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Committees

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Extract of section 8.2.4b of the Minutes of the 49th meeting of the Medicines Classification Committee
held in the Medsafe Boardroom, Level 6, Deloitte House, 10 Brandon Street, Wellington
on Monday 17 June 2013 at 9:30am

***Present:***

Dr Stewart Jessamine (Chair)
Dr Melissa Copland
Mr Andrew Orange
Dr Mark Peterson
Dr Enver Yousuf
Ms Andrea Kerridge (Secretary)

***Part Attendance (from Medsafe):***

Dr Carole Firth (Team Leader, Medicines Assessment)
Mr Martin Heeley (Advisor Science, Medicines Assessment)
Mrs Mary Miller (Senior Advisor Science, Medicines Assessment)

***Observers (for specific agenda items only):***

Aspen Pharma Pty Limited
Pharma Projects Limited
Pharmacybrands Limited
Salterelo Limited

**8. Harmonisation of the New Zealand and Australian Schedules**

**8.2.4.b Enobosarm, Selective Androgen Receptor Modulators, and the Medsafe submission regarding the classification of peptide-based performance and image enhancing drugs**

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| A new entry should be created for enobosarm and a new class entry should be created for selective androgen receptor modulators in Schedule 4 (prescription medicine). Enobosarm was being imported into Australia and used by body builders seeking its anabolic effects on muscle. These selective androgen receptor modulators are not captured by the anabolic steroids group entry. Although they appear to have an anabolic effect on bone and muscle, they are not steroids.In parallel to this harmonisation consideration, Sports New Zealand had contacted the Ministry of Health to bring attention to their concerns over the risks posed to individuals consuming a range of performance and image enhancing drugs that are based on peptides and hormones. The substances have limited safety information and / or are prohibited by the World Anti-Doping Agency for use by people participating in professional sport. Although some of the substances are already classified as prescription medicines, there remain a number that are not or that require clarification regarding whether they fall under an existing classification group entry (eg, hypothalamic releasing factors, anabolic steroids).Based on a variety of literature reports, clinical assessor comments and information from the Australian Crime Commission, Medsafe recommended:* + scheduling selective androgen receptor modulators to harmonise with Australia
	+ harmonising with Australia by creating the following prescription medicine entry; 'insulin-like growth factors, except when specified elsewhere in the Schedule'
	+ scheduling growth hormone releasing peptides under the term 'human growth hormone secretagogues' (if the Committee considers these substances not to be included under the current scheduled term 'hypothalamic releasing factors')
	+ creating a class entry for 'melanocyte stimulating peptides / hormones / substances' or 'melanotropic peptides / hormones / substances' in the Schedule to capture unscheduled analogues such as bremelanotide. (otherwise these substances may be scheduled individually under their substance names).

The [submission](http://www.medsafe.govt.nz/consultations/MCC-Submission-PIEDs.doc) (*Microsoft Word document, 1.25MB, 35 pages*) from Medsafe was published on the Medsafe website on 5 June 2013 to allow for public consultation. Four pre-meeting comments were received during this consultation period. Whilst it was noted that there was limited clinical data for most of the identified substances listed, all four generally supported Medsafe's recommendations and noted that:* + class entries would allow for 'new' substances to fall within current scheduling as they are created
	+ it would be useful to have individual substances listed under their commercial names
	+ such classifications would mean access to these substances could be better controlled and would allow appropriate regulatory action to be taken when necessary
	+ although on a smaller scale, New Zealand's performance and image enhancing drugs border inception data shows similar trends to that in Australia whose market has expanded rapidly in recent years
	+ classification would enable importation of these substances to be regulated and therefore reduce the risk of supply to New Zealand athletes
	+ classification would reduce risks and consequent damage to New Zealand sport's integrity.

Comments that did not support some of Medsafe's recommendations included:* 1. growth hormone variants and other substances should not remain unclassified, even though there is a lack of data, because of the risk to public health.

