

11 July 2018

WADA clarifies facts regarding UCI decision on Christopher Froome

On 2 July 2018, the World Anti-Doping Agency (WADA) announced that it would not be appealing the Union Cycliste Internationale's (UCI's) decision not to assert an Anti-Doping Rule Violation (ADRV) in the case involving British rider Christopher Froome.

WADA accepted that the analytical result of Mr. Froome's sample from 7 September 2017 during the Vuelta a España, which identified the prohibited substance salbutamol at a concentration in excess of the decision limit of 1,200 ng/mL, did not constitute an Adverse Analytical Finding (AAF). The Agency's decision not to appeal the ruling of the UCI, which was the results management authority with sole jurisdiction in this case, was taken on the basis of a full and careful review of all explanations and supporting evidence submitted by Mr. Froome in June 2018 (which the UCI shared with WADA), as well as thorough consultation with internal and external experts.

While WADA remains convinced that the UCI reached the right and fair outcome on this very complex case, the Agency wishes to clarify elements that have been subject to much speculation and misinformation.

The substance, the test and the science

Salbutamol is an effective therapeutic remedy for asthma with no known performance-enhancing properties when inhaled at a therapeutic dose. However, if used in excessive doses or by systematic routes (e.g. oral), it can be a stimulant or an anabolic agent, which is why it is on the [Prohibited List](#) with a threshold amount.

WADA considers that the current salbutamol threshold is at a correct level considering the scientific literature published on the substance over the past 20 years. Unlike most substances, given the variables that exist with salbutamol depending on conditions specific to each case, the rule is designed to afford athletes found to have exceeded the threshold with the opportunity to prove how it has occurred and justify proper therapeutic use.

In the Froome case, the test was applied the same as for any other athlete by looking at the unique physiological and circumstantial details that could be clearly determined. Mr. Froome was able to show the UCI

Tribunal how it was possible that he took a permitted dose of salbutamol (1,600 mcg/24 hours, not to exceed 800 mcg/12 hours) while still providing a sample with a concentration of the substance (1,428 ng/ml of urine, when adjusted for specific gravity) that was above the decision limit (1,200 ng/ml).

In some other cases, athletes have been able to demonstrate an unusually high salbutamol excretion by conducting a controlled pharmacokinetic study (CPKS). It was accepted by the UCI, however, that in this case such a study would not have provided reliable evidence as it would be impossible to adequately recreate similar conditions to when Mr. Froome was subjected to the test, taking into account his physical condition, which included an illness, exacerbated asthmatic symptoms, dose escalation over a short period of time, dehydration and the fact that he was midway through a multi-day road cycling race.

Based on the data and the fact there is scope in the system for athletes to demonstrate that they did not exceed the maximum dose, it is not unusual for cases involving salbutamol to be concluded without a sanction. From 2013-17, from the data available to WADA in the Anti-Doping Administration and Management System (ADAMS), of the 41 completed cases that involved salbutamol as the only substance:

- 20% (eight out of 41 cases) resulted in acquittal.
- Approximately 50% (21 out of 41) resulted in suspensions.
- The remainder of cases included a range of circumstances, including where the athletes received reprimands, where they were competing in a sport that was not a signatory to the World Anti-Doping Code or where they had valid Therapeutic Use Exemptions (TUEs).

In the same time period, 57 cases contained salbutamol, either on its own (see above) or in combination with other prohibited substances, and of those:

- 14% (eight out of 57 cases) resulted in acquittal.
- Approximately 50% (30 out of 57) resulted in suspensions.
- The remainder of cases included a range of circumstances, including where the athletes received reprimands, where they were competing in a non-signatory sport or where they had valid TUEs.

Specifically as it relates to road cycling, there has not been a major issue with salbutamol abuse. Not including the Froome case, only four of the 57 completed cases involving the substance have been from road cycling. Of those, three resulted in suspensions ranging from six to nine months and one resulted in acquittal.

Therefore, while the specific details of the Froome case are unique, the result the UCI arrived at is not unusual. WADA believes it was the right and fair outcome for a very complex case and that Mr Froome deserved to be treated with the same fairness as any other athlete.

In order to stay on top of this complex area of anti-doping, and as outlined in the background document on

salbutamol linked below, WADA has funded and supported a number of salbutamol studies over the years and continues to do so. Below is an extensive list of publications originating from WADA-sponsored studies related to salbutamol excretion as WADA encourages research teams to publish the results of their studies in peer-reviewed journals. (There have also been published studies, not sponsored by WADA, that have provided useful data.)

