

**Can further mandatory requirements  
for TUE applications and Declaration  
of Use be defined by an ADO**

*Ulrich Haas, University of Zurich*

# (1) Legal framework

- (1) The Code

Art. 4.4: „...Each *National Anti-Doping Organization* shall ensure, for all *Athletes* within its jurisdiction that have not been included in an *International Federation Registered Testing Pool*, that a process is in place whereby *Athletes* with documented medical conditions requiring the *Use of a Prohibited Substance* or a *Prohibited Method* may request a therapeutic use exemption. Such requests shall be evaluated in accordance with the *International Standard for Therapeutic Use Exemptions*. *International Federations* and *National Anti-Doping Organizations* shall promptly report to *WADA* through *ADAMS* the granting of any therapeutic use exemption except as regards national-level *Athletes* who are not included in the *National Anti-Doping Organization's Registered Testing Pool*. ...“

+ Art. 13.4, 14.5, 15.4 and Definitions

# (1) Legal framework

- (1) The Code
- (2) International Standard (TUE)

„The purpose of the *International Standard* for Therapeutic Use Exemptions is to ensure that the process of granting therapeutic use exemptions is harmonized across sports and countries.

The *Code* permits *Athletes* to apply for therapeutic use exemptions (TUE) i.e. permission to use, for therapeutic purposes, substances or methods contained in the List of *Prohibited Substances or Methods* where *Use* would otherwise be prohibited.

The *International Standard* for TUE includes criteria for granting a TUE, confidentiality of information, the formation of Therapeutic Use Exemptions Committees and the TUE application process.

This Standard applies to all *Athletes* as defined by and subject to the *Code* i.e. able-bodied *Athletes* and *Athletes* with disabilities.“

# (1) Legal framework

- (1) The Code
- (2) International Standards (TUE)
- (3) Guideline (Therapeutic Use Exemption Guidelines)

„These Therapeutic Use Exemption (TUE) Guidelines are a model for best practice developed as part of the World Anti-Doping Programme. They are based on the World Anti-Doping Code (Code or WADC) and the International Standard for TUEs established through the Code. These guidelines should, in particular, be read in conjunction with the principles set out in Article 4.4 of the WADC. They have been developed in order to guide and assist competent Anti-Doping Organisations (ADOs) throughout the entire TUE procedure.“

# (1) Legal framework

- (1) The Code
- (2) International Standards (TUE)

mandatory

Introduction WADC: *„All provisions of the Code are mandatory in substance and must be followed as applicable by each Anti-Doping Organization and Athlete or other Person.“*

23.2.1 WADC: *„The Signatories shall implement applicable Code provisions through policies, statutes, rules or regulations according to their authority and within their relevant spheres of responsibility.“*

WADC Purpose, Scope, etc.: *„The purpose of the International Standards is harmonization among Anti-Doping Organizations responsible for specific technical and operational parts of the anti-doping programs. Adherence to the International Standards is mandatory for compliance with the Code.“*

# (1) Legal framework

- (1) The Code
- (2) International Standards (TUE)
- (3) Guidelines (Therapeutic Use Exemption Guidelines)

not  
mandatory

Introduction: „As a model for best practice, these guidelines are not mandatory and have no legal status. Only the International Standard for TUEs is mandatory and, in the event of any differences or ambiguities between the present guidelines and the International Standard for TUEs, the latter shall prevail.“

## (2) Discretion left to ADOs

mandatory  
(how much autonomy  
for ADOs?)

Where the applicable  
rules specifically provide  
for this

Eg Art. 8.5 TUE: „*The TUE application form(s), as set out in Annex 1, can be modified by Anti-Doping Organizations to include additional requests for information, but no sections or items shall be removed.*“

## (2) Discretion left to ADOs

mandatory  
(how much autonomy  
for ADOs?)

