FOR DECISION Ref: 4-113323

BRIEFING NOTE

ISSUE
Amendment to the Medicines and Poisons Regulations 2016

KEY MESSAGES
- The *Medicines and Poisons Regulations 2016* (the Regulations) define "Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)" as "the document set out in Schedule 1 of the current Poisons Standard".
- The Standard for the Uniform Scheduling of Medicines and Poisons is set out in Schedule 2 of the Poisons Standard of June 2019 and not Schedule 1.
- The definition in the Regulations needs to be amended to accurately refer to the current Poisons Standard.

BACKGROUND
- The Commonwealth Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of States and Territories. It also includes model provisions about containers and labels, a list of products recommended to be exempt from those provisions, and recommendations about other controls on drugs and poisons. The Poisons Standard is intended to promote uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia.
- Regulation 3 of the Regulations defines the term "Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)" as "the document set out in Schedule 1 of the current Poisons Standard".
- "Poisons Standard" has the meaning given in the *Therapeutic Goods Act 1989* (Commonwealth) section 3(1) and in essence means the statutory instrument made under section 52D(2)(b) of that Act.
- In February 2019 the Poisons Standard was amended to move the Standard of the Uniform Scheduling of Medicines and Poisons from Schedule 1 to Schedule 2 of the current Poisons Standard.
- Amendment is required urgently as the incorrect reference to the current Poisons Standard directly impacts the operation of the *Medicines and Poisons Act 2014* and the Regulations, including the offences set out in the Act.

CURRENT SITUATION
- The Regulations require amendment to refer to Schedule 2 of the current Poisons Standard.
- The Better Regulation Unit has excluded this proposal under category 3 (Machinery of Government/Administrative changes) and no further regulatory impact assessment is required.
- Should the Minister approve the new amendment, the Department of Health will instruct Parliamentary Counsel to draft the amendment on an urgent basis.

RECOMMENDATION
It is recommended the Minister approves the drafting of an amendment to the *Medicines and Poisons Regulations 2016* as detailed above.

FOR DECISION

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Date: 9 July 2019

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Approved ☒

Not Approved ☐

Noted ☐

Comments:

Signed _____ **Date** 25/7/19.
MINISTER FOR HEALTH