

Montreal, 3 October 2018

# **Summary of Outcomes and Recommendations**

### Technical Document for Sport Specific Analysis (TDSSA) Expert Group Meeting - 11 September 2018 Montreal, Canada

Dear Colleagues,

The World Anti-Doping Agency's (WADA's) TDSSA Expert Group (EG) met in Montreal on 11 September 2018 and discussed the following main topics:

- the review of the level of TDSSA implementation by Anti-Doping Organizations (ADOs), taking into consideration ADAMS data from 2015 until the end of June 2018;
- the mandatory implementation of the haematological module of the Athlete Biological Passport (ABP) for the sports/disciplines with an Erythropoiesis Stimulating Agents (ESAs) Minimum Level of Analysis (MLA) of 30% or greater effective 1 January 2019;
- the mandatory application of the Growth Hormone (GH) MLAs in all relevant sports/disciplines effective 1 January 2019; and
- the review of the TDSSA and MLAs through a stakeholder consultation process planned for 2019.

The EG acknowledged that ADOs have made a collaborative effort to implement the TDSSA requirements in full and incorporate them into their risk assessments and Test Distribution Plans (TDPs). The implementation of the TDSSA was monitored through WADA's Code compliance monitoring program and, in particular, through the results of the Code Compliance Questionnaire (CCQ) and the Compliance Audit program. Through WADA's monitoring program, ADOs have provided information with regards to their testing plans and the application of the TDSSA. The data provided has been reviewed by WADA and any corrective actions have been communicated back to those ADOs that are not meeting or are partially meeting the MLAs. Implementing the TDSSA is considered as a Critical requirement under the International Standard for Code Compliance by Signatories (ISCCS).

The vast majority of Tier 1 and Tier 2<sup>1</sup> National Anti-Doping Organizations (NADOs) and International Federations (IFs), where applicable, are implementing or have a plan in place for 2018 to implement the requirements of the TDSSA. A very small number of ADOs are in the compliance procedure because, among other non-conformities, they are not implementing the TDSSA requirements.

A summary of core TDSSA figures are outlined below for 2015 to 2017 and include the first six months of 2018.

### Erythropoiesis Stimulating Agents (ESAs)

	# of samples	# of Sports	# of TAs	AAFs	# of blood ABP samples
2018 (1 Jan – 30 Jun)	25,263	102	189	28	15,757

<sup>1</sup> Classification according to the ISCCS <u>Prioritization Policy</u>.

2017 (Full year)	48,853	116	220	85	29,130
2016 (Full year)	46,710	108	212	67	28,111
2015 (Full year)	36,218	94	183	46	25,012

### Growth Hormone (GH)

	# of samples	# of Sports	# of TAs	AAFs
2018 (1 Jan – 30 Jun)	12,012	85	107	1
2017 (Full year)	20,482	90	124	0
2016 (Full year)	17,538	68	111	6
2015 (Full year)	13,264	74	103	4

# Growth Hormone Releasing Factors (GHRFs)

	# of samples	# of Sports	# of TAs	AAFs
2018 (1 Jan – 30 Jun)	29,384	110	187	7
2017 (Full year)	57,869	119	218	19
2016 (Full year)	42,730	111	207	15
2015 (Full year)	21,654	88	145	14

A summary of the main outcomes of the meeting and recommendations are outlined below.

# 1. The mandatory implementation of the haematological module of the ABP for the sports/disciplines with an ESAs MLA of 30% or greater will commence on 1 January 2019.

WADA's Executive Committee (ExCo) originally approved the mandatory implementation of the haematological module of the ABP by ADOs for the sports/disciplines with an ESAs MLA of 30% or greater in November 2016 to come into effect on 1 January 2018, which was extended to 1 January 2019. Following the review of the existing implementation of the haematological module and feedback from WADA's ABP team<sup>2</sup>, the EG saw no reason to postpone the mandatory implementation of the haematological module of the ABP for the sports/disciplines with an ESAs MLA of 30% or greater any longer and this requirement will therefore come into effect on 1 January 2019.

<sup>&</sup>lt;sup>2</sup> In 2018, almost 70% of Tier 1 and Tier 2 NADOs and IFs (where applicable) have ABP programs that are already in line with all applicable ABP Technical Documents and International Standards, including the ISTI.

The EG recognized that some blood transportation and analysis capacity issues remain in certain regions and WADA is working closely with those regions to find solutions as quickly as possible.

