

## 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 WADA Prohibited List Expert Advisory Group (LiEAG).

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

#### **Purpose**

Since January 2022, the International Standard of the Prohibited Substances and Methods (the Prohibited List), includes the prohibition of local injections of Glucocorticoids (GCs) during the in-competition period in addition to the oral, intravenous, intramuscular and 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 was established to re-evaluate the status of local injections in the Prohibited List as well as define GC-specific RCs.

To do so, the GCTWG gathered and reviewed the available literature (published and unpublished) on GC excretion studies to elaborate a novel approach that differentiates doping from acceptable medical use in sport.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, new Minimum Reporting Levels (MRLs) and washout periods (WPs) were also established for several GCs to support their use medically, to avoid the risk of an Adverse Analytical Finding (AAF) through legitimate medical use.

Originally it was forecasted that the GCTWG would complete its mandate within a 3-4-year period (i.e. from May 2018 to May 2022). During that period, they delivered recommendations to the LiEAG after each meeting, with a final recommendation in April 2020 to include the prohibition of local injections of GC in-competition, which was implemented on 1 January 2022 following a one-year delay to allow stakeholders time to adapt to the new rules.

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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.

### Extended Mandate (2023-2025 and 2026-2028)

To date, MRLs and WPs have only been established for some of the most common GCs. In addition, the GCTWG's ToR require that it monitors the effects of the 2022 change to the rules on the number of Therapeutic Use Exemptions (TUEs) and AAFs. Therefore, the mandate was first updated and extended for the GCTWG from January 2023 to December 2025.

As the GCTWG is monitoring an ongoing study using intravenous administration of GCs which, when complete, will require assessment in order to determine whether adjustments to the MRLs or WPs are required, the GCTWG's mandate will be further extended for the next three years (from January 2026 to December 2028).

The GCTWG will also continue the work it began in 2023, namely to (i) to monitor the effects of the 2022 change to the rules and determine if MRLs and WPs need to be adjusted, (ii) assess the results of other studies that may be published, (iii) determine which new studies will need to be funded to establish new MRLs and WPs for other less common GCs and, once results are available, (iv) define the MRLs and WPs and recommend them to the LiEAG. The necessary meeting timelines will be framed with this in mind.

### Objectives/Key Activities

- 1) Monitor, on a bi-annual basis, the effects of the 2022 change to the rules on the number of TUEs and AAFs and adjust new MRL and WP if needed.
- 2) Assess the results of intravenous GC administration studies and other similar studies.
- 3) Recommend further excretion studies for GCs where data is missing and evaluate the results when available.
- 4) Define urinary MRLs and routes of administration for these additional GCs.
- 5) Establish WP to support the use of these additional GCs medically out-of-competition, to avoid risk of a positive analytical finding.
- 6) Monitor existing and future trends in the GCTWG's fields of expertise having the potential to impact the anti-doping system and propose new ideas for consideration by WADA's internal Innovation Board.

### Reporting Structure

The GCTWG reports to the LiEAG and WADA Management.

### Membership/Composition

The composition of the GCTWG shall not exceed a maximum of 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.

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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 membership of the GCTWG is published on the WADA website.

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

Member terms reflect the current mandate of GCTWG, i.e. until December 2025. If the work of the 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 their proven record and expertise in GC pharmacology, pharmacokinetics, analytical chemistry, clinical use of GC or anti-doping.

The GCTWG Chair shall act as the official reporter who is responsible for ensuring appropriate coordination with WADA Management and the LiEAG and for providing accurate and timely information on all relevant issues.

### **WADA Liaison**

The WADA Science & Medicine Department, and in particular the Associate Director of the Prohibited List, will serve as the primary liaison between WADA and the GCTWG.

Additional WADA Science & Medicine 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 virtually via video or teleconference, or in-person (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.

## **Code of Ethics, Conflict of Interest, Confidentiality and Media**

Upon their appointment and again annually, all GCTWG members are required to sign a document, pursuant to which they undertake (i) to comply with the Code of Ethics adopted by the WADA Foundation Board (as amended from time to time); (ii) to comply with the Conflict of Interest policy adopted by the Foundation Board (as amended from time to time); (iii) to keep all matters related to WADA confidential; and (iv) to comply with the WADA Media Relations Policy issued by the Agency (as amended from time to time).

### **A) Code of Ethics**

The purpose of the WADA Code of Ethics is to establish clear ethical standards over the activities of WADA Officials (as defined in Section 2 of the Code of Ethics) to allow WADA to achieve its mission and protect its core values. WADA and all its Officials undertake to foster a culture of ethics, loyalty, and integrity within their respective areas of competence.

### **B) Conflict of Interest**

GCTWG members will be bound by the WADA Conflict of Interest policy. They will be required to annually complete and sign a Statement of Absence of Conflict of Interest in accordance with the policy, and to update such statement if and as necessary during the year.

### **C) Confidentiality**

All GCTWG members are required to sign a Confidentiality Declaration upon appointment and again annually. This ensures all members reflect on the confidential nature of their WADA work and confirm their adherence to such confidentiality rules.

### **D) 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 in the fight against doping in sport, they should first consult with the WADA Head of Media Relations or (if absent), with the WADA Communications Director.

### **Budget and Financial Support**

WADA shall provide the necessary administrative and operational resources for meetings. WADA will cover certain expenses and compensate members for meetings in accordance with its applicable indemnity policy.

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 indemnity to experts for such work carried out. The specific indemnity details are outlined in the "Overview of WADA Working Groups" document provided to Members each year.

### **Effective Date**

These ToR originally came into effect in May 2018.

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Following the completion of the original mandate of the GCTWG, the scope of their work was extended in December 2022 (for 2023-2025) and January 2026 (for 2026-2028). The ToR were updated to reflect the new objectives as listed above.

Administrative updates to the ToR were also made in December 2022 and January 2024.

These ToR are published on the WADA website.