Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed amendments to the Poisons Standard – ACMS #47 meeting, June 2025

14 May 2025

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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About this consultation

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the **Regulations**) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the **Act**) to amend the current Poisons Standard or decides to amend the Poisons Standard on his or her own initiative and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice.

In accordance with regulation 42ZCZK of the Regulations, the Secretary invites public submissions on scheduling proposals referred to the **June 2025** meetings of the Advisory Committee on Medicines Scheduling (ACMS). Submissions must be received by close of business **13 June 2025.**

Submissions should be provided through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS).

This consultation closes on 13 June 2025.

We aim to provide documents in an accessible format. If you're having problems using this document, please contact medicines.scheduling@health.gov.au.

1 Proposed amendment referred for scheduling advice to ACMS meeting #47

1.1 Somatrogon, lonapegsomatropin and somapacitan

Proposal

The Department of Health and Aged Care has proposed creating new Prescription only (Schedule 4) entries in the current Poisons Standard for somatrogon and lonapegsomatropin. A functional analogue, somapacitan is currently listed in Schedule 4. To impose additional controls on the possession and supply of somatrogon, lonapegsomatropin and somapacitan, inclusion of all 3 substances in Appendix D has also been proposed. Due the similarities in their function and therapeutic use, all the 3 substances are being considered together.

CAS numbers

Somatrogon: 1663481-09-1

Somapacitan: 1338578-34-9

Lonapegsomatropin: 1934255-39-6

Proposed Scheduling

SOMATROGON and LONAPEGSOMATROPIN are not specifically scheduled in the current Poisons Standard. The proposed amendments to the Poisons Standard are:[1]

Schedule 4 – New entry

SOMATROGON

Appendix D – New entry

SOMATROGON

Index – New entry

SOMATROGON

Appendix D

Schedule 4 – New entry

LONAPEGSOMATROPIN

Appendix D – New entry

LONAPEGSOMATROPIN

Index – New entry

LONAPEGSOMATROPIN

Appendix D

[1] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

SOMAPACITAN is scheduled as Prescription only (Schedule 4) medicine in the current Poisons Standard. The proposed amendments to the Poisons Standard are:

Schedule 4 – Existing entry

SOMAPACITAN

Appendix D – New entry

SOMAPACITAN

Index – Amend entry

SOMATROGON

Appendix D

Background

Somatrogon, lonapegsomatropin and somapacitan are functional analogues of somatropin, a synthetic version of the human growth hormone (HGH) produced in the pituitary gland. Somatrogon and somapacitan are amino acid sequence modified versions of somatropin. In the case of lonapegsomatropin the amino acid sequence of somatropin is attached to an inert carrier molecule. All 3 substances are long-acting versions of somatropin that perform the same function, and like somatropin, all are used to treat growth hormone deficiency in children. However, somatropin is injected daily while somatrogon, lonapegsomatropin and somapacitan can be dosed weekly due to their long-acting nature.

Summary of reasons for the proposal

Somatropin, somatrogon, lonapegsomatropin and somapacitan have similarities in function, usage and risk profile. Somatropin is specifically listed in Schedule 4 and Appendix D in the current Poisons Standard. Somapacitan is currently included in Schedule 4, but not in Appendix D. Somatrogon and lonapegsomatropin are new chemical entities which do not currently have separate entries in the current Poisons Standard. To ensure a consistent interpretation of the scheduling of these functional analogues of human growth hormone, new or amended entries are proposed in the Poisons Standard.

Somatrogon, lonapegsomatropin and somapacitan differ from somatropin in their primary structures and pharmacology. Somapacitan varies from somatropin by one amino acid change which allows it to bind albumin. Somatrogon carries the same 191 amino acid sequence of somatropin but additionally contains three copies of the C-terminal peptide (CTP) from the beta chain of human chorionic gonadotropin which has several glycosylation sites. The albumin-binding of somapacitan or the additional glycosylation of somatrogon results in reduced clearance from the body allowing for less frequent dosing than somatropin.

Lonapegsomatropin consists of unmodified somatropin sequence attached covalently to an inert carrier molecule, methoxypolyethylene glycol, via a transient linker.[2] The linker undergoes autohydrolysis under physiological conditions to release somatropin from the carrier molecular in a sustained manner. The pharmacokinetic profile of allows for weekly administration of

[2] Miller BS, Yuen KCJ. Spotlight on Lonapegsomatropin Once-Weekly Injection and Its Potential in the Treatment of Growth Hormone Deficiency in Pediatric Patients. Drug Des Devel Ther. 2022 Jun 29;16:2055-2066. doi: 10.2147/DDDT.S336285.

lonapegsomatropin which was found to be non-inferior to daily somatropin therapy with a comparable safety and tolerability profile.[3]

The World Anti-Doping Agency has listed somatrogon, lonapegsomatropin and somapacitan as prohibited substances[4] due to the potential misuse of their lipolytic and anabolic properties in sports.[5]

Key uses

Somatrogon, lonapegsomatropin and somapacitan are used to treat growth hormone deficiency in children and are sold under the brand names of Ngenla, Skytrofa and Sogroya, respectively. All the 3 substances are available as injectable solution in prefilled pens and are dosed weekly.

