

Anti-Doping Awareness in Sports

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Lecture -24

Therapeutic Use Exemptions (TUE)

Good morning, ladies and gentlemen, and welcome to Lecture 4 of Week 5 of this course on Anti-Doping Awareness for Sports. I am Colonel Dr. Anup Krishnan. I'm a sports physician and an international doping control officer, and I will be taking you through today's topic that is therapeutic use exemptions. I will be covering this topic under the following headlines: Introduction. When to apply for a TUE. Where to apply for a TUE. the application process for a TUE, what and where to submit, the conditions that must be met to obtain a TUE. We will also talk about something called retroactive TUE and we will conclude with a take-home message.

So let's come to a basic question which needs to be answered. I am an athlete. Can I use any prohibited substance or method for medical treatment? To recapitulate, I am an athlete. My question is, can I use any prohibited substances for medical treatment? The answer is not a simple yes or no. The answer is slightly complicated and it has got several categories of conditions.

So the answer is not all prohibited substances can be used for medical treatment. Prohibited substances can be used for medical treatment of sportspersons only under medical advice. They can be used if no reasonable alternative exists. They can be used if there is a life-threatening emergency and if any of the above conditions are fulfilled. They can be used only with a TUE.

So let's talk about some background. Athletes may have illnesses or conditions that require them to take particular substances or methods that are on the prohibited list. We are all aware of the WADA prohibited list. Since you have gone through the course and you are in week 5, I expect you guys to know what is the WADA prohibited list. A TUE gives the athlete the authorization to use the prohibited treatment and also compete in sports.

A TUE ensures that an athlete can be treated for a medical condition even if the treatment involves using a prohibited substance or method while avoiding the risk of being sanctioned. The ISTUE, the International Standards for Therapeutic Use Exemption, is a document which ensures that the process of granting TUEs is harmonized across sports and across countries. It means that whether you're playing badminton, whether you're playing basketball, whether you're weightlifting or football, The process for applying for and granting a TUE is the same whether you are in India, in the US, in the UK, Australia, New Zealand or any other country. The process will remain the same. The TUE may give an athlete an exemption to take the medication or use the method while competing in sport without invoking an anti-doping rule violation.

We all know that if a prohibited substance or method is found in your sample, it will immediately trigger an anti-doping rule violation. And if an anti-doping violation is triggered, there will be a sanction which is going to follow. A TUE allows an athlete an exemption to take the medicine, use the method while competing in sport without an ADRV being invoked and without the applicable sanction to follow. So when do you apply for a TUE? If an athlete is prescribed a prohibited substance or method or he becomes subject to anti-doping rules for the first time and he is using a prohibited substance or a method for treatment for an illness. Apply for a TUE as soon as possible.

Athletes should always contact their national anti-doping organization first, as the NADOs may have different rules regarding TUEs. There is something called the International Standard for TUE or ISTUE, which governs all the terms and conditions under which an athlete can be granted a TUE. It says, In legitimate medical conditions, TUE may be granted to an athlete. Permitting the presence of a prohibited substance or method in an athlete's sample or, The athlete's use or attempted use or possession and or administration or attempted administration of a prohibited substance or prohibited method for therapeutic reasons. Basically, it is covering the athlete against the possible ADRVs which have been listed above.

So, where do you apply for a TUE? Now please be aware, there are different agencies which can grant a TUE. TUEs can be granted by the World Anti-Doping Agency. TUEs can be granted by the National Anti-Doping Agency. TUEs can be granted by the International Federation. And TUEs can be granted by major event organizers.

Let's come to that. Suppose there is a World Cup being organized by FIFA. The TUE has to be applied to FIFA, and will be granted by FIFA for that particular World Cup or that particular event. If there are national games being organized in India, under the National Anti-Doping Agency, the TUE will be applied to the NADA and will be granted by the

NADA.

Similarly, if it's happening in the US, it will be applied to USADA, and will be granted by the USADA. If it is a major event like the Asian Games, the Commonwealth Games or the Olympics, the event organizers, they are called major event organizers, have the authority to accept TUE applications, to process the TUE applications and to grant the TUEs if they follow the proper procedure. Now let's come to the TUE application process. Now, it starts with the athlete visiting his physician and when he visits his physician and is diagnosed with a medical condition which requires the use of a prohibited substance or a method. The athlete has to take all relevant documents from the physician and he has to apply for a TUE.

The application for the TUE is done to the anti-doping organization under whose jurisdiction he or she comes. The anti-doping organization submits the completed application form to the TUE committee of the anti-doping organization. The TUE committee has got 21 days to render a decision. The decision is given to the anti-doping organization or the TUE manager or the administrator. The anti-doping organization will then inform the athlete regarding the decision of the TUE committee.

It may be yes, it may be no. Whatever the decision is has to be recorded in ADAMS. We all know what the ADAMS system is and then it is communicated to the athlete at the same time. So this is the process by which the TUE application process has to be completed. What and where to submit? This is again a very important topic.

