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**NOTE:** AS REFERENCED IN WADA'S MEDIA RELEASE OF 11 JULY 2018 , ON 5 MARCH, THE AGENCY PROVIDED THE PARTIES TO THE CASE WITH THE FOLLOWING BACKGROUND INFORMATION TO, AND THE RATIONALE FOR, THE DECISION LIMIT FOR SALBUTAMOL.

**5 March 2018**

**WADA Note regarding Salbutamol**

Beta2 agonists are substances prohibited under section S.3 ("*Beta-2 Agonists*") of the 2017 International Standard of the Prohibited List and Methods (Prohibited List). This class of substances has been prohibited since WADA established the first Prohibited List that came into force on January 2004 under the World Anti-Doping Code, and was prohibited before 2004 by the IOC List of Prohibited Substances and Prohibited Methods under section I.C.2 ("*Other anabolic agents and beta-2 agonists with anabolic properties*") released under the Olympic Movement Anti-Doping Code.

It should be noted that according to Section 3 of the 2017 and 2018 Prohibited Lists, all beta-2 agonists are prohibited. However, exception was made for three beta-2 agonists, namely salbutamol, formoterol and salmeterol, for which thresholds are presented in the Prohibited List itself [1,2]. As a general concept, the threshold indicates a urinary concentration under which the concentration is not considered to reflect a prohibited use of the substance and above which, taking into account the measurement uncertainty for the analyte, the finding is reported by WADA accredited laboratories.

For salbutamol, the threshold value is established at 1000 ng/mL and reported by laboratories at urinary concentrations above 1200 ng/mL after applying the measurement uncertainty [3]. This threshold was established based upon the approach of prohibiting systemic routes of administration of salbutamol versus the allowed route via inhalation. Based upon the scientific publications available [4], studies sponsored by WADA [5] including examining inhaled versus systemic routes, the vast amount of data collected over the years from routine anti-doping tests [6] emanating from thousands of asthmatic athletes treated with salbutamol, in 2017 the rule in force established that "*Inhaled salbutamol: maximum 1600 micrograms over 24 hours, not to exceed 800 mcg every 12 hours".* This was further refined in 2018 by clarifying that the maximum dose of 1600 mcg per 24 hours was to be taken in divided doses not to exceed 800 micrograms "*over 12 hours starting from any dose*".

This rule, like any other modification to the Prohibited List, was proposed by the experts of the WADA List Committee which is comprised of experts from various scientific and medical disciplines, including pharmacology and, more specifically, in the pharmacology of beta-2 agonists. Such proposal was circulated to WADA stakeholders for review and finally approved by the WADA Executive Committee at its Executive Committee meeting in September. It is only after a broad consultation phase of several months and collecting comments from various stakeholders with multiple layers of expert reviews that the Prohibited List is approved, published at the end of September and comes into force on 1 January of each year.

WADA is well aware of the variability in salbutamol urinary excretion and therefore inserted in the rules a unique provision to address this possibility. WADA allows an athlete for whom a urinary concentration above 1200 ng/mL is reported to request an excretion study in a controlled environment to confirm

whether a specific individual metabolism could negate an Adverse Analytical Finding for salbutamol. Such a situation is extremely rare, but as a matter of fairness to all athletes, it was considered important to insert such a provision in the rules and more specifically in the Prohibited List.

**References**:

1. 2017 List of Prohibited substances and Methods
2. 2018 List of Prohibited substances and Methods
3. 2018 Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances.
4. Berges et al, Clin Chem 46:1365 (2000); Ventura et al, Ther Drug Monit. 22:277 (2000); Elers et al Med Sci Sports Exerc. 42:244 (2010); Pichon et al., Int J Sports Med, 27:187 (2006); Pillard et al. Respiratory Res, 16:155 (2015); Fitch, Clin Rev Allergy Immunol, 31 :259 (2006);
Schweitzer et al., Clin J Sport Med 14 :312 (2004); McKenzie et al., Clin J Sport Med, 14 :318 (2004)
5. Sporer et al, Med Sci Sports Exerc. 40:149 (2008); Sporer et al., Clin J Sport Med 18:282 (2008); Elers et al, Int J Sports Med 32: 574 (2011); Elers et al, Clin J Sport Med 22 :140 (2012); Dickinson et al., Clin J Sport Med 24:482 (2014); Haase et al., Drug Test Anal 8:613 (2016); Horstrup et al., Drug Test. Anal 6:528 (2014); Mareck et al., Drug Test Anal 3 : 820 (2011).*
6. WADA compilation of testing figures: https://www.wada-ama.org/en/resources/laboratories/anti-doping-testing-figures

* Research results, when not peer reviewed or published yet, are not provided.