Australian regulations

- According to the TGA Ingredient Database, somatrogon and somapacitan are both:
  - Available for use as an Active Ingredient in: Export Only, Prescription Medicines
  - Not available as an Excipient Ingredient in any application
  - Not available as an Equivalent Ingredient in any application.

  Lonapegsomatropin is available only for use as active ingredients in Prescription Medicines.
- As of 9 May 2025, the Australian Register of Therapeutic Goods (ARTG) lists 2 Prescription only medicines containing somatrogon and 3 Prescription only medicines containing somapacitan. All the 5 medicines are listed as active. No product containing lonapegsomatropin is currently listed.
- None of the 3 substances are included in the Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2025 and therefore, not permitted to be included in listed medicines.
- The TGA prescribing medicines in pregnancy database classifies somatrogon and somapacitan as below. Lonapegsomatropin is not included in the database.

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Somatrogon	B1	Endocrine System	Hormonal agents	
Somapacitan	B1	Endocrine System	Hormonal agents	
Category B1 – Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have not shown evidence of an increased occurrence of foetal damage.				

[3] Maniatis AK, Casella SJ, Nadgir UM, Hofman PL, Saenger P, Chertock ED, Aghajanova EM, Korpal-Szczyrska M, Vlachopapadopoulou E, Malievskiy O, Chaychenko T, Cappa M, Song W, Mao M, Mygind PH, Smith AR, Chessler SD, Komirenko AS, Beckert M, Shu AD, Thornton PS. Safety and Efficacy of Lonapegsomatropin in Children With Growth Hormone Deficiency: enliGHten Trial 2-Year Results. J Clin Endocrinol Metab. 2022 Jun 16;107(7):e2680-e2689. doi: 10.1210/clinem/dgac217.

[4] WADA Prohibited List 2025 www.wada-ama.org/en/prohibited-list

[5] Walpurgis K, Thomas A, Sato M, Okano M, Geyer H, Thevis M. Detection of the GH analog somatrogon in sports drug testing: Immunological approaches and LC-HRMS/MS. Drug Test Anal. 2025 May;17(5):634-646. DOI: 10.1002/dta.3766.

- There are no warning statements pertaining to somatrogon, lonapegsomatropin or somapacitan in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 8 May 2025, there were 8 reports of adverse events for somatrogon on the TGA's Database of Adverse Event Notifications (DAEN) for all of which somatrogon was the single suspected medicine. However, there were no reports of deaths associated with somatrogon use or no reports of adverse events for lonapegsomatropin or somapacitan.
- As of 8 May 2025, no products containing somatrogon, lonapegsomatropin or somapacitan are listed on the Public Chemical Registration Information System Search (PubCRIS).
- In financial years 2009-2019, no adverse experiences were recorded for somatrogon, lonapegsomatropin or somapacitan in the Australian Pesticides and Veterinary Medicines Authority's Adverse Experience Reporting Program database.
- As of 8 May 2025, somatrogon, lonapegsomatropin or somapacitan are not listed on the Australian Inventory of Industrial Chemicals.

International regulations

- Canada's National Drug Schedules Database classifies both somatrogon and somapacitan as Schedule I (Prescription only) medicine. The Health Canada Drug Product Database lists 2 products containing somatrogon and 3 products containing somapacitan. All 5 products are currently marketed. Lonapegsomatropin is not listed.
- The New Zealand Medsafe Medicines Classification Database lists somapacitan as a Prescription medicine. Somatrogon and lonapegsomatropin are not listed in the database.
- In Europe, one somatrogon product (Ngenla) is listed in the Union Register of Medicinal Products as centrally authorised, human use medicinal product for the treatment of growth hormone deficiency in children and adolescents from 3 years of age. For somapacitan and lonapegsomatropin, 2 products are listed for each of the substances. The products are authorised for either human use or as Orphan medicinal products. Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect no more than 5 in 10,000 people in the European Union.
- The United Kingdom Electronic Medicines Compendium lists 2 prescription-only medicines containing somatrogon and 2 prescription-only medicines containing somapacitan. There are no products containing lonapegsomatropin in the compendium.
- In Ireland, the Health Products Regulatory Authority included 2 products containing somatrogon, 9 products containing lonapegsomatropin and 3 products containing somapacitan in the Authorised Medicines for Human Use database.
- According to the United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA), 2 products containing somatrogon, 9 products containing lonapegsomatropin and 1 product containing somapacitan are approved as prescription medicine in the US.

How to respond

Submissions must be provided by the closing date of 13 JUNE 2025 through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS).

What will happen

All public submissions will be published on the TGA website, unless marked confidential.

Following consideration of public submissions received before the closing date and advice from the expert advisory committee/s, decisions on the proposed amendments will be published as interim decisions on the TGA website.

Therapeutic Goods Administration

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