The TUE application is to be completed by the physician with required supporting information. What is the supporting information? I am a physician. I am treating an athlete. How did I diagnose this particular condition in this athlete? What are the standard tests which I have performed on this athlete to diagnose this condition? There is a World Anti-Doping Agency guideline for diagnosing each and every disease which requires prohibited substances for treatment. And as a physician, I am supposed to be aware of and follow those guidelines and conduct those tests and attach those test reports with the TUE application form.

Once I do that, the athlete or the athlete coach or the Athlete Federation can submit the TUE to any one anti-doping organization. Generally, it is submitted either to WADA or the International Federation or the National Anti-Doping Agency or the major event organizer, depending on which event is being organized. It is always a good idea when you are submitting a TUE application to send a copy to your National Federation and International Federation. There is a series of checklists which is provided by the WADA. There is a series of checklists which WADA provides to ensure that all supporting

document is included with the application.

Again, applications can be directed to WADA. They can be submitted in electronic or paper form to the anti-doping agency. It can be done for a national level athlete to the National Anti-Doping Organization. And international level athletes may apply to their international federation to WADA or the MEO, Major Event Organizers. It can be done in electronic form or in paper form.

There is a checklist for TUE application. Please note that the completed TUE application form alone is not sufficient. Supporting documents must be provided. I repeat, supporting documents must be provided. A completed application and checklist Do not guarantee the granting of a TUE.

The application form included should ensure that all the handwritten information is legible and all the sections are completed. All information is in a language which is generally accepted by the anti-doping organization. The applying physician has signed on the TUE document. The athlete has signed on the TUE document. The medical report should include medical history, symptoms, age of onset, course of disease, start of treatment, findings on physical examination, interpretations of symptoms, signs and test results by the physician.

The diagnosis of the condition is based on current internationally accepted criteria. The physician cannot say, I feel this is so. The diagnosis has to be done by using currently accepted international criteria. If in doubt, the WADA guidelines for that particular disease should be consulted. The medical report should also include the substance which has been prescribed for treatment, the dosage which has been prescribed for treatment, the frequency of administration, that means how many times a day it has to be prescribed, and the route of administration, oral, intravenous, intraarticular, subcutaneous, intradermal, intrathecal, intracanal, etc.

There should be clear-cut evidence of follow-up or monitoring of the athlete by the physician. That means evidence of regular follow-up should be there by the physician on the athlete. Laboratory tests or diagnostic tests should be included either with copies of the original or printouts attached. They can be laboratory tests or they can be X-ray, MRI, CT scan, ultrasound, PET scan, whatever. Now, there are some errors which people commonly make in the TUE application form.

And we must be aware of all this. The drug name, dosage, route and duration is not mentioned. This is very commonly seen. Names of the medicine in TUE application are not generic. So this needs a bit of explanation. If you talk about a drug which is

commonly used for fever, we say Crocin commonly. Crocin is a brand name. The drug is Paracetamol, which is the generic name. Now in the TUE application we are supposed to mention the generic names of drugs because the TUE application may be processed in another country where the doctors may not be familiar with the brand names of your home country. So that is why all drug names should be in generic names. The drug is not in the prohibited list but you have applied for it. It is really not required. Medical illness documents are incomplete.

Findings are not written. Examination findings are not documented. Investigations are not complete. Symptoms are not clear. Signs elicited have not been documented. So all these have to be complete in all respects.

The chronology of documents should be maintained correctly. You cannot have the disease diagnosed in January and the MRI report of March. It does not seem logical. So everything should be logical chronologically and all the documents should be attached chronologically. Make sure before the TUE application is submitted, a sports physician is always consulted to examine the TUE application.

Post the TUE application, they are reviewed by the anti-doping organization's TUE committee. This committee has 3-4 experts and they are authorized to call the athlete in front of them. They are authorized to examine the athlete. They are also authorized to even ask for any diagnostic tests which they feel is required to confirm or negate the diagnosis. They will not take a decision only on the medical documents which have been supplied.

ADOs must render a decision within 21 days of receiving a completed application. The athletes will receive a TUE certificate or letter from their anti-doping organization with details about their decision. On acceptance, the permission certificate is granted indicating dosage and length of time. All right, now this is important. The TUE certificate is valid for three months or next competition, whichever is early.

To further elucidate, I have been given a TUE on 1st of January. Usually it remains valid till 30th of March. However, there is a competition on 15th of January. There is another competition on 15th of February.

There is another competition on 20th of March. This TUE certificate Will be valid only till the first competition on 15th of January. It will not continue to be valid till 30th of March. So it is valid for 3 months usually. Or till the next competition which falls within these 3 months.