Where applicable  
rules specifically  
provide for this

where rule in question is a  
blanket /sweeping clause

Eg Art. 4.1 TUE : „*The Athlete would experience a significant impairment to health ... Use would produce no additional enhancement of performance ... there is no reasonable Therapeutic alternative to the Use ...*“

## (2) Discretion left to ADOs

mandatory  
(how much autonomy  
for ADOs?)

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graph TD; A["mandatory (how much autonomy for ADOs?)"] --- B[ ]; B --- C["Where applicable rules specifically provide for discretion"]; B --- D["where rule in question is a blanket /sweeping clause"]; B --- E["where applicable rule contain a lacunae"]
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Where applicable  
rules specifically  
provide for discretion

where rule in question is a  
blanket /sweeping clause

where applicable rule  
contain a lacunae

# Example

Lower-national  
level

National level



International level

In the meantime?

*Art. 8.13: TUE „In normal circumstances, decisions of the TUEC should be completed within 30 days of receipt of all relevant documentation ...“.*

# Example

Lower-national  
level

National level

International level



In the meantime?

Guidelines: „If the TUE is approved, the athlete may commence treatment and/or sporting practice only after receipt of notification of authorisation from the relevant organisation. ... In relation to sporting practice, athletes should consider not using the substance prior to receiving notification of authorisation, otherwise they would be using a prohibited substance ... without authorisation. This would constitute an anti-doping rule violation in the event of denial of the TUE by the TUEC.“

# Example

Lower-national  
level

National level

International level



In the meantime?

*Art. 4.3 TUE: „an application for TUE will not be considered for retroactive approval except in cases where:  
Due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit ... an application prior to Doping Control“.*

# (2) Discretion left to ADOs

Where applicable rules specifically provide for discretion

where applicable rule provide for blanket /sweeping clause

where applicable rule provide for a lacunae

Monitoring by WADA (Art. 23.4 WADC)

Art. 24.3 WADC

Review TUE Decisions by WADA (Art. 10 TUEC)

**Limits (interpretation / spirit of the rules)**

Review TUE Decisions ultim. by CAS (Art. 13.4 WADC)

Review by other authorities (eg data protection, etc.)

~~Limits according to state / int. law~~

Review by state courts?

# Therapeutic Use Exemption Form (see Annex 1 TUE)

- **(1) Athlete information**
- **(2) Medical Information**
  - \* Diagnosis
  - \* if permitted medication possible, provide clinical justification for the requested use of prohibited substance
- **(3) Medical Details**
  - \* prohibited substance, dose, route frequency, duration, previous TUE
- **(4) Medical practitioner's declaration**
- **(5) Athlete's declaration**

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- **(1) Athlete information**

