



AUSTRALIAN
SENATE

Senate Standing Committee for the
Scrutiny of Delegated Legislation
Parliament House, Canberra ACT 2600
02 6277 3066 | sdlc.sen@aph.gov.au
www.aph.gov.au/senate_sdsc

8 October 2020

The Hon Greg Hunt MP
Minister for Health
Parliament House
CANBERRA ACT 2600

Via email: Minister.Hunt.DLO@health.gov.au

CC: rezana.berman@health.gov.au


Dear Minister,

Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020 [F2020L00946]

The Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee) assesses all legislative instruments subject to disallowance, disapproval or affirmative resolution by the Senate against scrutiny principles outlined in Senate standing order 23. The committee has identified scrutiny concerns in relation to the above instrument, and the committee seeks your advice in relation to this matter.

Element of offence specified in delegated legislation

Senate standing order 23(3)(j) requires the committee to consider whether an instrument contains matters more appropriate for parliamentary enactment (that is, matters that should be included in primary, rather than delegated, legislation).

Subsections 41MP(1) and 41MPA(1) of the *Therapeutic Goods Act 1989* (Act) provide that certain persons must notify the secretary of certain information relating to adverse events within the timeframe specified in the Therapeutic Goods (Medical Devices) Regulations 2002 (principal regulations). Failure to comply with this requirement attracts a criminal penalty of 12 months imprisonment or 1,000 penalty units, or both, or a civil penalty of 3,000 penalty units for an individual or 30,000 penalty units for a body corporate.

Item 2 of Schedule 3 to the instrument amends the principal regulations to specify that the timeframe for providing such information to the secretary is 60 days after the person becomes aware of the information in any case other than those listed in paragraphs 5.7(1)(a) to (c) of the principal regulations.

The committee generally considers that all elements of a criminal offence, particularly those subject to custodial penalties, should be set out in primary, rather than delegated,

legislation. This is due to the additional level of parliamentary scrutiny attached to the legislative process for primary legislation.

While noting that the Act permits regulations to prescribe the timeframe for notifying the secretary of certain information, the committee is concerned about the use of delegated legislation to specify important details relating to an element of the offence.

The committee therefore requests your advice as to why it is considered necessary and appropriate to use delegated legislation, rather than primary legislation, to specify important details relating to an element of the offence and civil penalty provision in subsections 41MP(1) and 41MPA(1) of the Act. In particular, the committee requests your advice as to why it would not be possible to instead specify these details on the face of the Act.

The committee's expectation is to receive a response in time for it to consider and report on the instrument while it is still subject to disallowance. If the committee has not concluded its consideration of an instrument before the expiry of the 15th sitting day after the instrument has been tabled in the Senate, the committee may give notice of a motion to disallow the instrument as a precautionary measure to allow additional time for the committee to consider information received.

Noting this, and to facilitate the committee's consideration of the matters above, the committee would appreciate your response by **22 October 2020**.

In the interests of transparency, this correspondence and your response will be published on the committee's website.

If you have any questions or concerns, please contact the committee's secretariat on (02) 6277 3066, or by email to sdlc.sen@aph.gov.au.

Thank you for your assistance with this matter.

Yours sincerely,

Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation



The Hon Greg Hunt MP
Minister for Health
Minister Assisting the Prime Minister for the
Public Service and Cabinet

Ref No: MC20-040141

Senator the Hon Concetta Fierravanti-Wells
Chair
Standing Committee for the Scrutiny of Delegated Legislation
Parliament House
CANBERRA ACT 2600

27 OCT 2020

Dear Chair

I refer to your letter of 8 October 2020 concerning the Therapeutic Goods Legislation Amendment (2020 Measures No.1) Regulations 2020.

You have sought advice as to why it is necessary and appropriate to use delegated rather than primary legislation to specify the periods of time within which a sponsor of a medical device must give information to the Secretary about problems with their device, for the purposes of the criminal offence and civil penalty provision in sections 41MP and 41MPA of the *Therapeutic Goods Act 1989* (Act), rather than specifying these in the Act.

The principal reason that these periods are set out in regulations, rather than the Act, is to ensure flexibility and the ability to respond to changed circumstances in an agile fashion, e.g. if a particular safety concern were to arise.

Regulation 5.7 of the Therapeutic Goods (Medical Devices) Regulations 2002 sets out a number of different periods for the purposes of sections 41MP and 41MPA, depending on the seriousness of the information - e.g. within 48 hours after the person becomes aware of information relating to an event that represents a serious threat to public health, and within 30 days for an event that might lead to death or a serious deterioration of a person's health if it were to happen again.

Setting these periods out in regulations ensures that any changes to these, or any new such circumstances, may be made without delay.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt



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Scrutiny of Delegated Legislation**

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12 November 2020

The Hon Greg Hunt
Minister for Health
Parliament House
CANBERRA ACT 2600

Via email: Minister.Hunt.DLO@health.gov.au

CC: rezana.berman@health.gov.au


Dear Minister,

**Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020
[F2020L00946]**

Thank you for your response of 27 October 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation, in relation to the above instrument.

The committee considered your response at its private meeting on 11 November 2020. On the basis of your advice, the committee has concluded its examination of the instrument.

In the interests of transparency, I note that this correspondence will be published on the committee's website and recorded in the *Delegated Legislation Monitor*.

Thank you for your assistance with this matter.

Yours sincerely,

Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation