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PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting March 2019 (ACMS #26)

Comments by The Pharmacy Guild of Australia to the proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling

1. Paracetamol (modified release)

Date 31 October 2018

Contact [redacted]

[redacted]

PARACETAMOL (MODIFIED RELEASE)

- Amend the terminology in the Poisons Standard from 'slow release' paracetamol to 'modified release' paracetamol; and
- Up-schedule modified release tablets or capsules containing less than or equal to 665 mg of paracetamol from Schedule 2 to Schedule 3.

Overview

We have no objection to the proposed changes to the scheduling of this particular paracetamol formulation. We agree that consumers would benefit from pharmacist counselling on the correct dose and the risks of this particular formulation.

The risks and benefits of the use of a substance

Risks

As noted in the Product Information (PI) documents approved by TGA paracetamol overdose may cause liver failure which may require liver transplant or lead to death. In addition it states that patients who have been diagnosed with liver impairment must seek medical advice before taking this medication.

We also note that paracetamol modified release has an unpredictable pharmacokinetic profile requiring additional blood level monitoring and creating difficulties with treatment nomograms for management of overdose.

Benefits

We believe there is a benefit to the use of paracetamol in immediate and modified release formulations for the indicated conditions and that access in a community pharmacy is appropriate as consumers have access to the advice of trained staff.

We note that the Australian Medicines Handbook states that *"in osteoarthritis, regular paracetamol alone is the preferred treatment but is underused*"[1].

Given the risks associated with paracetamol modified release formulations it would make sense to classify these medicines as Schedule 3 so that professional interaction is provided when consumers are purchasing this particular formulation.

The purposes for which a substance is to be used and the extent of use of a substance

We note from the TGA-approved PI that paracetamol modified release is used as an analgesic, antipyretic and for the relief of persistent pain associated with osteoarthritis, muscular aches and pains; temporary relief of pain, discomfort associated with headache, cold and flu, toothache, period or dental pain.

This particular formulation of paracetamol was listed on the Pharmaceutical Benefits Scheme (PBS) for many years and would often have been prescribed by a GP and dispensed by a pharmacist. This level of involvement in the supply of paracetamol, whist not present in all the supply instances of this product, would have provided some level of professional oversight.

[1] https://amhonline.amh.net.au/chapters/analgesics/drugs-pain-relief/non-opioid-analgesics/paracetamol?menu=hints

Since the product was de-listed from the PBS the majority of sales are now over the counter and consumers would not necessarily be counselled by pharmacy staff on the safe use of this medicine.

Given that the product is kept with other paracetamol products consumers may not realise that the product is a modified release and has a different dosing regimen to immediate release paracetamol products.

We note that the Australian Medicines Handbook in the paracetamol entry states the following:

> *Counselling*
> *There are many brands of paracetamol. It is also contained in many cough and cold products. Prevent overdosing by checking carefully which strength product is being used, and the correct dose for that product. Avoid using more than one product containing paracetamol at the same time. Too much paracetamol can cause liver damage.*
>
> *Adult: do not take more than 8 tablets or capsules (500 mg strength) or 6 controlled release tablets each day.*

By classifying this formulation as Schedule 3 consumers will benefit from the advice of a pharmacist when purchasing this product, especially after establishing other medications taken, and possible duplication of paracetamol from other products.

The toxicity of a substance

Paracetamol is generally considered a safe medicine but we note the concerns relating to this particular formulation especially in the case of overdose.

We note the regulatory changes in Europe and New Zealand with respect to this formulation. We believe that as Australia's scheduling system is intended to ensure the safe use of medicines with an appropriate level of access, it would be sensible to have pharmacist involvement in the sale of this formulation of paracetamol. Pharmacists will be able to provide counselling on the correct dosage of this formulation and be available to advise consumers more generally about the treatment of chronic pain.

The dosage, formulation, labelling, packaging and presentation of a substance

Paracetamol (and its many brands) is popular with consumers in Australia but this particular formulation has a different dosing regimen which may not be apparent to all consumers and could lead to unintentional overdosing.

According to the ACSQHC National Statement on Health Literacy[2]

> *"Only about 40% of adults have the level of individual health literacy needed to meet the complex demands of everyday life.*
>
> *This means, for example, that only about 40% of adults can perform tasks such as combining information in text and a graph to correctly assess the safety of a product. It means that only 40% of adults can understand and follow health messages in the way in which they are usually*

[2] https://www.safetyandquality.gov.au/publications/health-literacy-national-statement/

presented. It also means that only about 40% of adults will be able to make good choices based on a thorough understanding of the issues they face and the choices available."

