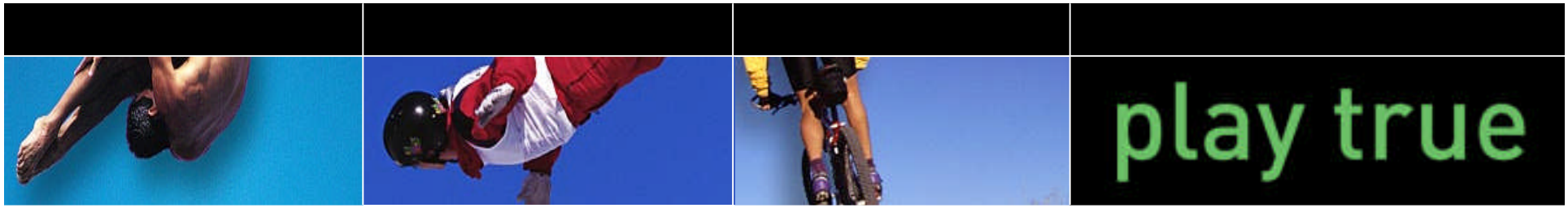
WORLD ANTI-DOPING AGENCY

International Standard for TUE Update

Dr Alain Garnier, MD

WADA Medical Director



IF/NADO symposium- April–1st 2008

Some history.....

Where are we coming from?

- No harmonization
- No right to treatment
- Possibility of cheating

TUE philosophy

« To improve medical cover of athletes while avoiding inadvertently doping risks »

TUE philosophy

- Recognition of the Athletes' right to best medical treatment.
- Harmonized and medically coherent measures (common culture).
- A more medical than disciplinary approach that will give responsibility to the physician and the athlete.

TUE general principles

- The medical interest of the athlete is always favoured to the sporting stakes.
- TUEC decisions are administrative authorizations. They certify the use of prohibited substance in the sporting field. They do not, in any case, approve or disapprove medical prescriptions.
- In an emergency case the use of a prohibited substance is allowed with an exceptional a posteriori justification.

Main steps of consultation process

- First proposal discussed by WADA TUE Working Group (Pr David Gerrard) in March 2007 based on comments received
- Amendment by Code Project Team (CPT) confirmed by legal advisory group
- Presentation of different options to Executive Committee (EC) in May 2007

Main steps of consultation process

- New draft in July based on EC recommendation
- Reviewed and finalized by CPT in August 2007
- Draft released for consultation in early September with 3 options

Three options, 1st consultation round

- The current draft applying to all athletes.
- The retroactive process, not applying to athletes who are members of an international registered testing pool who will need a standard TUE before competing
- No change to the current abbreviated process

Main steps of consultation process

- Outcomes of first consultation round:
  - 2/3 of stakeholders not in favour of retroactive process
  - Request for further consultation
- New draft prepared by WADA TUE Working Group and circulated in February 2008 based on stakeholders feedback, in order to facilitate the implementation of ISTUE

Context of the new proposal (for asthma)

- Asthma and its clinical variants are common in the athlete population
- There is no reason to manage asthma differently in athletes than other patients.
- There is a clear misuse of inhaled B2 agonists by athletes, which is not consistent with medical good practices (IOC consensus)
- Indiscriminate use of such substances carries significant health risks (IOC consensus)
- Oral administration of B2 agonists can be performance enhancing

Context of the new proposal
(for GCS)

- Due to a limitation of the current technology the laboratories cannot accurately distinguish the route of administration of GCS
- Some clinical applications are requiring a rapid therapeutic response which makes the application for TUE not realistic
- Retroactive approval can only apply for obvious emergency situation
- GCS are prohibited in competition only
- Therapeutic choice of GCS to be balanced with potential health risks

Main provisions and changes

- A TUE is considered as a mandatory requirement before using any prohibited substances
- The “Standard” TUE process is not modified
- The Abbreviated process is abrogated
- A TUE is required in case of asthma and clinical variants
- A simple declaration is required for local application of GCS

What to do with ATUE process ?

- Rationale to consider differently a particular class of substances ?
- To consider the medical condition (asthma) as a whole more than to consider a class of drugs
- To be consistent with the medical good practices for asthma treatment and its clinical variants (GINA, ERS….)

Current situation with ATUE process

- Workload issue mentioned by all stakeholders
- Partial inefficiency regarding the control of use
- Only two ways:
  - to renounce and authorize ?
  - to increase efficiency

Proposal for asthma

Strongly supported by the WADA working group

- A TUE based on consistent medical data
- Granted for 4 years
- Annual review by the prescribing doctor (signing the application for TUE)
- Notification of any change to the diagnosis or therapy to the responsible ADO during that period

Scope of the proposal (for asthma)

- To treat all athletes the same way would result in a lenient control (current situation)
- Due to the consequent workload, acceptable only if applied to a restricted population
- To decrease the number of athletes while increasing the quality of control
- Only athletes members of a RTPool of IF or NADO are concerned or any athletes taking part in an international event.

What for other athletes ?

- TUE procedure could be left at the discretion of the NADO?
- A retroactive process could be used if considered as appropriate ?
- A simple declaration as for GCS could be proposed ?

Proposal for GCS

- Systemic GCS : TUE
- Inhaled GCS: TUE
- Topical GCS: not prohibited
- Local injection: simple declaration ?

Principle of declaration

- Name of the drug, dose and duration
- Name of the precribing doctor
- To be declared through ADAMS

To monitor the prevalence of use by athlete population more than for disciplinary purposes

Outcomes of consultation process

Outcomes of consultation round on this draft:

- 2/3 of stakeholders are in favour of the proposal, with some restriction regarding the simple declaration proposal for non-systemic, non-inhaled GCS which is perceived as too lenient by some.
- No real alternative proposed by any stakeholder except what had already been rejected by the majority during the first round of consultation

Mutual recognition

"Subject to the right to appeal provided in Article 13, Testing, therapeutic use exemptions and hearing results or other final adjudications of any *Signatory* which are consistent with the *Code* and are within that Signatory's authority, shall be recognized and respected by all other *Signatories*." WADC 2009, Article 15.4.1

Within that Signatory's authority…

- IF TUEs are valid on international and national level
- But national decisions are only valid on national level and not international level
- Harmonization in the international field

IFs and NADO decisions

- An IF can decide to recognize a decision taken by a NADO
- The IF has to endorse the decision, which becomes its own decision
- Clear identification of IF endorsing a NADO decision (name and logo on approval notification)

Conclusions

- Thanks to all NADOs and IFs for their relevant contribution
- A wide majority seems to support this new approach
- Proposal appears to be more consistent with medical practice
- In favor of a better athlete's care
- No increase in workload after the initial period and ADAMS
- In line with IOC approach for the games

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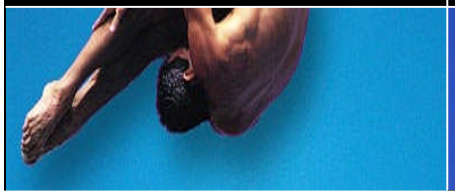

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