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The Royal Australasian College of Physicians' submission to the Ministry of Health

Proposed changes to paracetamol warning and advisory statements

January 2020

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback to the Ministry of Health on the proposed changes to paracetamol warning and advisory statements.

The RACP works across more than 40 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

1. Do you agree that the two current paracetamol conditions in the Label Statements Database should be replaced by three new conditions for different dosage forms?

The RACP strongly agrees with the proposal to replace the two current paracetamol conditions with three new conditions for different dose forms. Basing the conditions on dose forms represents a move that orients health impacts to the forefront of thinking and has the potential to contribute to preventing harm from accidental therapeutic overdoses of paracetamol.

2. Do you agree that the current paracetamol dosing table should be revised?

The RACP agrees with the rationale used to justify revising the paracetamol dosing table. However, the proposed table is much more complex than the existing table, which could create confusion in consumers, and thus fail to realise its intended benefits. As such, we believe that a new table should be developed which simplifies the information presented in the proposed table.

3. Do you agree that the current paracetamol dosing table should be revised to only include one dose per age/weight bracket?

The RACP agrees with the simplification of the dosing table to a single dose per age/weight bracket. Increasing the accessibility of the dosage table by providing a certain level of dose which is appropriate has the potential to avoid harm caused by consumers misunderstanding the dose table and should be encouraged.

4. The proposed paracetamol dosing table provides one dose per age/weight bracket that is calculated from the maximum recommended dose for the low-end weight of the age/weight bracket (ie, 15 mg/kg). This means that a minimum dose of 10 mg/kg is achieved for the high-end weight of the age/weight bracket – Do you think that this is appropriate?

The RACP agrees with this approach. It is prudent to err on the side of caution in cases such as this, where an overdose can prove harmful. Conversely, it will not be damaging for people who fall into the higher end of the age/weight bracket to receive a lower dose:if it is not sufficient to address pain, it can be supplemented with other medicines.

5. The proposed paracetamol dosing table provides an additional age/weight bracket for consumers >12 years with a weight between 42 kg and 60 kg in line with Martindale. This is in order to better capture those consumers whose weight is not high enough to take a full 1 g adult dose – Do you think that this is appropriate?

The inclusion of this category and the intention behind it is wholly appropriate. However, the way it is represented in the dosing table could cause confusion for consumers. The proposed dosing table is complex, and the addition of multiple permutations of the same category in this way could provoke uncertainty. As such, we believe that the inclusion of the category is prudent, but as part of a redesigned and more easily interpretable dosing table.

6. In the proposed paracetamol dosing table, should the volume be absolute or rounded to the nearest 0.5 mL (shaded column)?

Most household measuring instruments do not measure to absolute levels (instead measuring to 0.5 or 1ml). Because of this, it seems logical to round doses to these levels, to increase usability by consumers. However, this presents the noted problem with rounding creating either an over or under dose in children aged 1-3 months. Despite this, the RACP believes that this exception should be allowed, with all other doses rounded to easily measurable numbers.

7. If the dose is greater than the total of the syringe provided in the packaging, should this be given as two administrations (for example, if the dose is 7.5 mL should the label statement be one 5 mL dose plus one 2.5 mL dose)?

Labelling should clearly explain to the consumer how the medicine can be taken safely. This would be better accomplished by the labelling explicitly outlining a 5ml and 2.5ml dose, and the reason why this is necessary.

8. Medsafe proposes removing the possibility for sponsors to use wider age/weight brackets on their packaging/labelling, so that only the age/weight brackets shown in the proposed paracetamol dosing table are used. This is in order to ensure that consumers receive an accurate dose – Do you agree with this?

The RACP strongly supports this proposal. Standardising the use of age/weight brackets across all paracetamol products will greatly increase accessibility and comprehension in consumers. Logically, this should also lead to a reduction in accidental therapeutic overdose.

9. Should packaging for liquid oral paracetamol include the measuring device to enable accurate dosing?

The RACP strongly agrees that measuring devices should be included in packaging for liquid oral paracetamol, to reduce the incidence of accidental therapeutic overdose.