- Sporer, Sheel & McKenzie, *Med Sci Sport Exerc* 2008, 40:149
- Sporer, Sheel, Taunton, Rupert & McKenzie, *Clin J Sports Med* 2008 18:282.
- Mareck, Guddat, Schwenke, Beuck, Geyer, Flenker, Elers, Backer, Thevis & Schanzer, *Drug Test Analysis*, 2011, 3:820
- Elers, Morkeberg, Jansen, Belhage, Backer, *Scan J Sport Med* 2012b: 22: 232–239
- Dickinson, Hu, Chester, Loosemore & Whyte. *Clin J Sport Med*. 2014, 24:482
- Elers, Pedersen, Henninge, Hemmersbach, Dalhoff & Backer, *Int J Sport Med* 2011, 32:574
- Elers, Pedersen, Henninge, Hemmersbach, Dalhoff & Backer, *Clin J Sport Med* 2012, 22:140
- Dickinson, Hu, Chester, Loosemore & Whyte, *J Sport Sci Med*, 2014, 13:271
- Dickinson, Hu, Chester, Loosemore & Whyte, *Clin J Sport Med* 2014, 24:482
- Haase, Backer, Kalsen, Rzeppa, Hemmersbach & Hostrup, *Drug Test Analysis* 2016, 8:613
- Hostrup, Kansel, Auchenberg, Rzeppa, Hemmersbach, Bangbo & Backer, *Drug Testing Analysis* 2014 6:528 (final abstract is pending)

In addition to these, there is a number of ongoing studies in this area. Under the terms of the agreements between the research teams and WADA, it is the research teams that have ownership of the data/studies. Therefore, WADA is not permitted to disclose unpublished data either from completed or ongoing projects. However, all WADA-funded grants are posted in the [Research section of our website](#), and include a summary of the project aims as well as a summary of the results and conclusions if applicable.

As a matter of course, when dealing with complex cases such as this, WADA consults with internal and independent external experts, including members of the WADA List Expert Group. The List Expert Group is responsible for providing expert advice, recommendations and guidance to WADA's Health, Medical and Research Committee on the overall publication, management and maintenance of the List.

The process

From start to finish, the UCI was solely and exclusively in charge of the procedure and dealt with all procedural aspects of the case. Despite not being party to proceedings, WADA was responsive throughout the UCI's results management process and provided support where appropriate.

Following notification of the presumptive AAF in September 2017, the UCI and Mr. Froome, on 28 December 2017, entered into an ad-hoc procedural agreement (WADA was not involved in any fashion in the process leading to this procedural agreement). The UCI and Mr. Froome agreed that Mr. Froome's evidentiary requests would be decided by the UCI Anti-Doping Tribunal. The requests were ultimately determined by the tribunal in mid-March 2018 after substantial submissions by Mr. Froome and the UCI.

On 31 January, Mr. Froome sent a letter to WADA requesting specific information regarding the scientific bases for the salbutamol threshold and decision limit. On [5 March](#), WADA provided the parties to the case with background information to, and the rationale for, the decision limit for salbutamol.

In April, WADA requested to intervene in the UCI proceedings as a third party so as to meet any challenge to the salbutamol regime but its request was denied by the UCI Tribunal. Despite this denial, and in order to assist the parties, WADA provided a further detailed note on the salbutamol regime on [15 May](#), addressing the substance of Mr. Froome's questions.

When WADA received Mr. Froome's substantial explanations and evidence on 4 June, the Agency promptly reviewed them together with both in-house and external experts and liaised with the UCI before communicating its position statement on 28 June. Then, on 2 July, UCI announced its decision to close the case.

It should be noted that, until WADA received Mr. Froome's detailed explanations on 4 June, WADA considered that this case merited going through a CPKS and, if necessary, disciplinary proceedings at both the UCI and Court of Arbitration for Sport level.

However, based on what was provided by UCI to WADA, and once Mr. Froome's explanations were assessed by the appropriate internal and external experts, it became clear to WADA that, in particular, the combination of his within-subject variability for salbutamol excretion, the sudden and significant increase in salbutamol dosage prior to the doping control, and the number of consecutive doping controls meant that the analytical result could not be considered inconsistent with the ingestion of a permissible dose of inhaled salbutamol.

For the reasons mentioned above, WADA considers that accepting Mr. Froome's explanations was the appropriate course of action and is the fair outcome.

The future

Each case is assessed on its own merits and this decision changes nothing about the test or the regime. At present, there is no evidence that a change to the threshold or decision limit for salbutamol is required. WADA has noted some public comments questioning the salbutamol threshold and how it was determined. It should be pointed out that studies conducted over the past 10 years – both WADA-funded and independent – have reinforced the legitimacy of the current threshold.

However, mindful of the complexity of some specific salbutamol cases, in particular the fact that different routes of administration cannot be distinguished by urine analysis, WADA will continue to consult experts in the field and carry out research in this area. As with every aspect of the Prohibited List, as fresh scientific data is made available, WADA assesses it in order to ensure the latest research is being applied and that all athletes' rights are best protected.



“ WADA's mission
*is to lead a collaborative
worldwide movement for
doping-free sport.* ”