





Shayna Jack, sports supplements and regulators

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<http://www.medreach.com.au>


Surf Coast Spring Skepticamp VII, September 14, 2019



1



Shayna Jack tested positive for a banned substance



She revealed banned Ligandrol (a SARM) was behind her doping suspension from swimming. "It could be mushrooms", said her manager Phil Stoneman

<https://www.abc.net.au/news/2019-07-29/shayna-jack-swimming-australia-defends-competitor/11355498>

2



Posted on Instagram 21 December 2018




<https://www.instagram.com/p/Bro4BNpIF9X/> <https://www.extremo.com.au/>

3




EXTREMO Post Sports Recovery



- Eliminates fatigue,
- Increases hydration,
- Repairs muscle damage and soreness,
- Gets you back to peak performance faster so you can play better.

<https://www.extremo.com.au/product-one>

4



Who regulates sports supplements?

- Supplements may be regulated as either a food or a medicine, depending on whether it meets the requirements outlined in the FSANZ Standard 2.9.4 (Formulated supplementary sports foods) or the *Therapeutic Goods Act 1989*.
- The TGA notes that determining whether a sports supplement is a food, or a medicine, can be complex (FMIGT).
- In addition, FSANZ standard 2.9.4 is currently under review.
- Information about ingredients or substances that are not permitted for specific sports can be found at the Australian Sports Anti-Doping Authority website.

<http://www.foodstandards.gov.au/consumer/nutrition/sportfood/Pages/default.aspx>
<https://www.tga.gov.au/food-medicine-interface-guidance-tool-fmig>
<https://www.tga.gov.au/food-medicine-interface-guidance-tool-fmig>

5



ASADA: supplements in sport



- ASADA advises that no supplement is safe to use because many are contaminated or deliberately adulterated with substances prohibited in sport.
- A 2016 survey of 67 common supplements available for purchase in Australia found one in five products contained one or more substances banned in sport.
- Some supplements are screened for prohibited substances by independent companies, such as HASTA or Informed Sport. This does not offer a 100% guarantee, but the risk is less.
- Neither of the two auditing websites listed Extremo (promoted by Shana Jack).

<https://www.asada.gov.au/substances/supplements-sport>

6

The rise of SARMs

6/11/18

- ASADA has noted that an increasing number of athletes appear to be using SARMs.
- They are claimed to induce muscle (and bone growth) without the side effects associated with steroid use.
- SARMs are associated with serious safety concerns including liver toxicity and the potential to increase the risk of heart attack and stroke.
- The TGA classifies SARMs as Schedule 4, prescription-only medicines, some are Schedule 10 (totally prohibited).
- SARMs have been prohibited by the World Anti-Doping Agency (WADA) since 2008.

<https://www.asada.gov.au/news/blog-rise-igd-4033>

7

SARMs

- In 2010, one athlete tested positive for SARMs worldwide. In 2016, 39 tested positive including 6 Australians in triathlon and motorcycling sports.
- In 2018 there were at least 10 SARMs online stores with Australian domain names.
- The owner of one of the largest of these sites says sales have gone from 10 to 100 vials a day in under two years.
- A 30ml vial of SARMs (enough for a 30-day cycle) costs \$149-\$199. That works out to more than \$15,000 worth of SARMs per day, or over \$5 million revenue per year.

<https://www.abc.net.au/triplej/programs/hack/massive-blackmarket-in-sarms-research-chemicals/9666006>

8

TGA fails to act on illegal sports supplements

March 30, 2019

TUESDAY 17 APRIL 2018 10:36AM

SARMs: The massive black market in illegal bodybuilding 'research chemicals'

First it was prohormones, then it was peptides - now a new black market sports supplement hyped as the "holy grail" has taken the Australian market by storm.

Complaint to CRP, 29 March 2018, referred to TGA, 5 April 2018 (2018/03/015) AusLabs SAMS, STACKS, PCT & SUPPORT, PEPTIDES. No outcome to-date; products still being sold today.

