Submission to the Therapeutic Goods Administration

Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia

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1.0 About Exercise & Sports Science Australia

Exercise & Sports Science Australia (ESSA) is the peak professional association for exercise and sports professionals in Australia, representing more than 8,000 members, including university qualified Accredited Exercise Physiologists (AEPs), Accredited Sports Scientists (ASpSs), Accredited High-Performance Managers (AHPMs) and Accredited Exercise Scientists (AESs).

AEPs are nationally recognised allied health professionals (AHPs) who provide clinical exercise interventions aimed at primary and secondary prevention; managing acute, sub-acute and chronic disease or injury; and assist in restoring optimal physical function, health and wellness. Exercise physiology is a recognised and funded profession under compensable schemes such as Medicare Benefit Services (MBS), Department of Veteran Affairs (DVA), the National Disability Insurance Scheme (NDIS), private health insurance (PHI), and state and territory-based workers' compensation schemes.

Accredited Sports Scientists provide expert advice and support to athletes and coaches to help them understand and enhance sports performance; adopting evidence-based, quality-assured practice to evaluate and develop effective strategies or interventions in training and/or competition. An ASpS may operate in one or more roles from pure researcher to applied practitioner and may also work in fields outside sport where human physical performance is an important factor.

An Accredited High Performance Manager (AHPM) applies leadership and management skills, working with a team of Sports Science and Sports Medicine (SSSM) and coaching professionals to assist athletes to optimise sports performance in an ethical manner. This is achieved through the utilisation of best-practice principles to oversee the design, planning, implementation, and evaluation of evidence-based and quality assured SSSM programs for sporting teams, organisations or clubs.

ESSA is recognised by the Australian Institute of Sport and Sport Australia as the peak accrediting body for athlete support personnel working in Australian sports science i.e. Accredited Sports Scientists and Accredited High Performance Managers.

Accredited Exercise Scientists apply the science of exercise to design and deliver physical activity and exercise-based interventions to improve health, fitness, well-being, performance and assist in the prevention of injury and chronic conditions. They coach and motivate to promote self-management of physical activity, exercise and healthy lifestyles and work in the National Disability Insurance Scheme (NDIS) as personal trainers and allied health assistants (AHAs), in fitness businesses, for sporting bodies, in corporate health and as AHAs for exercise physiologists and other allied health professionals.

2.0 Introduction

Point-of-care testing (POCT), such as blood glucose testing, cholesterol testing etc is within scope of practice for [redacted] typically involves a lancet [redacted] placement of a blood droplet into a machine for analysis.

ESSA highlights several high level issues for the Therapeutic Goods Administration (TGA) to consider:

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a. Is the use of medical devices to optimise sports performance considered appropriate for mandating reporting or not?

Accredited Sports Scientists use in vitro diagnostic medical devices (IVDs) as per the current TGA's definition and and active devices to gather data to monitor various aspects of human physical performance to assist athletes to optimise sports performance.

ASpSs frequently use blood lactate analysers/blood lactate testing equipment (e.g. the Lactate Pro 2 e.g. https://www.cosmed.com/en/products/cardio-pulmonary-exercise-test/lactate-monitor) to test lactate levels in blood during field and laboratory testing.

ASpSs use other point-of-care analysers from time to time for more in-depth monitoring of various blood markers, for example to monitor physiological and/or metabolic processes, and responses to training interventions (e.g. Abbott i-STAT 1 System https://www.blockscientific.com/abbott-i-stat-1-system#attr=).

In addition, ASpSs also use software or a combination of non-invasive hardware and software or wearables to collect and analyse data on various physiological functions (e.g. cardiac rhythms, respiration rates etc.) and use this data to work collaboratively with health professionals (e.g. Chief Medical Officers in the cases of professional sporting teams) and/or Sports Science and Sports Medicine Managers and/or Accredited High Performance Managers to design, plan, implement and evaluate the effectiveness of evidence-based and quality assured SSSM programs.

Given the TGA's 2020 declaration under subsection 7(1) of the *Therapeutic Goods Act 1989 (the Act)* that certain sports supplements are regulated as therapeutic goods (medicines) for the purposes of following therapeutic uses including, but not limited to:

- gaining muscle;
- increasing mental focus;
- increasing metabolism;
- increasing stamina;
- increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;
- losing weight or fat;
- preparing for workout;
- recovering from workout

for consistency purposes, it would seem that ESSA Accredited Sports Scientists and ESSA Accredited High Performance Managers should also be factored into considerations on mandatory reporting requirements, though the risk of an adverse event triggered by medical devices used by Accredited Sports Scientists and Accredited High Performance Managers is low.

b. Depending on the answer to the question a. above, are the use of the terms 'health practitioner' and [redacted] broad enough to capture the use of IVDs by non-health practitioners and nonhealthcare facilities?

