NOTIFICATION

Addendum

The following communication, dated 30 September 2020, is being circulated at the request of the delegation of Australia.

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**Title:** Proposed declaration under section 7 of the Therapeutic Goods Act 1989 that certain sports supplements are therapeutic goods.

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| **Reason for Addendum:** |
| [  ] | Comment period changed - date:  |
| [X] | Notified measure adopted - date: 18 September 2020 |
| [X] | Notified measure published - date: 23 September 2020 |
| [X] | Notified measure enters into force - date: 30 November 2020 |
| [X] | Text of final measure available from[[1]](#footnote-1): <https://www.legislation.gov.au/Details/F2020L01204/Download><https://www.tga.gov.au/changes-regulation-sports-supplements-australia> |
| [  ] | Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:  |
| [  ] | Content or scope of notified measure changedNew deadline for comments (if applicable):  |
| [  ] | Interpretive guidance issued and text available from1:  |
| [  ] | Other:  |

**Description:**

On 23 September 2020 a declaration under subsection 7(1) of the Therapeutic Goods Act 1989 (the Act) was published clarifying that, from 30 November 2020, certain sports supplements are regulated as therapeutic goods (medicines).

Under the declaration, the following goods are therapeutic goods:

Goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity, and that:
a. contain, or are represented (expressly or by implication) to contain, one or more of the following substances (however described or named):
i.  a substance included in a schedule to the current Poisons Standard; or
ii.  a substance expressly identified on the Prohibited List that is added as an ingredient to the goods; or
iii.  a relevant substance that is added as an ingredient to the goods; or
iv. a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; or
b. on or after 30 November 2023, are supplied in the dosage form of a tablet, capsule or pill other than those goods containing glucose only

when the goods are used, advertised, or presented for supply:

a. for therapeutic use; or
b. in a way that is likely to be taken to be for therapeutic use;
including, but not limited to, one or more of the following therapeutic uses:
c. gaining muscle;
d. increasing mental focus;
e. increasing metabolism;
f. increasing stamina;
g. increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;
h. losing weight or fat;
i. preparing for workout;
j. recovering from workout

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)