<https://www.medreach.com.au/tga-fails-to-act-on-illegal-sports-supplements/>

9

Austlabs.co website

August 9, 2019 & today

Sent to TGA on 9 August 2019, update on 5 April 2018 complaint requested

10

Update on Complaint 2018/03/015

August 13, 2019

From: TGA Advertising <tga_advertising@tga.gov.au>
Sent: Tuesday, 13 August 2019 14:13
To: <ken.harvey@medreach.com.au>
Subject: RE: TGACRP Complaint: AusLabs Co - Selective Androgen Receptor Modulators (2018/03/015) [SEC=OFFICIAL]

Dear Dr Harvey

Thank you for email about CRP complaint 2018/03/015 which relates to AusLabs Co and their advertising of Selective Androgen Receptor Modulators (SARMs).

An open case regarding this matter is being managed by the Regulatory Compliance Section (RCS), the CRP matter was referred to RCS to be incorporated into their investigation.

The new information you have provided below will also be forwarded to RCS for their consideration. I trust this information is of assistance to you.

Regards,
 Adelina Tan
Director, Advertising Compliance Unit

11

Complaint AC-C7NJKYV/2018 submitted: 11 Dec 2018

This complaint must be accorded **'critical'** priority because "The King Kong Stack" is being promoted and sold by **Evolution Supplements** (ABN: 99 382 528 968) without being listed on the ARTG; a breach of s.42DL(1)(g) of the Therapeutic Goods Act 1989.

In addition, some products within "The King Kong Stack" contain SARMs such as Cardarine (Schedule 10) of such danger to health that they are prohibited from sale, supply and use to Australian consumers.

Furthermore, "The King Kong Stack" is just one of what appears to be many illegal products being promoted and sold by Evolution Supplements.

12

TGA advertising direction notice

January 23, 2019

Direction under section 42DV of the Act
Issued to: Mr Cumhuri Keskin (*Evolution Supplements*)
About: Advertising of therapeutic goods not entered in the ARTG, including substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard and substances, or goods containing substances, included in Schedule 10 to the current Poisons Standard.
Direct you to: Cease the advertising of, and the publication of references to, any substances entered on Schedule 4 of the current Poisons Standard.

13

Outcome: Complaint AC-C7NJKYV/2018

June 20, 2019

REFERENCE NUMBER	CASE NUMBER	RECEIVED DATE	FINALISED DATE	RISK CATEGORY
AC-C7NJKYV/2018	CC-L3JFQJ22/2018*	11-Dec-2018	20-Jun-2019	Medium

PRODUCTS

- Blackstone Labs - Metha-Quad Extreme
- DMHA - Brawn Nutrition
- Evolution Laboratories - Evo Labs - Kong
- Olympus Labs - Ar1Macare Pro
- Olympus Labs - Sup3r PCT
- Selective Androgen receptor modulators (SARMs)

RESPONSIBLE PERSON
 Whatsapp - Supplement Store

CASE OUTCOME
 20-Jun-2019 Case resolved

<https://compliance.tga.gov.au/investigations-database/complaints/?ref=AC-C7NJKYV%2F2018&case=CC-L3JFQJ22%2F2018%2a>

14

Outcome: Complaint AC-C7NJKYV/2018

June 20, 2019

ALLEGED BREACHES

THERAPEUTIC GOODS ACT 1989

42DL(10) - advertisement refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 of the current Poisons Standard but not in Appendix F, other than a reference authorised or required by a government or government authority

42DL(12) - advertisement refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government/government authority (not including a foreign government/authority)

The TGA reviewed the material provided by the complainant and the advertiser. The TGA confirmed the advertisement refers to substances, or goods containing substances, 'Selective Androgen Receptor Modulators (SARMs)' included in Schedule 4 to the current Poisons Standard and was therefore in breach of subsection 42DL(10) of the Therapeutic Goods Act 1989 (the Act). As the advertised products are not included in the Australian Register of Therapeutic Goods (ARTG) and are not exempt from the requirement to be included in the ARTG the TGA considered the advertising also breached subsection 42DL(12) of the Act.

<https://compliance.tga.gov.au/investigations-database/complaints/?ref=AC-C7NJKYV%2F2018&case=CC-L3JFQJ22%2F2018%2a>

15

Outcome: Complaint AC-C7NJKYV/2018

June 20, 2019

ACTIONS

17-Apr-2019 **Warning Letter requiring action sent to advertiser**
 The TGA required the advertiser to remove all references to schedule 4 substances and goods not included in the ARTG and advised of the sanctions and penalties which may apply.

OUTCOMES

20-Jun-2019 **Case resolved**
 The advertiser has removed the non-compliant advertising from the website

<https://compliance.tga.gov.au/investigations-database/complaints/?ref=AC-C7NJKYV%2F2018&case=CC-L3JFQJ22%2F2018%2a>

16

Case resolved? AC-C7NJKYV/2018

September 13, 2019

Are you ready for our new formula? Introducing you KONG! Highest MG per capsule. Highest purity 5 SARMs STACK.

Benefits OF KONG:

- Lean Mass Gains
- Muscle Definition
- Endurance
- Fat Loss

2 CAPSULES CONTAIN:

- MK2866-25mg
- LGD4033-10mg
- GW501516-20mg
- MK-677-20mg
- GW501516-20mg

For Research Purposes Only. Not For Human Consumption.

**MK-2866 (Enobosarm)
 LGD4033 (Ligandrol)
 MK-677 (Ibutamoren)
 GW501516
 Cardarine**

<https://evolutionsupplements.com.au/evo-labs-kong-60-capsules/> Sept 13, 2019

17

More complaints

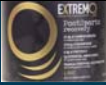
ADD9604 1 x 5ml Vial \$269.00
 ADD9604 2 x 5ml Vials \$419.00
 ADD9604 4 x 5ml Vials \$695.00
 ADD9604 Cream 20ml \$250.00

<https://peptidesdirect.com.au/aod9604/> AC-BK2694MW/2019

PCT (5ml) \$415.00
SARMs (5ml) \$146.00
Weight Loss (2 x Hex, 2 x SARMs) \$99.00

<https://musclepeptidesaustralia.com.au/product-category/all/> AC-LS3ZWDQA0/2019

18




What has the TGA achieved in 2019?

- January 23, 2019 - Directions notice to *Evolution Supplements* about advertising schedule 4 products. Said compliance achieved (for an advertiser not complained about) but it has not for *Evolution Supplements*.
- July 23, 2019 - \$10 million fine awarded by the Federal Court against *Peptide Clinics Pty Ltd* for advertising schedule 4 products. But the company went into liquidation some months earlier and did not pay.
- August 6, 2019 - Directions notice to *Auzsupps Pty Ltd* about advertising schedule 4 products. Web site currently down, says, "back soon".
- August 6, 2019 - Directions notice to *ESR YOU Pty Ltd* about advertising schedule 4 products including SARMs. Offending products removed.

<https://www.tga.gov.au/advertising-directions-notice>
<https://www.abc.net.au/news/2019-08-06/peptide-clinics-fined-10-million-over-false-drug-claims/11387062>

19




What has the TGA achieved in 2019?


- September 10, 2019 - Australian business *Redback SARMs* paid penalties of \$15,210 after the TGA issued six infringement notices for the alleged advertising of Schedule 4 (prescription-only) substances, including SARMs.
- September 10, 2019 - Australian company *PharmaCare* paid penalties of \$12,600 after the TGA issued an infringement notice for the alleged advertising of a therapeutic good after it had been cancelled from the ARTG.
- For companies with revenue of over \$5 million per year are these fines likely to be a deterrent?

<https://www.tga.gov.au/media-release/redback-sarms-pays-fine-advertising-prescription-only-substances>
<https://www.tga.gov.au/media-release/pharmacare-pays-12600-fine-alleged-advertising-cancelled-therapeutic-good>

20



What could the TGA achieve?



<https://evolutionsupplements.com.au>
14/09/2019

- Under the Therapeutic Goods Act, the TGA has the power to issue infringement notices against suppliers, apply for a court injunction to stop sales, or seek civil and criminal penalties.
- The maximum penalty of serious individual breaches of the Therapeutic Goods Act by a corporation is \$10.5 million, but breaches can be additive.
- Also, imprisonment for up to five years can be imposed.

21



The TGA says:



"Please report non-compliant advertisements to the TGA, such as those promoting unapproved therapeutic goods and inappropriate and misleading uses. We will investigate and act".

So, let's encourage the TGA to grow bigger teeth by continuing to submit complaints and monitoring their outcome.

<https://compliance.tga.gov.au/advertising-complaint/>

22