As the modified release is often sold alongside immediate release formulations of paracetamol consumers may assume it's simply another brand name of paracetamol and that the same maximum daily dosage applies. By classifying this formulation as Schedule 3 consumers will benefit from pharmacist involvement.

The potential for abuse of a substance

There is a low level of intentional abuse of this substance as it has no addictive properties. However, there is the potential for inadvertent overdose or intentional overdose and we acknowledge the concerns raised in the submission with respect to the difficulties with treating paracetamol overdose where it is often unknown what formulation has been used.

With the recent up-scheduling of codeine combination medicine consumers may be taking incorrect doses of the modified release paracetamol unknowingly – thinking it has the same maximum daily dose as other paracetamol products.

Other matters

Appendix H – Schedule 3 Poisons Permitted to be Advertised

We note that the TGA has recently reviewed the Scheduling Policy Framework (SPF) and as part of this it was agreed that the policy intent for advertising of Schedule 3 substances should be to allow these substances to be advertised directly to consumers unless it is determined they should not be. As part of the reforms a mandatory statement for inclusion on all advertisements for products containing Schedule 3 substances was developed in collaboration with stakeholders representing consumers, industry and healthcare professionals. The new statement, *"Ask your pharmacist – they must decide if this product is right for you"*, is included in the revised Therapeutic Goods Advertising Code.

We do not believe there is any reason why this particular paracetamol formulation should not be included in Appendix H. Any advertising will include the mandatory statement that the pharmacist will decide the appropriateness of the product.

Medsafe decision

We note that the New Zealand Medicines Classification Committee considered the classification of modified release paracetamol at its 60th Meeting held in April 2018[3]. The Committee recommended that modified release paracetamol be reclassified from a pharmacy-only medicine to a restricted medicine. We also not that this is to be reconsidered at the 61st Meeting to be held on 2 November 2018.

Pharmacist Education

We would be happy to assist in the education of pharmacists to ensure that they are well aware of the scheduling change and we would provide resources to assist them in helping consumers adapt to the change.

Scheduling Policy Framework

We note the following factors for pharmacist only medicines (schedule 3) from the Scheduling Policy Framework with our comments:

[3] http://www.medsafe.govt.nz/profs/class/Minutes/2016-2020/mccMin26April2018.htm

1. The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.

The consumer can identify the ailments or symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use. Consumer consultation with a pharmacist is necessary to reinforce and/or expand on aspects of the safe use of the medicine.

We believe that this particular formulation would benefit from pharmacist consultation to reinforce and expand on safe use of the medicine.

2. The use of the medicine is not expected to produce dependency at either the established therapeutic dose or at supratherapeutic doses. Where risk of misuse, abuse or illicit use is identified, the risk can be minimised through pharmacist-consumer consultation.

There is a risk of supratherapeutic doses long term if consumers are taking 8 tablets a day rather than the maximum of six a day – this risk can be minimised through pharmacist-consumer consultation.

3. The risk profile of the medicine is well defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist.

The risk of incorrect dosing of this formulation, and use in concurrent conditions such as liver disease, is manageable by pharmacist interaction with the consumer.

4. Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or other authorised prescriber.

The consumer may not be able to self-monitor the safe ongoing use of the medicine. The condition does not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.

Consumers using this medicine for a chronic condition would benefit from consultation with the pharmacist to ensure optimal use and management of their condition.

5. The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.

Pharmacist-consumer consultation is required to detect the risk of masking a serious disease or compromising medical management of a disease, and to deal with it appropriately.

Pharmacist-consumer consultation would detect incorrect patient use of this medicine and ensure that consumers were not using it inappropriately.

Summary

We do not object to the proposed amendment as this will ensure that consumers are advised of the correct dosage of this particular formulation of paracetamol.

There may be a mistaken belief by some consumers that this is simply another formulation of paracetamol for osteoarthritis but it is in fact a modified release formulation. We agree that there is likely some confusion with the maximum dose of 8 tablets per day for the immediate release formulation as compared to 6 tablets per day for the modified release formulation and subsequent unintended overdose over an extended period.

We agree with the sentiment expressed in the application to the ACMS that by up-scheduling paracetamol modified release from Schedule 2 to Schedule 3 consumers will benefit from appropriate patient counselling on correct dosing and the risks associated with overdose.

Pharmacists are the experts in medicines and this is an opportunity for patients to discuss their request with their pharmacist who will be able to provide advice on the condition and the treatment options available.