In addition, the EG recommends that the following mandatory criteria apply to the implementation of the haematological module of the ABP and are to be included within the TDSSA document for approval at WADA's November 2018 ExCo meeting:

- a) The mandatory implementation of the ABP haematological module shall apply to all athletes from those sports/disciplines with an ESAs MLA of 30% or greater (as identified in the TDSSA) that are referenced in an ADO's TDP, and are part of the ADO's Registered Testing Pool (RTP);
- b) The program shall be compliant with all applicable ABP Technical Documents and International Standards, including the International Standard for Testing and Investigations (ISTI) and the Technical Document for Athlete Passport Management Units (TD-APMU);
- c) At a minimum, an average of three blood ABP tests shall be planned annually across all athletes from those sports/disciplines with an ESAs MLA of 30% or greater<sup>3</sup> who are part of the RTP of an ADO and therefore part of the ADO's ABP haematological module program; and
- d) The distribution of these tests shall be carried out according to the status of the athlete's Passport, as well as any intelligence the ADO may have access to and the recommendations of the Athlete Passport Management Unit (APMU), so that athletes with atypical/suspicious Passports receive more tests than those with normal Passports.

ADOs will be required to report the details of their RTP to WADA through ADAMS or another system approved by WADA. An ADO's compliance in relation to its haematological ABP program will be monitored by WADA as part of its wider compliance monitoring program based on the criteria outlined above. As a guide to WADA's assessment of the required number of blood ABP tests per ADO (see criterion c) above), the annual number of blood ABP tests conducted by the ADO and recorded in ADAMS will be divided by the number of athletes in the RTP from the sports/disciplines with an ESAs MLA of 30% or greater.

As an example, if a NADO has 100 athletes in its RTP, of which 25 are from sports/disciplines with an ESAs MLA of 30% or greater, then the ADO shall plan to perform a minimum of 75 blood ABP tests (three tests x 25 athletes) during the course of that year. Athletes with atypical or suspicious Passports, as identified by the APMU, should have greater than three blood ABP tests during the course of the year. Athletes with normal Passports should have at least one blood ABP test during the course of the year.

For an athlete from a sport and discipline with an ESAs MLA of 30% or greater with no previous blood ABP tests, the ADO shall plan to conduct a minimum of three blood ABP tests within the first year to establish a baseline and then adjust the testing frequency, in consultation with the ADO's APMU.

These requirements do not prevent the implementation by an ADO of the ABP haematological module on athletes outside of its RTP or those found in the RTP of another ADO.

Implementation of the ABP haematological module for those sports/disciplines for which the MLA for ESAs is 15% is strongly recommended. For those sports/disciplines with an MLA for

<sup>&</sup>lt;sup>3</sup> According to existing ADAMS data, 19,523 blood samples from 6,332 athletes in sports/disciplines with an ESAs MLA of 30% or greater have been collected in the last 12 months, which equates to an average of 3.1 samples per athlete.

ESAs of 10%, ADOs are encouraged to consider the benefits of implementing the ABP haematological module. When implementing the ABP haematological module for sports/disciplines with an ESAs MLA of 15% or less, ADOs are encouraged to apply the same mandatory criteria outlined above.

The above recommendations for the mandatory criteria are proposed to be presented for approval at WADA's ExCo meeting in November 2018. WADA welcomes any comments or feedback that ADOs may wish to submit regarding these criteria. Please send any comments to <u>tdssa@wada-ama.org</u> by 16 October 2018.

ADOs that would like to receive more information or who may have questions on the implementation of the ABP are invited to contact WADA's ABP team at <u>athletepassport@wada-ama.org</u>.

# 2. The mandatory implementation of the GH MLAs for all sports/disciplines will be postponed until the endocrine module of the ABP is ready for implementation

With respect to the mandatory implementation of GH testing in 2019 by all ADOs, which was originally approved by WADA's ExCo (in November 2016) to come into effect on 1 January 2018 and was then extended to 1 January 2019, the EG recommends that the mandatory implementation of GH testing (in accordance with the MLAs as defined in the TDSSA) shall be postponed until the endocrine module of the ABP is ready for implementation.

During the period of postponement:

- ADOs are strongly encouraged to continue their best efforts to conduct GH testing and meet the existing GH MLAs for those sports/disciplines listed in the TDSSA;
- In situations where samples are reported as atypical for GH, and/or where investigations indicate reliable intelligence on possible GH abuse, ADOs should target test the athlete for GH analysis. In addition, ADOs are strongly encouraged to store the samples for future analysis and/or re-analysis when further technological advancements for GH analysis are available; and
- ADOs will not be held accountable under WADA's compliance monitoring program for fully meeting the GH MLAs.

WADA and the EG will continue to monitor the implementation of GH testing within ADOs' testing programs globally and will review its position in due course.

The above recommendation is proposed to be presented for approval at WADA's ExCo meeting in November 2018. WADA welcomes any comments or feedback that ADOs may wish to submit regarding this change. Please send any comments to <u>tdssa@wada-ama.org</u> by 16 October 2018.

