



## GLUCOCORTICOIDS THRESHOLD WORKING GROUP Terms of Reference

The WADA Glucocorticoids Threshold Working Group Working Group [GCTWG] is a specific Working Group<sup>1</sup> created by WADA Management at the request of the List Expert Advisory Group.

*These Terms of Reference are approved by the WADA Director General, following consultation with the responsible Director in charge of the Group.*

### **Purpose**

In the current International Standard of the Prohibited Substances and Methods (the Prohibited List), Glucocorticoids (GCs) are prohibited during the in-competition period when administered by oral, intravenous, intramuscular or rectal routes.

In 2004, a urinary concentration of 30 ng/ml was initially established as a temporary reporting concentration (RC). Afterwards, WADA proceeded to sponsor a number of excretion studies which aimed to provide the evidence needed to improve the specificity of the RCs for individual drugs and the various routes of administration. As more data became available, it was evident that when GCs were administered by permitted local injections in doses used for legitimate medical use, the concentrations found in the urine could reach levels similar to those of prohibited routes, indicating systemic distribution of the drug.

As a consequence, the GCTWG<sup>1</sup> was established to re-evaluate the status of local injections in the WADA Prohibited List as well as define GC-specific RC.

To do so the GCTWG will gather and review the available literature (published and unpublished) on GC excretion studies to elaborate a novel approach that differentiates doping from acceptable medical use in sport. Through this review, washout periods will also be established to support the use of GCs medically, to avoid the risk of an *Adverse Analytical Finding* through legitimate medical use.

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<sup>1</sup> WGs are created on an as-needed basis only, and generally with a defined mandate requiring deliverables within a set timeframe. Where the expected deliverables are not met, an extension of mandate is possible, however it is not expected that WGs continue indefinitely. If it is considered that their work should be ongoing in nature, whether WG should be elevated to an Expert Advisory Group would need to be determined.

It is forecast that the GCTWG will complete its mandate within a 3-4-year period (i.e. from May 2018 to May 2022). It will deliver recommendations to WADA periodically after each meeting, with a final recommendation anticipated in May 2022. The necessary meeting timelines will be framed with this in mind.

### **Objectives/Key Activities**

- 1) Review the literature related to GC including pharmacokinetics, performance enhancement, urinary excretion studies using different routes of administration.
- 2) Develop a novel approach to define acceptable (therapeutic) and non-acceptable (supratherapeutic) use of GC in sport based on normal cortisol production, cortisol equivalents, performance enhancement and risk for health.
- 3) Establish permitted and prohibited routes of administration based on the above.
- 4) Define urinary RC specific for different GC.
- 5) Establish washout periods to support the use of GCs medically out-of-competition, to avoid risk of a positive analytical finding.
- 6) Recommend further excretion studies if data is missing and evaluate the results when available.

### **Reporting Structure**

The GCTWG reports to the List Expert Advisory Group and WADA Management.

### **Membership/Composition**

The composition of the GCTWG shall not exceed a maximum of 8-10 members, however an exception may be applied if deemed necessary.

The WADA Director General, following consultation with the responsible Director in charge of GCTWG, will appoint members to the GCTWG.

Members are selected on the basis of their relevant background and experience (e.g. expertise in the areas of GC pharmacology, pharmacokinetics, analytical chemistry, clinical use of GC and anti-doping).

The Members of the GTWG are as follows:

1. Dr. Mark Stuart (UK) – *Chair*
2. Prof. Frank Buttgerit (Germany)
3. Prof. Catherine Collomp (France)
4. Dr. Peter Daley-Yates (UK)
5. Prof. Martial Saugy (Swiss)
6. Dr. Rosa Ventura Alemany (Spain)
7. Dr. Olivier Rabin (France)
8. Dr. Irene Mazzoni (Argentina/Canada)

*If required, additional experts may be called upon on an ad-hoc basis for their contributions.*

Member terms reflect the mandate of GCTWG, i.e. until May 2022. If the work of a GCTWG is not completed within the originally planned timeframe, and is extended, the composition and terms of members are reviewed to ensure their relevance remains.

