



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Seeking advice on proposed scheduling amendments

According to subsection 52E(4) of the Act, in exercising a power under subsection 52D(2), the Secretary may seek advice from any person or any committee that the Secretary considers appropriate (whether or not the committee is established under the Act or the *Therapeutic Goods Regulations 1990* (the Regulations)). This includes an evaluator, the Advisory Committee on Medicines Scheduling (ACMS) and/or the Advisory Committee on Chemicals Scheduling (ACCS). Subsection 52E(3) of the Act also sets out that, where the Secretary decides to seek the advice of the ACMS and/or the ACCS, the Secretary must have regard to that advice.

Delegations

As a Medical Officer Class 5 in the Medicines Regulation Division you have [powers delegated by the Secretary of the Department of Health](#) under subsections 52D(2) and 52E(4) of the *Therapeutic Goods Act 1989* (the Act) to amend or replace the Poisons Standard [52D(2)] and in doing so, seek advice from any person or committee that the Secretary considers appropriate [52E(4)].

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Timeframes

ACMS or Joint ACMS-ACCS

If you decide these matters require ACMS or Joint ACCS-ACMS advice, then the public notice of proposed amendments must be published on the TGA website on 31 August 2023. Your decision regarding referral to ACMS or Joint ACMS-ACCS for advice and your confirmation of the details to be included in the public notices is required by **11 August 2023**.

Delegate-only decision

1. If you decide that an application *does not require ACMS or Joint ACMS-ACCS advice* and that a delegate-only decision is appropriate and that it is *the same as the applicant's proposal*, then the final decision and reasons for the decision will be published on the TGA website with the June 2023 cycle final decisions, in November 2023. Your final decision is therefore required by **1 September 2023**; or
2. If you decide that an application *does not require ACMS or Joint ACCS-ACMS advice* and that a delegate-only decision is appropriate but that it is *different from the applicant's proposal*, then the decision will be an interim decision and will be published on the TGA website with the November 2023 cycle interim decisions in February 2024. The secretariat will also notify the applicant in writing of your interim decision and provide the applicant at least 20 working days to make a written submission in response to your decision. Delegate-only decisions that are different from the applicant's proposal are therefore required by **1 November 2023**.

Astodrimer sodium

R1. Having considered the attachments listed below, that you decide to consider this matter as a delegate-only decision.²

AGREE
DISAGREE

Reasons: N/A

R2. That you decide to refer this matter to the ACMS.

AGREE
DISAGREE

Reasons: The exclusion of a specific dosage forms of the substance from the Schedule 3 entry requires referral to the appropriate Committee for discussion.

R3. That you decide that the application requires an external evaluation.

AGREE
DISAGREE

Reasons: Sufficient information on this substance is already available.

Signed in TRIM

s22

Director, Advanced and Biological Therapies Section

11 August 2023

Attachments for Astodrimer sodium

Attachment A: Application for astodrimer sodium [E23-195500](#)

² Please note that by accepting this recommendation the delegate is not making an interim decision or final decision