Please note that there is no change to the mandatory implementation of GHRF testing (which came into effect on 1 January 2017 through the TDSSA). The analysis of GHRFs is not a substitute for GH analysis.

### 3. Ongoing monitoring of the implementation of the TDSSA requirements

The EG endorsed WADA's proposal to monitor the implementation of the TDSSA requirements by ADOs twice per year for the next two years. Such review will be based on WADA's <u>prioritization policy</u> and following the outcomes of such monitoring, the EG will review the results at its annual meeting. ADOs can utilize the <u>Reporting Guide to Monitor Testing</u> to monitor their compliance with the TDSSA, based on accurate ADAMS testing data.

# 4. TDSSA Testing Guides in ADeL

The accessibility of the TDSSA Testing Guides will be revised by the EG and WADA by the end of 2018. WADA will consider uploading the updated versions in <u>ADeL</u>, WADA's Anti-Doping e-Learning platform for ADOs, early in 2019 so ADOs' testing staff have easier access to them. The TDSSA Testing Guides for ESAs, GH and GHRFs provide valuable information and guidance for implementing an effective risk assessment and TDP for specific analyses of these substances.

### 5. Prohibited Substances on the TDSSA in 2019

No new categories of specific analyses are proposed to be added to the TDSSA in 2019.

### 6. Stakeholder consultation process in 2019

Following last year's EG decision for a review of the existing MLAs to be conducted by WADA in 2019, the EG agreed to the following timelines of such a review:

Action	Timeline
Stakeholder Consultation Starts	15 March 2019
Stakeholder Consultation Ends	30 April 2019
Annual TDSSA EG Meeting	Mid-June 2019
WADA Executive Committee Meeting	23 September 2019
Revised TDSSA comes into effect	1 January 2020

### 7. Availability of TDSSA analyses at WADA-accredited Laboratories

A list of WADA-accredited laboratories and the types of TDSSA analysis they currently can provide (as of 26 September 2018) can be found in the Annex of this Summary.

We hope you find the above update on the TDSSA informative. Should you have any comments or questions regarding the above or the implementation of the TDSSA, please contact WADA at tdssa@wada-ama.org.

Thank you for your continued commitment to clean sport.

Yours sincerely,

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Matt Fedoruk Chair of the TDSSA Expert Group

Annex 1: TDSSA analysis per WADA-accredited Laboratory (as of 26 September 2018)

		ESAs		GH		GHRFs	
Laboratory	Urine	Serum	Plasma	Isoforms	Biomarkers	GHRPs/GHS	GHRH
Ankara, Turkey	*	*		*	*	*	
Athens, Greece	*	*		*		*	
Bangkok, Thailand	*	*	*	*		*	
Barcelona, Spain	*	*	*	*	*	*	*
Beijing, China	*	*	*	*		*	
Bloemfontein, South Africa	*	*	*	*		*	*2
Bogota, Colombia <sup>1</sup>	*	*	*	*		*	*
Bucharest, Romania <sup>1</sup>	*	*	*	*		*	
Cologne, Germany	*	*		*	*3	*	*
New Delhi, India	*	*		*		*	
Doha, Qatar	*	*	*	*		*	
Dresden, Germany	*	*	*	*	*	*	
Ghent, Belgium	*	*	*	*	*	*	
Havana, Cuba	*	*		*		*	
Helsinki, Finland	*	*		*		*	
Lausanne, Switzerland	*	*	*	*	*	*	
Lisbon, Portugal <sup>1</sup>	*	*	*	*		*	*
London, UK	*	*	*	*	**	*	
Los Angeles, USA	*			*	*	*	
Madrid, Spain	*	*	*	*		*	
Montreal, Canada	*	*	*	*	**	*	
Oslo, Norway	*	*	*	*	*	*	
Paris, France	*	*	*	*	*	*	
Rio de Janeiro, Brazil	*	*	*	*	**	*	*
Rome, Italy	*	*	*	*	*	*	*
Seibersdorf, Austria	*	*	*	*	*	*	*
Seoul, Korea	*	*	*	*	**	*	*
Stockholm, Sweden	*	*	*	*	*	*	
Sydney, Australia	*	*	*	*	*	*	
Mexico City, Mexico	*	*		*		*	*
Tokyo, Japan	*	*		*	*4	*	
Salt Lake City, USA	*	*	*	*	**	*	*
Warsaw, Poland	*	*	*	*	*	*	
** Only these Laboratories can conduct confirmation of the GH Biomarkers method							

<sup>1</sup> Suspended Laboratories as of 26 September 2018.

<sup>2</sup> Only CJC 1293 and CJC 1295.

<sup>3</sup> Only IGF-I by LC-MS

<sup>4</sup> Expected to receive its accreditation for this method by December 2018.