10. Do you agree with the proposed changes to the paracetamol warning statements for 'when sold in liquid oral dose form'?

The RACP agrees with all proposed changes to paracetamol warning statements for 'when sold in liquid oral dose form'.

11. Are there any additional warning statements you think would be appropriate to include in the proposed condition for paracetamol 'when sold in a liquid oral dose form'?

It could be prudent to include a warning of the ease of overdose when paracetamol is taken in a liquid oral dose form. This may have the effect of increasing the vigilance of consumers in accurately measuring their dose and reduce the incidence of accidental therapeutic overdose.

Additionally, in the case of an unknown dosage being taken, a warning to promptly seek medical attention could prove useful in cases where either a child, or a vulnerable person gains access to paracetamol. This is especially important for liquid oral dose form, due to the ease of ingestion.

12. Do you have any other comments about the proposed condition for paracetamol 'when sold in a liquid oral dose form'?

It would be useful for the consultation document to have also included justifications for the breakdown of dose forms into three proposed conditions for paracetamol. Without this, it is difficult to comment on the breakdown in this way. Despite this, the RACP is strongly supportive of the categories selected for the proposed conditions.

13. Do you agree with the proposed changes to the paracetamol warning statements for 'all other dosage forms, excluding modified release'?

The RACP agrees with all proposed changes to paracetamol warning statements for 'all other dosage forms, excluding modified release'.

14. Are there any additional warning statements you think would be appropriate to include in the proposed condition for 'all other dosage forms, excluding modified release'?

In the case of an unknown dosage being taken, a warning to promptly seek medical attention could prove useful in cases where either a child, or a vulnerable person gains access to paracetamol.

15. Do you have any other comments about the proposed condition 'all other dosage forms, excluding modified release'?

It would be useful for the consultation document to have also included justifications for the breakdown of dose forms into three proposed conditions for paracetamol. Without this, it is difficult to comment on the breakdown in this way. Despite this, the RACP is strongly supportive of the categories selected for the proposed conditions.

16. Do you agree with the proposed changes to the paracetamol warning statements for ‘modified release’?

The RACP agrees with all proposed changes to paracetamol warning statements for ‘modified release’. Especially, splitting statements for adolescents from that for children is an important change.

17. Are there any additional warning statements you think would be appropriate to include in the proposed condition ‘modified release’?

In the case of an unknown dosage being taken, a warning to promptly seek medical attention could prove useful in cases where either a child, or a vulnerable person gains access to paracetamol.

18. Do you have any other comments about the proposed condition ‘modified release’?

As indicated in our response to question 15 above: it would be useful for the consultation document to have also included justifications for the breakdown of dose forms into three proposed conditions for paracetamol. Without this, it is difficult to comment on the breakdown in this way. Despite this, the RACP is strongly supportive of the categories selected for the proposed conditions.

19. Do you agree with the proposed implementation timeframe of 18 months following the publication of the consultation outcome on the Medsafe website?

18 months is a reasonable length of time for producers of paracetamol to adjust and implement new label statements on their products. If it is possible to implement new label statements faster, this could be preferable, as the new labels would then have a greater opportunity to prevent harm. However, acknowledging the changes being made, the RACP believes that 18 months is a reasonable time frame for implementation.

20. Do you have any other comments?

The RACP believes that, while labelling will have an effect on reducing accidental therapeutic overdoses in Aotearoa New Zealand, it does not address the main causes of paracetamol overdoses. An overwhelming proportion of paracetamol overdoses in Aotearoa New Zealand are due to intentional self-harm. This must be addressed to significantly reduce overdoses, and to this end, the RACP believes that legislative reform which reduces the amount of paracetamol available for purchase is required. It has been shown that similar laws in countries such as the United Kingdom have had an effect in reducing intentional overdose, and this could be applied almost directly to Aotearoa New Zealand.

Conclusion

The RACP thanks the Ministry of Health for the opportunity to provide feedback on the proposed changes to paracetamol warning and advisory statements. To discuss this submission further, please contact the Aotearoa NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nāku noa, nā

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