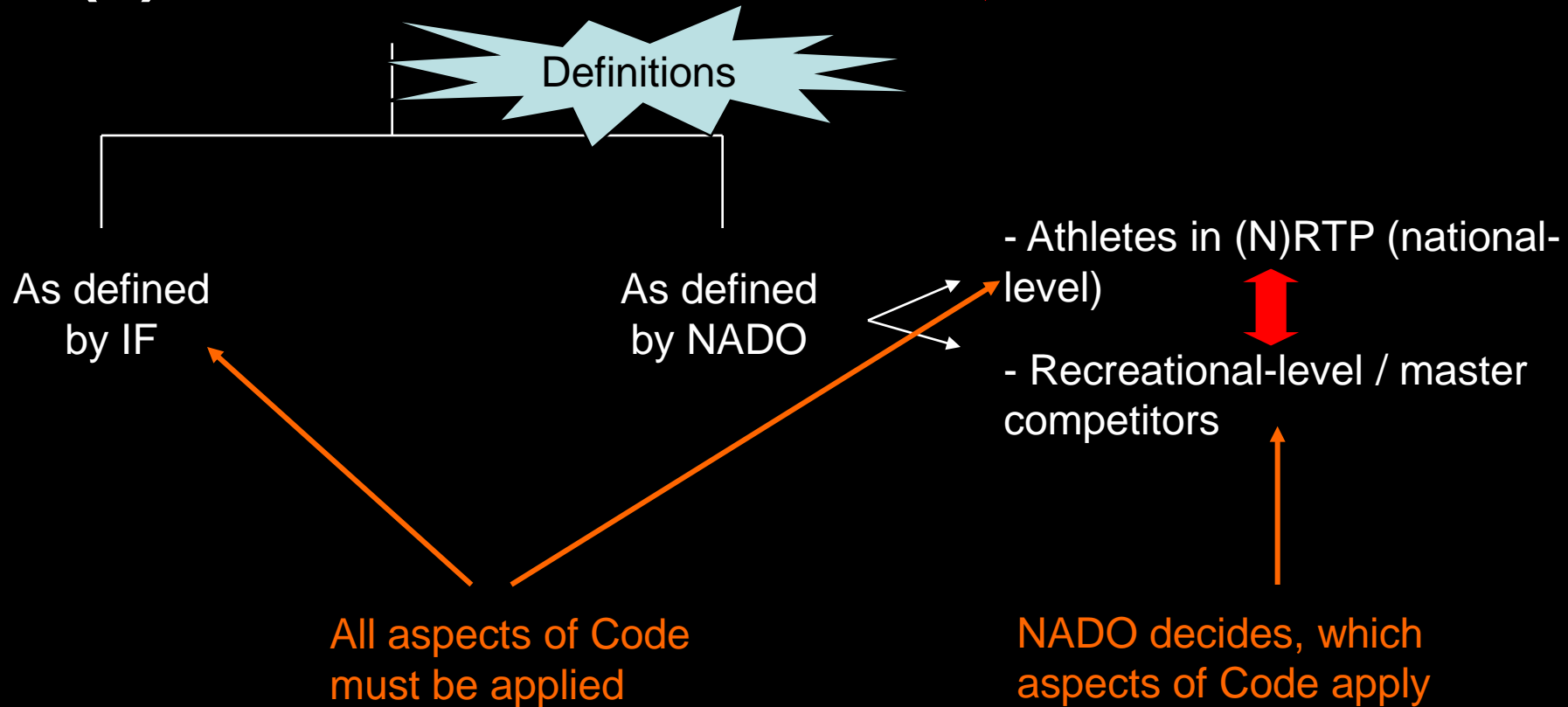


Art. 8.7 TUE:

The application shall identify the *Athlete's* level of competition (e.g., International Federation *Registered Testing Pool*), sport and, where appropriate, discipline and specific position or role.