The Committee noted that only a two week period had been available for comments on the submission before the meeting took place. The Committee therefore decided that they would foreshadow their classification recommendations for the peptide-based performance and image enhancing drugs. The recommendations would then be finalised out-of-session following a further two month consultation period after publication of the minutes. This two month consultation period would also allow for any objections to be raised regarding the proposed classifications, and for submitters to indicate whether any qualifying conditions (eg, concentration limits) might be required.The Committee discussed using class entries but, where possible, also scheduling individual substances in order to provide greater clarity to anyone searching for ingredients scheduled under the Medicines Regulations 1984. ***Scheduling selective androgen receptor modulators to harmonise with Australia***The Committee agreed with the concept of harmonising with Australia on this matter and, therefore, foreshadowed that a class entry should be created for selective androgen receptor modulators as prescription medicines. Also, a new entry should be created for enobosarm (otherwise known as ostarine) as a prescription medicine. Enobosarm has already been scheduled in Australia, and it is one of the most commonly cited substances falling under the selective androgen receptor modulator class entry.***Harmonising with Australia by creating the following prescription medicine entry; 'insulin-like growth factors, except when specified elsewhere in the Schedule'***IGF-1 is currently classified as a prescription medicine under the name 'mecasermin' but its synthetic analogues do not appear to be. The Committee foreshadowed that a class entry should be created for insulin-like growth factors as prescription medicines, except when specified elsewhere in the Schedule. This harmonises with the Australian Standard for the Uniform Scheduling of Medicines and Poisons and allows for scheduling the synthetic analogues and splice variants of IGF-1. These include:* 1. IGF-1 LR3
	2. IGF DES (1-3)
	3. MGF.

No discussion regarding classification of the analogues under their individual names occurred as there are no INN or 'official' names for these analogues.The relevance of this classification to deer velvet was specifically discussed. Deer velvet, a natural product, is reported to contain insulin-like growth factors. One of these, IGF-1, has been scheduled for a long time as a prescription medicine under the name mecasermin, with no impact on the deer velvet industry. The Committee expected levels of any other insulin-like growth factors to be low, but did not know exact concentrations, so would welcome comments from the deer velvet industry on the potential impact of this group classification. ***Scheduling growth hormone releasing peptides under the term 'human growth hormone secretagogues'***The Committee foreshadowed that a class entry should be created for human growth hormone secretagogues as prescription medicines. While these substances may already be covered under the current class entry of hypothalamic releasing factors, there is a sufficient lack of clarity that it was deemed useful to create a new and clearer entry specifically for this class.To further enhance clarity, the Committee also discussed adding individual substances to the Schedule. Sermorelin is already scheduled as a prescription medicine. It was foreshadowed that other synthetic growth hormone releasing peptides listed in the submission with recognised names should also be individually scheduled as prescription medicines. These substances are:* 1. ipamorelin
	2. hexarelin
	3. tesamorelin.

Individually scheduling a naturally occurring stimulator of growth hormone secretion, ghrelin, was also discussed. Committee members had no significant objections to this, but were open to receiving comments during the consultation period. The Committee agreed with Medsafe in that it was not appropriate to classify the growth hormone variants mentioned in the submission because they were too ill defined to capture with any clarity. However, any comments received during the consultation would be accepted if additional information did become available in the meantime.***Creating a class entry for 'melanocyte stimulating peptides / hormones / substances' or 'melanotropic peptides / hormones / substances' in the Schedule to capture unscheduled analogues such as bremelanotide***The Committee discussed the classification of melanotan I, II, and any potential analogues. Melanotan I is already scheduled under the name 'afamelanotide'. Melanotan II / bremelanotide is not currently scheduled. The Committee foreshadowed that a class entry should be created for melanocyte stimulating compounds, rather than scheduling the substances individually under their substance names. The term 'compound' was chosen so that both peptides and hormones would be included in the class entry while omitting naturally occurring melanotropic effects such as sunshine.There are a large number of human growth hormone secretagogues and other performance and image enhancing drug type substances currently in supply, many with little to no data regarding their use. Due to this, the Committee agreed that Sports New Zealand should be encouraged to make submissions to the Committee to classify peptide-based performance enhancing drugs as they become aware of them in the future. ***Recommendations***Foreshadow that New Zealand should harmonise with Australia, and a class entry should be created to classify selective androgen receptor modulators as prescription medicines.Foreshadow that New Zealand should harmonise with Australia, and classify enobosarm as a prescription medicine.Foreshadow that a class entry should be created to classify insulin-like growth factors as prescription medicines; except when specified elsewhere in the Schedule.Foreshadow that a class entry should be created to classify human growth hormone secretagogues as prescription medicines.Foreshadow that ipamorelin, hexarelin, tesamorelin and ghrelin should be classified as prescription medicines.Foreshadow that a class entry should be created to classify melanocyte stimulating compounds as prescription medicines.That the classification recommendations for the peptide-based performance and image enhancing drugs discussed should be finalised out-of-session following a further two month consultation period after publication of the minutes. Consideration will be given as to whether qualifying wording is required, based on the submissions received.That Sports New Zealand should be encouraged to make submissions to classify peptide-based performance and image enhancing drugs as they become aware of such drugs in the future. |