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Australian Government
Department of Health
Therapeutic Goods Administration

Medicines Advisory Statements Specification updates

4 January 2022

An updated edition of the Therapeutic Goods (Medicines Advisory Statements) Specification (https://www.legislation.gov.au/Details/F2021L01888) (the '2021 Specification') has been registered on the Federal Register of Legislation (FRL) (https://www.legislation.gov.au).

The 2021 Specification includes an updated version of the Required Advisory Statements for Medicine Labels (RASML) (//www.tga.gov.au/publication/required-advisory-statements-medicine-labels-rasml) document ('RASML No. 6') with updated advisory statement requirements that were the subject of public consultation between April and September 2021.

As usual, the 2021 Specification allows for an 18-month transition period for adoption of the new and amended advisory statements in RASML No. 6 onto medicine labels. During this transition period, from 1 January 2022 to 30 June 2023, affected medicine labels may comply with either RASML No. 5 (https://www.legislation.gov.au/Details/F2019L00213), contained in Medicines Advisory Statements Specification 2019, or with RASML No. 6 (https://www.legislation.gov.au/Details/F2019L00213).

Changes in RASML 6

- RASML No. 6 includes the new and amended statements that were the subject of public consultation between April and September 2021, as follows:
  - Consultation: Proposed minor changes to Required Advisory Statements for Medicine Labels (RASML): Chlorhexidine, hydrocortisone, ibuprofen (https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-rasml-chlorhex-hydrocort-ibup/) 6 August 2021 (Outcome published 17 November):
    - Outcome: current advisory statements for **chlorhexidine** are updated as follows:

      Existing entries updated to improve clarity of requirements

      Existing warnings reworded to state as follows:

        - for dermal use preparations: "Mild skin irritation may occur; stop use if it becomes more severe"
        - for all topical use preparations: "Chlorhexidine can cause severe allergic reactions. Seek immediate medical assistance if this occurs."
    - Outcome: current advisory statements for **hydrocortisone** are updated as follows:

      Inclusion of reference to the more stringent age restriction statement of "Do not use for children under 12 years of age", applicable for dermal preparations in specific cases when required by the Poisons Standard. This update is consistent with current requirements of the Poisons Standard and is a clarification rather than a new labelling requirement.
      The word "CAUTION" is deleted from existing warning statements.
    - Outcome: current advisory statements for **ibuprofen** are updated as follows:

      In entry 3 of 6 for ibuprofen, the qualification of "Unless a doctor has told you to" is removed from the warning statement "Unless a doctor has told you to, do not use in children 6 years of age or less" and wording revised to "Do not use in children under 7 years of age." The change is a correction to reflect existing requirements of the Poisons Standard for unscheduled ibuprofen-containing medicines for oral use in children under 12 years of age.
- Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Lidocaine (lignocaine) (https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-rasml-lidocaine/) 6 April 2021 (Outcome published 16 November).
    - Outcome: current advisory statements for **lidocaine** are updated as follows:

      Inclusion of the warning "Do not use for teething pain in children" for preparations for topical oral use containing more than 1.5 per cent lidocaine.
- Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Melatonin (https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-rasml-melatonin/) 6 August 2021 (Outcome published 16 November).
    - Outcome: addition of warnings for modified-release tablets containing 2mg or less of **melatonin**.
- Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Menthol (https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-rasml-menthol/) 6 April 2021 (Outcome published 16 November).
    - Outcome: addition of warnings for preparations containing **menthol** for dermal use.
- Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Methyl salicylate (https://consultations.tga.gov.au/medicines-

regulation-division/proposed-changes-to-rasml-methyl-salicylate/) 6 April 2021 (Outcome published 16 November).
    - Outcome: addition of warnings for preparations containing **methyl salicylate** for dermal use.
  - Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Mometasone (https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-rasml-mometasone/) 6 August 2021 (Outcome published 16 November).
    - Outcome: addition of warnings for dermal and nasal spray preparations containing **mometasone**.
  - Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Sedating antihistamines (https://consultations.tga.gov.au/medicines-regulation-division/rasml-sedating-antihistamines/) 6 April 2021 (Outcome published 16 November).
    - Outcome: current advisory statements for **sedating antihistamines** are updated as follows:

      Removal of the warning regarding use in pregnancy for diphenhydramine and doxylamine when indicated for short term use in insomnia.
      Addition of a warning statement regarding use in pregnancy in all alimemazine and promethazine RASML entries (already required by TGO 92 but included for consistency and clarity, to ensure compliance).
      For antihistamines indicated for short term use in insomnia, removal of the alternative wording option of "Not recommended for use in breastfeeding women", but retention of the warning "If breastfeeding, consult a doctor pharmacist before use".
  - Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Triptans (https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-rasml-triptans/) 6 August 2021 (Outcome published 17 November).
    - Outcome: addition of warnings for divided oral preparations containing **triptans** (sumatriptan, zolmitriptan, rizatriptan, eletriptan) for relief of migraine.
- RASML No. 6 will also include the removal of codeine entries (no longer available as OTC medicines) and a minor correction in Entry 2 for pyridoxine to state "Contains vitamin B6".

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Tags: specifications, medicine labels
URL: https://www.tga.gov.au/node/753793 (https://www.tga.gov.au/node/753793)