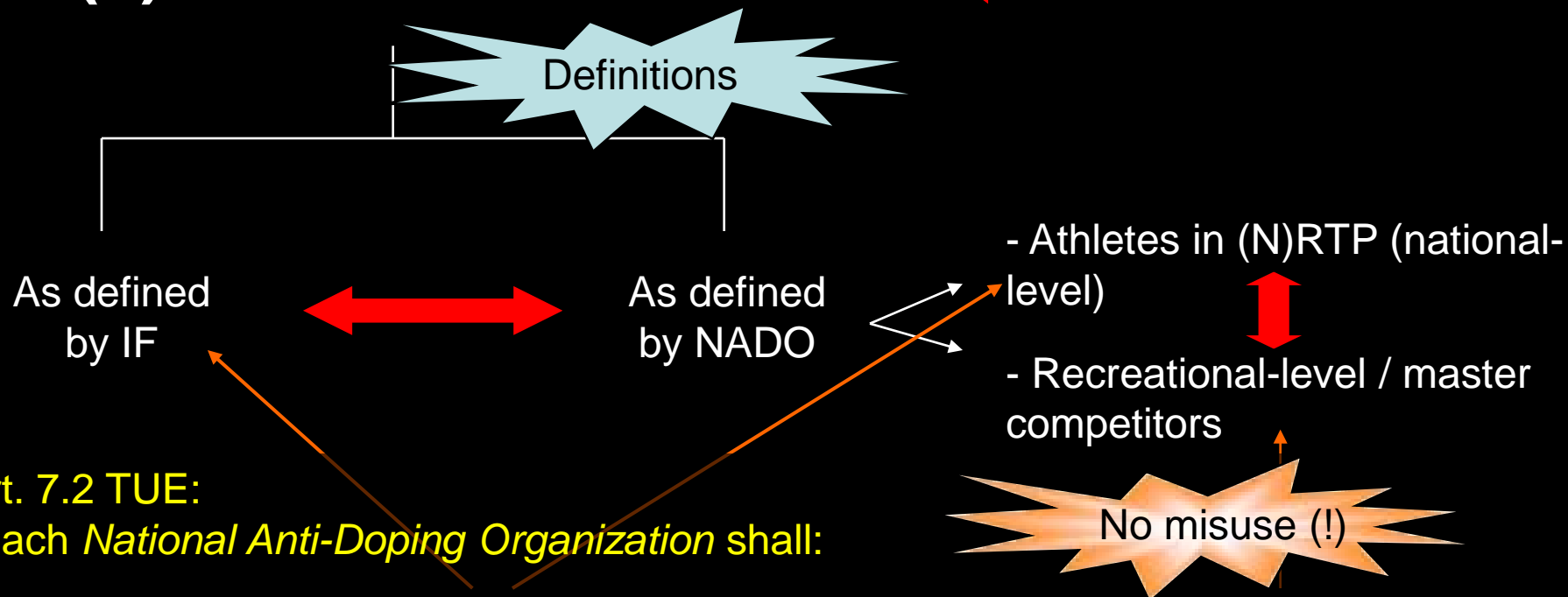
# Therapeutic Use Exemption Form (see Annex 1 TUEC)

## • (1) Athlete information



# Therapeutic Use Exemption Form (see Annex 1 TUEC)

## • (1) Athlete information



Art. 7.2 TUE:

„Each *National Anti-Doping Organization* shall:

...

(b) Identify and publish those categories of *Athletes* within its jurisdiction, who are required to obtain a TUE before *Using a Prohibited Substance or a Prohibited Method*. At a minimum, this shall include all *Athletes* in the *National Anti-Doping Organization's Registered Testing Pool* and other national-level *Athletes* as defined by the *National Anti-Doping Organization*.”

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- (1) Athlete information
- (2) Medical Information

\* Diagnosis



Art. 8.9 TUE:

„The application shall include a comprehensive medical history and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis ... should be guided by the WADA Medical Information to Support the Decisions of the TUECs“.

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- (1) Athlete information
- (2) Medical Information




- \* Diagnosis

- \* if permitted medication possible, provide clinical justification for the requested use of prohibited substance

Art. 8.11 TUE:

„The application shall include a statement by an appropriately qualified physician ... describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.“.

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- (1) Athlete information
- (2) Medical Information 
  - \* Diagnosis
  - \* if permitted medication possible, provide clinical justification for the requested use of prohibited substance
  - \* further requirements as to qualification of doctor?

Art. 8.11 TUE:

„The application shall include a statement by an appropriately qualified physician ... describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.“

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- (1) Athlete information
- (2) Medical Information

- \* Diagnosis
- \* if permitted medication possible, provide clinical justification for the requested use of prohibited substance
- \* further requirements as to qualification of doctor?
- \* further information (quantity, quality)



harmonisation

Art. 8.5 TUE:

„The TUE application form(s) ... can be modified by ADOs to include additional requests for information, but no sections or item shall be removed.“

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- (1) Athlete information
- (2) Medical Information

- \* Diagnosis
- \* if permitted medication possible, provide clinical justification for the requested use of prohibited substance
- \* further requirements as to qualification of doctor?
- \* further information (quantity, quality)