The current definition of a 'health practitioner' within Chapter 1 Preliminary: Clause 3 Interpretation in the *Therapeutic Goods Act 1989* does not include provision for the TGA to require non-health practitioners and non-healthcare facilities to be included in any mandatory reporting requirements. ESSA notes *the Act* currently also does not include any definition for a healthcare facility.

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Depending on whether the use of medical devices to optimise sports performance is considered appropriate for Mandatory Reporting, then additional inclusions for Accredited Sports Scientists and ESSA Accredited High Performance Managers may need to be made within *the Act*.

3. Responses to Selected Questions

3.1 Item 1: Potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia

Questions:
• *Should Australia introduce mandatory reporting for medical device related adverse events by healthcare facilities?*
– *Why should Australia introduce mandatory reporting for medical device-related adverse events by healthcare facilities?*
or
– *Why should Australia not introduce mandatory reporting for medical device-related adverse events by healthcare facilities?*
• *Can you identify any unintended consequences of introducing mandatory reporting of adverse events by healthcare facilities?*

ESSA recommends and supports mandatory reporting of medical device adverse events to ensure that the health and safety of patients is protected through the earlier detection and communication of adverse events to an agency which can identify patterns of events, begin investigations and/or commence actions to address safety concerns with manufacturers or sponsors of medical devices, and communicate risks to patients and health practitioners in a timely manner.

ESSA further recommends that wherever possible, any reporting system be embedded within an existing accreditation system to avoid duplication.

ESSA provides feedback in the following responses on how a risk management approach to potential adverse events which factors in the level of risk associated with each device should be adopted.

Item 2: Facilities that could be included and/or excluded from mandatory reporting

Questions:
• *Are there any healthcare facilities licensed/accredited through national schemes (listed in the discussion paper) that should not be included in any proposed mandatory reporting of medical device adverse event reports?*
– *If so, why?*
• *Are there any other frequent users of medical devices that could potentially be included? Please select from the provided list or provide examples of other types of services:*
[redacted] *e services* [redacted]
– *Dental and orthodontic practices*
– *Chiropractic practices (who conduct diagnostic imaging)*
– *Pharmacy practices (who supply medical devices)*
– *Non-medical specialist cosmetic procedure centres*
– *Other residential care providers*
– *General practices*

– Specialist medical practices
– Allied health practices
– Community-based health services (e.g., district nursing services)
– Other (Please provide)
• Are you aware of a reporting, accreditation or licencing body that would be able to mandate potential mandatory reporting of medical device related adverse events?
• Are you aware of any specific state and territory legislation, health service licencing or other requirements that would prevent potential mandatory reporting?

There are many healthcare facilities which are frequent users of medical devices which are not accredited through national schemes. ESSA has highlighted above employees of sports science facilities and sporting organisations are also frequent users of medical devices.

Whilst allied health practices are another example employing frequent users of medical devices, there are currently no national mandatory accredited schemes for allied health practices.

ESSA notes that allied health practices will be able to voluntarily gain accreditation to the Australian Commission on Safety and Quality in Health Care (Commission)'s Primary and Community Healthcare Standards from mid-2022.

These Standards contain the following definition for invasive medical devices:

> ''devices inserted through skin, mucosal barrier or internal cavity, including central lines, peripheral lines, urinary catheters, chest drains, peripherally inserted central catheters and endotracheal tubes".

Ideally the TGA definition of an 'in vitro diagnostic medical device' should be harmonised with the Commission's definition of an 'invasive medical device' as a starting point for the Commission to mandate potential mandatory reporting of medical device related adverse events.

The bigger barrier is that until such time as primary and community healthcare facilities need mandatory accreditation with the Commission, then the Commission prevents potential mandatory reporting.

Potentially, the Australian Health Practitioner Regulation Agency (Ahpra) could mandate mandatory reporting of medical device related adverse events by the health professionals it regulates, though there are gaps between the full range of professions regulated by Ahpra and the current definition of a 'health practitioner' within Chapter 1 Preliminary: 3 Interpretation of the *Therapeutic Goods Act 1989*.

The Act defines 'health practitioner' as follows:

> "health practitioner means a person who, under a law of a State or internal Territory, is registered or [redacted] any of the following healt[redacted]
> (a) Aboriginal and Torres Strait Islander health practice;
> (b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);
> (c) medical;
> (d) medical radiation practice;
> (e) nursing;

(f) midwifery;
(g) occupational therapy;
(h) optometry;
(i) pharmacy;
(j) physiotherapy;
(k) podiatry;
(l) psychology."

All of the above 12 professions are regulated by the Australian Health Practitioner Regulation Agency under a nationally consistent *National Health Practitioner Law* passed by each state and territory parliament.

