RACGP
Royal Australian College of General Practitioners

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6 February 2024

Medicines Repurposing Team
Business Systems Review & Reporting Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration, Department of Health and Aged Care

Email: medicines.review@health.gov.au

Dear Medicines Repurposing Team,

Re: Medicines repurposing program consultation

The Royal Australian College of General Practitioners (RACGP) thanks the Department of Health and Aged Care for the opportunity to respond to this important consultation.

The RACGP supports the proposed initiative, noting that it aligns well with key elements of the National Medicines Policy and RACGP feedback to the Policy.

Some key areas for further consideration are outlined below.

1. Process of identification of eligible medicines and selection criteria

Further detail is required about the criteria for including medicines for repurposing, and the level of evidence that will be considered in this selection process.

The criteria in terms of the potential impact on health outcomes that are being sought is also not clear. For instance, whether a large clinical effect size for a small number of people, or a smaller effect size over a greater population would be deemed reasonable?

It is noted that public health impacts will be assessed by the TGA, however, it may also be reasonable to ask sponsors to collate this information as well.

Ideally evidence for effectiveness should come from systematic reviews of the literature, rather than individual industry-sponsored trials. Processes such as GRADE (Grading of Recommendations, Assessment, Development and Evaluations)[i] provide objectivity and transparency in the translation of evidence to clinical decision-making.

In regard to the application process, applications for drug repurposing should also be accepted from clinician peak-bodies. These groups are missing from the proposed framework.

The RACGP recommends:

- that applications for drug repurposing also be accepted from clinician peak-bodies.
- that evidence for effectiveness should come from systematic reviews of the literature, rather than simply individual industry-sponsored trials.

2. Evaluation and safety

The introduction to the document states that sponsors will provide supporting evidence for the safety and efficacy of medicines. The RACGP notes that a focus exclusively on clinical outcomes fails to acknowledge other important outcomes such as:

- value-for-money,
- patient-reported measures such as Quality of Life,
- equity issues such as substantial co-payments or other access barriers eg. The need for specialist review.

Furthermore, safety data in the original trials most likely excluded many patients at higher risk of side-effects.

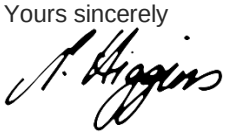
In terms of program viability, evaluation of the first 5 medicines and the subsequent benefits and costs should inform the future of the program. The cap of 5 fee-waiver applications should be seen as a starting point with a view to wider implementation of the repurposing activity in future years.

The RACGP recommends:

- The safety of the medication needs to be established in any new patient group and there should be consideration of a broader list of outcomes.

The RACGP thanks the Department of Health and Aged Care for the opportunity to provide this feedback. If you have any queries regarding this submission, please contact Mr Stephan Groombridge, National Manager, e-Health, Quality Care & Standards on (03) 8699 0544 or at stephan.groombridge@racgp.org.au.

Yours sincerely



Dr Nicole Higgins
RACGP President

[i] What is GRADE? https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/ [accessed 24 January 2024].