MEMO

1. Do you support the proposal for certain sports supplements to be declared to be therapeutic goods? What are the reasons for your answer?

Level of support - Strongly support

ASADA has ongoing concerns about the impact of sports supplements on athletes. Surveys have shown that a notable number of sports supplements available in Australia contain World Anti-Doping Agency (WADA) Prohibited Substances and Scheduled Poisons. This impacts on athletes because taking supplements containing prohibited substances could result in Anti-Doping Rule Violations (ADRV) and subsequent sanctions including periods of ineligibility from participating in sport. In addition, ingesting prohibited substances may have serious health impacts on athletes.

The current regulatory framework for Sports Supplements is complex and difficult for athletes and National Sporting Organisations (NSO) to navigate.

ASADA support the proposal as it is expected to decrease the risk to athletes of consuming WADA Prohibited Substances and Scheduled Poisons.

2. Would the proposed declaration have an impact on the availability and choice of sports supplements for consumers? What are the reasons for your answer?

Impact - somewhat positive

The proposed declaration would have a somewhat positive impact on the availability and choice of sports supplements for athletes. ASADA currently advise athletes that certain types of sports supplements, such as pre-workout supplements, are high-risk in terms of Doping. Modified regulation of these supplements should decrease the risk associated with these products and so increase athletes' ability to utilise these products.

3. Would the proposed declaration provide greater clarity for industry as to whether their products should be marketed as foods or medicines? What are the reasons for your answer?

Level of support – Strongly agree

ASADA believe that the proposed declaration will provide greater clarity for consumers. The current regulatory system is complex for consumers to understand as products which may appear similar to consumers can be subject to different regulation. Under the proposed declaration, if the good contains a substance which is expressly identified on the WADA Prohibited List, it is identified as a therapeutic good. This declaration and classification will remove the confusion and make it clear to the consumer that the good must be carefully considered in that light.

4. Are you aware of products on the market that would not be captured by the proposed declaration but should be? What are the reasons for your answer? Please provide specific details and the rationale for why these products should be therapeutic goods. ASADA is content with the proposed declaration.

5. Are you aware of products on the market that would be captured by the proposed declaration but should not be?

What are the reasons for your answer? Please provide specific details and the rationale for why these products should not be therapeutic goods.

ASADA is content with the proposed declaration.

- 6. What impact would the proposed declaration, if made, have on your business? If there would be a positive impact, what are the reasons for your answer? If there would be a negative impact, please provide the following information (identified as confidential in the consultation submission cover sheet):-the number of products affected -operational impacts on your business
 - -approximate costs that these changes may impose on your operation

Impact on business – Positive Impact

The proposed declaration is expected to have a positive impact on ASADAs operations as well as positive impacts for Athletes and NSOs.

ASADA has ongoing concerns about the potential negative health impacts of some sports supplements due to the demonstrated presence of Scheduled Poisons and WADA Prohibited Substances. The proposed declaration is expected to have a positive impact on the health of athletes, and others, who use sports supplements.

ASADA

ASADA currently invest significant resources into educating athletes about the risks associated with supplements and managing enforcement actions of Anti-Doping Rule Violations (ADRVs) which arise from supplement use. The key risk is that of ingesting a WADA Prohibited Substance or scheduled poison due to incorrect labelling or poor manufacturing practices. The consequences to athletes include negative health impacts and ADRVs which damage their reputation and career. ASADAs supplement-related operations include

- o Education ASADA provides education through multiple means to a broad range of athletes and support personnel. This includes both face-to-face and online education. The audience ranges from schools programs to elite athletes. Due to the current risk associated with supplements a significant proportion of ASADAs education activities are focused on informing athlete about the risks associated with the supplements, how athletes can navigate the complex regulatory system and risk mitigation strategies. The risks associated with supplements are included in each ASADA face-to-face education session.
- Tools and Resources In response to the doping risk of supplements, ASADA have developed multiple tools and resources to raise awareness and assist with risk mitigation. These include
 - the ASADA App a key purpose of this App developed by ASADA is to assist athletes address the risk of supplements

- Posters, Postcards and other materials
- Communications ASADA also uses other means of communications including social media and outreach events to raise awareness amongst athletes of the risk associated with supplements.
- Enforcement Approximately one athlete per month receives an Adverse Analytical Findings (AAFs – Positive tests) which is associated with supplement use. From 1 January 2016 to 30 June 2019, ASADA has dealt with 31 Athletes who received an AAF which could be directly attributed to, or highly likely caused by, the use of supplements. Each matter requires significant ASADA resource to manage through the Anti-Doping Rule Violation process including investigative and legal resources. The quantum of resources required varies from case to case.

The proposed declaration is expected have a positive impact for ASADA through a decrease in the Doping risk due to supplements. Specifically it is expected to

- Decrease the number of ASADAs enforcement matters related to supplements.
- Decrease the priority of supplements in ASADAs education and communications This would decrease the resources which ASADA needs to invest in supplement –related operations.