Queensland, as the lead jurisdiction for implementing the National Law, can submit amendments to its parliament, in a form agreed by the Ministerial Council. Once changes are accepted by the Queensland Parliament, then changes automatically apply in all other parliaments, except Western Australia (which needs to pass legislation to amend its *Health Practitioner Regulation National Law (WA) Act 2010)* and South Australia (which enacts a regulation to modify the *Health Practitioner Regulation National Law (South Australia) 2010*).

If all Ahpra regulated health professions are to be required to mandatory report potential adverse medical device adverse events, then the current TGA definition of 'health practitioner' would need to be expanded to include the following health professions:

- Chinese Medicine
- Chiropractic
- Osteopathy

and the *National Health Practitioner Law* amended by Queensland, WA and SA.

If other 'health practitioners' not regulated by Ahpra are to be included, then the TGA will need to consider expanding its definition of 'health practitioner' to include self-regulated and independently regulated health practitioners operating under the *National Code of Conduct for health care workers*.

ESSA recommends that should other 'health practitioners' not regulated by Ahpra be included in a mandatory reporting scheme, then at a minimum, those health professions self-regulating under National Alliance of Self Regulating Health Professions (NASRHP) and with a Medicare item be added to the TGA definition of 'health practitioner' to ensure consistency of mandatory reporting requirements by 'health practitioners' within healthcare facilities. In addition, adding more self-regulated classes of 'health practitioners' who are permitted to perform, or supervise the performance of various tests under *the Act* would provide greater parity for allied health practitioners.

This would mean adding the following 'health practitioners':

[redacted], speech pathologists, dieti[redacted] bodies are full members of NASRHP and

- social workers whose professional body is a qualifying member of NASRHP.

Many allied health assistants (AHAs) including ESSA Accredited Exercise Scientists use point-of-care testing, such as blood glucose testing, cholesterol testing etc., as these functions are within the scope of practice for all AESs.

Whilst ESSA is aware of the establishment of a new professional body, the Allied Health Assistant Network of Australia in September 2020 for allied health assistants, this body is not yet recognised as an accrediting body by state or federal governments, nor does it have the resources to become an accrediting body without support from government.

This leaves most AHAs (unlike AESs) completely unregulated though some state and territory governments have developed frameworks and guidelines to support the employment of AHAs in their jurisdiction.

ESSA understands whilst the TGA is not responsible for specifying the 'health practitioners' it can regulate in section 3 of *the Act*, it is in a position to recommend to the Minister for Health and the Australian Government that the definitions within the legislation be amended.

ESSA re-iterates the question asked in the introduction of this submission: are medical devices to optimise sports performance considered appropriate for mandating or not? If the answer is yes, then consideration should be given to including Accredited Sports Scientists and Accredited High Performance Managers within *the Act*.

Inclusion of Accredited Sports Scientists and Accredited High Performance Managers within *the Act* may also strengthen the regulation of sports supplements.

Notwithstanding that allied health practices and sports science facilities are frequent users of medical devices, ESSA recommends that allied health and sports science facilities (and the health and sports science professionals employed within these facilities) be NOT subject to mandatory reporting of medical device adverse events because of the low risks that associated with the medical devices used in these facilities and by these practitioners.

Item 3. The type of medical device-related incidents or events that could be reported to the TGA

Questions:

• *What type of medical device-related incidents or events do you consider should be reported through to the TGA?*
– Incidents resulting in death
– Incidents resulting in serious injury
– Near misses that could have resulted in death or serious injury
– Issues identified during routine maintenance where the device is fixed or replaced prior to use
– Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility
– Other (please specify and provide reason)
• *If you work in a healthcare facility, will the harm metrics that your healthcare facility utilises allow for identification of reportable incidents (including the types mentioned in the preceding question)?*
• *When an adverse event occurs, what medical device-related information is collected by facilities through incident or other information management systems?*
– The suspected involvement of a medical device
– The brand/trade name of the medical device
– Where the medical device came from (e.g. facility/health professional)
– The current location of the medical device
– Other (please specify)

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ESSA recommends that a risk management framework with a hierarchy of incidents from death to lower order issues which can trigger potential adverse events be developed. The framework should take into account the level of risk associated with using each device and how invasive the procedure is for using and activating the device, particularly for IVDs where surgery to implant a device would represent a much higher risk than a pin prick to draw blood.

The WHO guidelines on drawing blood outline the risks and risk-reduction strategies (mainly by following best practices in infection prevention and control). The risks for drawing blood with a lancet, provided best practices in infection prevention and control are used, are minimal.

ESSA supports only the mandatory reporting of high risk incidents or events, including

- **Incidents resulting in death**
- **Incidents resulting in serious injury**
- **Near misses that could have resulted in death or serious injury.**

ESSA recommends that low risk incidents or events should NOT be subject to mandatory reporting through to the TGA.