### **Chair/Rapporteur**

The GCTWG Chair<sup>2</sup> is selected based on his/her proven record and expertise in GC pharmacology, pharmacokinetics, analytical chemistry, clinical use of GC or anti-doping.

He/she shall act as the official reporter who is responsible for ensuring appropriate coordination with WADA Management and the List Expert Advisory Group and for providing accurate and timely information on all relevant issues.

### **WADA Liaison**

The WADA Science & Medical Department, and in particular the Senior Manager of the Prohibited List, will serve as the primary liaison between WADA and the GCTWG.

Additional WADA Science & Medical Department staff may also participate in GCTWG meetings as WADA experts on particular subject matters and to provide general support to the group where required.

### **Meetings and Working Norms**

The GCTWG will meet in person, or virtually via video or teleconference (as determined by WADA) as many times as is necessary to complete its mandate.

The GCTWG normally operates on the basis of consensus and maintains as informal a manner as is possible or appropriate for the conduct of business. Consensus will be sought whenever possible. In the event of divergence of opinion or disagreement concerning recommendations, the absolute majority (determined by vote by hand) will rule. In the event of a tie, the Chair has the casting vote. There is presently no formal practice concerning a quorum. The Chair has the responsibility to determine if a quorum is present. Meeting notes will record any dissenting opinion on request.

The Chair may limit discussion of resurfacing issues by referring to previous recommendations or conclusions of previous discussions.

Meeting notes of the GCTWG meetings, reports and correspondence relative to the group's work shall be open, recorded and retained at the WADA Headquarters.

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<sup>2</sup> There are occasions where WADA staff may chair a WG, e.g. when an external chair is not deemed to be practical.

## **Conflict of Interest**

GCTWG members will be bound by the Conflict of Interest policy adopted by the WADA Foundation Board in November 2019<sup>3</sup>, and will be required to annually complete and sign a Statement of Absence of Conflict of Interest in accordance with the policy.

## **Confidentiality**

All group members are required to sign a Confidentiality Agreement upon appointment (and again at the start of each year if their appointment is renewed). This ensures all members reflect on the confidential nature of their WADA work and confirm their adherence to such confidentiality rules. Signing this document each year is a new process as of 2020 (as a result of the governance changes approved in 2019); previously members were only required to sign once.

## **Communications and Media**

All GCTWG members must read and comply with WADA's Media Relations policy. If a member should receive a request for an interview in relation to their role in WADA or WADA's work they should first consult with the WADA Media Relations Senior Manager or (if absent), with the WADA Communications Director.

## **Budget and Financial Support**

WADA has budgeted for the GCTWG for up four years. Should an extension of the mandate be required, additional budget will need to be approved prior to final confirmation of the group continuing.

WADA shall provide the necessary administrative and operational resources for meetings. WADA will meet all travel and accommodation costs, as well as most meals onsite. A daily indemnity is provided to cover incidental costs during travel to and from the meeting.

Where meetings are held virtually and meet certain rules such as a minimum duration, a daily indemnity for virtual attendance is disbursed.

It is acknowledged that some experts go above and beyond, including providing extensive advice throughout the year, outside of annual meetings. WADA offers a further daily indemnity to experts for such work carried out. The specific indemnity details are outlined in the full "Overview of WADA Working Groups" document provided to Members.

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<sup>3</sup> WADA's Foundation Board approved a set of governance reforms in November 2018 at its meeting in Baku, Azerbaijan. In 2019, WADA's Statutes were modified to reflect these reforms, and a new set of bylaws and operational regulations were created to supplement the formal Statutes. They were approved by WADA's Foundation Board in November 2019 in Katowice, Poland.

## **Effective Date**

These ToR originally came into effect on May 2018. The mandate remains the same as initially drafted and/or approved. The ToR have however been updated to reflect practical changes to the way in which WADA manages its Working Groups which were approved in November 2020 and come into effect on 1 January 2021.

These ToR are published on the WADA website.