This would enable ASADA to invest these resources into other identified risks. For example, investigative and legal resources could be re-directed towards targeting high-level facilitators and suppliers of prohibited substances to ensure dangerous substances are kept out of sport and away from athletes. Education resources could be refocused towards how athletes can make better and more informed decisions by placing more emphasis on ethical making decision making pathways.

Athletes

The current supplement regulation has negative impacts on athletes through the complexity of complying with Anti-Doping (AD) requirements, the health impacts and the consequences of ADRVs.

The impact on athletes is described by this statement from Chris Bond, OAM, Australian Paralympic gold medallist wheelchair rugby, ASADA Athlete Advisory Group member

24/11/2019

To who it may concern,

Doping affects the integrity of sport and cheating is not within the values I compete and train under as a clean and proud Australian elite athlete. The more steps we can take as a nation to eradicate performance enhancing substances in sport the better. Supplements have always been a risk for representative athletes and are generally used as a quick solution for busy athletes living busy lives undertaking full time training programs and competitions each year while juggling study, work and family life to ensure they get the fuel they need to recover and perform again and again. I believe in a food first approach to nutrition and recovery and to lower the risk of athletes consuming banned substances I endorse the proposal to move sports supplements from the food group to be a therapeutic

good/medicine. This should ensure more regulation, creating a higher quality product and lowering the risk of inadvertent doping in Australian athletes.

Chris Bond OAM, Australian Paralympic gold medallist wheelchair rugby, AAG member

There is a far greater impact on athletes who receive an ADRV due to supplement use. The consequences for these athletes include

- Sanction from sport which means they are unable to compete, train, coach or participate. This may range from a few months to 4 years dependant on the circumstances of the case.
- Disqualification of results if they competed on or since the date of the AAF.
- Reputational damage
- Damage to their sporting career

[REDACTED]

The proposed declaration is expected to have a positive impact for athletes through a decrease in the Doping risk due to supplements. Specifically it is expected to

- Decrease the number of athlete subject to ADRVs and hence sanctions from sport due to supplement use
- Decrease the complexity of complying with AD regulations related to supplements

The proposed declaration is expected to have a positive impact on the health of athletes, and others, who use sports supplements. ASADA has ongoing concerns about the potential negative health impacts of some sports supplements.

Surveys have shown the presence of Scheduled Poisons and WADA Prohibited Substances in some sports supplements. Athletes, and other consumers, who use sports supplements are at an increased risk of consuming these substances.

The proposed declaration is expected to have a positive impact for athletes and other consumers through

- Increased clarity with regards to regulation of supplements
- Reduction in inadvertent exposure to Scheduled Poisons and WADA Prohibited Substances which can be harmful to health

National Sporting Organisations (NSO)

The current sports supplement regulation has negative impacts on NSOs through the complexity of complying with Anti-Doping (AD) requirements and the enforcement of ADRVs associated with supplement use.

The current complexity of supplement sports regulation makes supplement management a difficult responsibility for NSOs. NSOs carry a high risk of making a mistake when providing advice and also the risk of their athletes suffering consequences from supplement use. The proposed declaration is expected to increase clarity of regulation and hence decrease the complexity of complying with AD regulations related to supplements,

The enforcement of ADRVs associated with supplement use requires resources from NSOs. This includes

- Providing support and guidance to the affected athletes
- Implementing and managing the sanctioning of athletes
- Managing the disqualification of results of affected athletes

The proposed declaration is expected to have a positive impact for NSOs through decreasing the number of ADRVs associated with supplement use and hence decrease the NSO resources required to manage supplement-related ADRVs, This will enable NSOs to re-direct these resources to other priorities.

7. Do you have any other comments related to the consultation?

UNESCO Convention

The UNESCO Convention against Doping in Sport places a binding obligation on State Parties (including the Australian Government) to restrict the availability and use of prohibited substances in sport (article 8 below) and to encourage producers and distributors of nutritional supplements to establish best practices in the marketing and distribution of nutritional supplements, including information regarding their analytic composition and quality assurance (article 10 below). The proposed declaration would contribute to the Australian Government's measures to meet this obligation.

UNESCO International Convention Against Doping in Sport

Article 8 – Restricting the availability and use in sport of prohibited substances and methods 1. States Parties shall, where appropriate, adopt measures to restrict the availability of prohibited substances and methods in order to restrict their use in sport by athletes, unless the use is based upon a therapeutic use exemption. These include measures against trafficking to athletes and, to this end, measures to control production, movement, importation, distribution and sale.

- 2. States Parties shall adopt, or encourage, where appropriate, the relevant entities within their jurisdictions to adopt measures to prevent and to restrict the use and possession of prohibited substances and methods by athletes in sport, unless the use is based upon a therapeutic use exemption.
- 3. No measures taken pursuant to this Convention will impede the availability for legitimate purposes of substances and methods otherwise prohibited or controlled in sport.

Article 10 - Nutritional supplements

States Parties, where appropriate, shall encourage producers and distributors of nutritional supplements to establish best practices in the marketing and distribution of nutritional supplements, including information regarding their analytic composition and quality assurance.