Item 4. Recognising and reporting events that might cause (or be causing) harm to consumers

Questions:
Do current reporting systems need to be improved to incorporate patient symptoms that might have been caused by a medical device?
– If so, what needs to be improved?
• What level of patient symptoms should be flagged by healthcare facilities?
– symptoms causing pain or discomfort
– symptoms that cause impairment of function
– symptoms that require additional medical care
• Do healthcare facilities routinely collect the following information relating to potential or actual device malfunctions?
a. Issues identified during routine maintenance where the device is fixed or replaced prior to use:
▪ Is this information recorded? If so,
Where is this information recorded?
▪ Is this information reported? If so,
Who or where is this information reported to?
b. Issues successfully managed by clinical staff e.g. near misses:
▪ Is this information recorded? If so,
Where is this information recorded?
▪ Is this information reported? If so,
Who is this information reported to?
c. Incidents that occur outside of a hospital setting e.g. malfunction of an implant and the patient presents to a healthcare facility:
▪ Is this information recorded? If so,
Where is this information recorded?
▪ Is this information reported? If so,
Who is this information reported to?

There are no formal mechanisms for allied health to report events that might cause (or be causing) harm to consumers, unless an incident needed to be reported for legal reasons (e.g. to workplace health and safety agency if incidents that impact upon staff). This information is recorded within allied health and sports science facilities.

Should it be determined that potential mandatory reporting of medical device related adverse events needs to apply to allied health and sports science facilities, a formal system to report events that might cause (or be causing) harm to consumers would need to be established.

Item 5. Reducing duplication of data entry and/or analysis by healthcare facilities

Questions:
What platform/s does your organisation currently use (or provide, if you are a software vendor) to record medical device-related incidents, adverse events, potential incidents, or device failures (examples below)?
o Patient medical records (for symptom related data)
o Incident management systems (for events that impact upon patients)
o Workplace health and safety systems (for incidents that impact upon staff)
o Equipment maintenance records or databases
o Hospital purchasing records (e.g. for returned products)
o Patient/staff complaints data
o Other (please specify)
▪ *Does the platform include the capability to generate or send reports or summaries of the incidents in standards and formats such as FHIR, XML or JSON?*
▪ *If a healthcare facility, do you already submit data to the TGA for COVID-19 vaccine reaction reporting?*
▪ *If you have more than one platform that records device incidents, are there issues with integrating current information systems?*
▪ *Is it feasible for an adverse event module to be added to your current platform/s to facilitate data transfer to the TGA?*
– If so, please outline how this integration could occur, the potential costs and timeframes, and any potential blockers.
– If not, could a system adaptor be utilised?
▪ *If so, please outline which information systems would benefit from an adaptor, the potential costs and timeframes, and any potential blockers.*
▪ *If not, why?*

ESSA is unable to provide detailed responses to these questions as there are around 120 different systems used by allied health, including the use of My Health Record for patient data. Whilst it appears there is work underway to encourage some parts of the health sector to improve the interoperability of systems, particularly where there is less diversity of systems, a significant challenge remains in addressing interoperability for those professions where there is greater diversity of systems and profession specific needs [redacted] [redacted]

Any data requirements should meet the national digital health standards being developed by the Australian Digital Health Agency and meet whole-of-government approaches to regulate digital platforms. Currently, Australian Competition & Consumer Commission's Digital platform services inquiry 2020-2025 and Australian Human Rights Commission's Human Rights and Technology Final Report recommendations are being considered by multiple departments.

Item 6. Quality assurance of the incident information

Questions:
• *Is there a current minimum data set that is collected for adverse event/incident reporting?*
– *If so, what does this data set consist of?*
– *Does this currently undergo quality assurance checks?*
– *If so, who is responsible for undertaking this check?*
• *Within healthcare facilities, which health professionals are responsible for reporting adverse events as part of their accreditation requirements?*
– *Nurse manager*
– *Quality and safety consultant*
– *Clinical nurse specialist*
– *Bio-medical engineer*
– *Clinician*
• *Other (please specify)*

ESSA supports a minimum data set for adverse event/incident reporting and offer no other comments on the questions.

7. Accountability for mandatory reporting

Questions:
• *What existing legislative, accreditation or other mechanisms should be explored in relation to potential mandatory reporting and why?*
• *What type of compliance schemes could be implemented to reinforce potential mandatory reporting?*
– *Modification to current accreditation schemes*
– *Organisational recognition and reward schemes*
– *Risk-adjusted funding arrangement*

Potential mandatory reporting should be consistent across the various sectors: medical, nursing and allied health.

ESSA does not support potential mandatory reporting only for those allied health professions regulated by Ahpra. If potential mandatory reporting is to be introduced for allied health, then legislative amendments will need to be made to the *Therapeutic Goods Act 1989*.

[redacted] [redacted]