Whichever is early. This is the legal document which says there are certain criteria which is to be met for grant of TUE. There are four criteria which need to be met. I'll read the legalese first and then we will talk about it in simplified fashion. The prohibited substance or prohibited method in question is needed to treat a diagnostic medical condition supported by relevant clinical evidence. The therapeutic use of the prohibited substance or method will not, on the balance of probabilities, produce any additional enhancement of performance beyond what is anticipated by a return to the athlete's normal state of health following the treatment of medical conditions.

The prohibited substance or prohibited method is an indicated treatment for the medical condition and there is no reasonable permitted medical alternative. The necessity of use of the prohibited substance or prohibited method is not a consequence wholly or in part of the prior use without a TUE of a substance or method which was prohibited at this time of such use. Now this is legalese, may be confusing. Now let's talk simplified. Basically, the TUE committee has to be clear and has to be convinced that this particular athlete is suffering from a diagnosed medical condition.

Number one. Number two, the athlete needs to treat the diagnosed medical condition with a prohibited substance or a prohibited method. This treatment is unlikely to enhance the athlete performance other than returning him to their normal state of health. The substance or the method is an indicated treatment for the medical condition and there is no reasonable permitted therapeutic alternative. Be clear, you cannot use a substance or method which is not an accepted method for treating a particular condition.

Just to get a TUE and improve the athlete's performance. Be very clear. And you also have to prove that there is no reasonable permitted therapeutic alternative. That means if you are using a drug A and that drug is a prohibited drug. But medical literature also says there is drug B, C and D which is available for this particular treatment. and drug B, C and D is not on the prohibited list, you will have to prove why you cannot use drug A, be a C and D and why you are using drug A only.

And necessity of use must not result from prior use of a prohibited substance or method without a valid exemption. That means you have used a prohibited substance or method for any reason and now you There is a competition coming up. You are afraid that it will be detected in your sample and you have applied for a TUE. It will not be granted.

All right, now let's go through the process. If the TUE is granted, you will get a letter which says that Dosage, frequency, route of administration and duration has to be strictly followed and it will be provided. If there is any change in the conditions, dosage, route of administration or duration, the athlete must inform the ADO that has approved the TUE.

That finishes that process. If the TUV is not granted, the ADO will explain why and the athlete can appeal. The national level athletes will appeal to the appeal body of the National Anti-Doping Organization. International level athletes will appeal to WADA first. If WADA refuses to review or if there is a disagreement between the International Federation and the National Anti-Doping Organization, then WADA will review it and give a decision. If WADA refuses to review or WADA denies it, the athlete can appeal to the Court of Arbitration for sport or ICAS. This is all about TUEs. Now, there is something called Retroactive TUE. which means applying for a TUE after you have used the prohibited substance or method.

If you apply for a TUE for a prohibited substance or a prohibited method after using or possessing the substance or method in question, it is called retroactive TUE. You have to prove that emergent or urgent treatment of a medical condition was necessary. You have to prove that there was insufficient time, opportunity or other exceptional circumstances and you could not apply for a TUE. If the anti-doping agency has tested an athlete who is not international or national level, that means he is not within the registered testing pool of the athlete. The athlete may apply for a TUE stating that he was not in the registered testing pool. May ask for a retroactive TUE. Or the athlete used an out of competition prohibited drug for therapeutic reasons. And that drug is prohibited only in competition. So to protect himself, he or she may apply for a retroactive TUE. These are generally the only conditions in which a retroactive TUE will be accepted and processed. Whether it will be granted is a completely different scenario altogether.

These are the criteria for retroactive TUE. The athlete required emergency urgent treatment of a medical condition. There was insufficient time, opportunity or other exceptional circumstances that prevented the athlete from submitting the TUE application or having it evaluated before the test was conducted. As per the NADO anti-doping rules, the athlete was not permitted or required to apply in advance for a TUE. The athlete was a lower-level athlete who was not under the jurisdiction of an international federation or national anti-doping organization when they were tested. The athlete tested positive after using a substance out of competition that was only prohibited in competition.

So let's come to the take-home message or the conclusion. Always make your doctor aware you're an athlete bound by specific rules in your sport. If you're an athlete support personnel, make sure you're aware of the specific rules of your sport. If you experience a medical condition that requires a particular medicine, but that substance falls under the prohibited list, apply for a TUE certificate. National level athletes apply to the national anti-doping organizations. International level athletes apply to the International Federation, the Event Organizing Committee or the World Anti-Doping Agency.

It is reviewed by a TUE committee, generally processed 21 days prior to participating in an event. On acceptance, permission certificate is granted, indicating dosage and length of time. Proper documentation is key to TUE approval. The TUEs balance athlete health with clean competition. And WADA guidelines maintain the integrity of the sport, ensures consistency and fairness in the TUE process.

These are the references which I have used in this lecture and I strongly urge you to go through them if you are interested in further detailed study of the topic. You should also be going through them before appearing for the week ending exam and also the course ending exam. I thank you for your patience and listening, ladies and gentlemen. There will be an exam, week-ending assignment, which you will have to submit within the stipulated period. Thank you for listening, ladies and gentlemen, and Jai Hind.