## Guidelines 1.3.4:

„Furthermore, ADOs are advised not to add further requirements to the forms that may thwart efforts to harmonise, result in confusion or discredit the procedure. Consequently, any changes must be limited to the adaption of the forms by ADOs through the inclusion of their logo and contact details, for example.“

# Therapeutic Use Exemption Form (see Annex 1 TUEC)

- (1) Athlete information
- (2) Medical Information
- (3) Medical Details



## Art. 8.8 TUE:

„The application shall list any previous and/or current TUE requests, the body to whom that request was made, the decision of that body, and the decision of any other body on review or appeal.“

## Art. 8.9 TUE:

„The arguments related to the ... treatment, as well as duration of validity, should be guided by the WADA Medical Information to Support the Decisions of TUEC's.“

## Art. 8.10 TUE:

„Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* before approval will be undertaken at the expense of the applicant.“

# Declaration of Use

- No Appendix to TUE Standard, just rules in Art. 9

Legal basis?

## Art. 9 TUE

„9.1 The List identifies certain substances and methods that are not prohibited but for which an Athlete is required to file a declaration of Use. ...“

Art. 4.4 WADC: „...Each *National Anti-Doping Organization* shall ensure, for all *Athletes* within its jurisdiction that have not been included in an *International Federation Registered Testing Pool*, that a process is in place whereby *Athletes* with documented medical conditions requiring the *Use of a Prohibited Substance* or a *Prohibited Method* may request a therapeutic use exemption. Such requests shall be evaluated in accordance with the *International Standard for Therapeutic Use Exemptions*. *International Federations* and *National Anti-Doping Organizations* shall promptly report to *WADA* through *ADAMS* the granting of any therapeutic use exemption except as regards national-level *Athletes* who are not included in the *National Anti-Doping Organization's Registered Testing Pool*. ...“

# Declaration of Use

- No Appendix to TUEC, just rules in Art. 9 TUEC



Legal basis?

Art. 9 TUE

„9.1 The List identifies certain substances and methods that are not prohibited but for which an Athlete is required to file a declaration of Use. ...“

Art. 4.5 WADC: „...WADA, in consultation with the Signatories and governments, shall establish a monitoring program regarding substances which are not on the Prohibited List, but which WADA wishes to monitor in order to detect patterns of misuse ...“

# Declaration of Use

- No Appendix to TUEC, just rules in Art. 9 TUEC
- Requirements as to form?

Art. 9 TUE

„9.1 ...An athlete should satisfy the requirement by declaring the Use on a Doping Control Form and when available by filing a declaration of use through ADAMS.“

„and/or“ in Guidelines


# Declaration of Use

- No Appendix to TUEC, just rules in Art. 9 TUEC
  - Requirements as to form?
  - Requirements as to time? (what is the latest point in time)
  - Requirements as to contents?
  - Consent for use of information (Art. 5 TUEC)
- In principle no sanction

## Art. 9 TUE

„9.2 ...An athlete's failure to declare Use on a Doping Control Form and through ADAMS when available ... shall not be an anti-doping-rule violation.“

# Declaration of Use

- No Appendix to TUEEC, just rules in Art. 9 TUEEC
  - Requirements as to form?
  - Requirements as to time? (what is the latest point in time)
  - Requirements as to contents?
  - Consent for use of information (Art. 5 TUEEC)
- In principle no sanction
- 

Art. 9 Comment TUE

„9.2 ...ADO with jurisdiction ... may impose consequences other than anti-doping rule violation for a failure to declare.“

# Declaration of Use

- No Appendix to TUEC, just rules in Art. 9 TUEC
- Requirements as to form?
- Requirements as to time? (what is the latest point in time)
- Requirements as to contents?
- Consent for use of information
- Arbitration (not covered by Art. 13 WADC)

In principle no sanction



**Thank you very much  
for your attention**

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