations that could be easily avoided and to focus on catching the real cheaters.

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