

OVER-THE-COUNTER MEDICINES BUSINESS PROCESS REFORM CONSULTATION PAPER

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Independent, not-for-profit and evidence based, NPS enables better decisions about medicines and medical tests. We are funded by the Australian Government Department of Health and Ageing.

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Submission

NPS appreciates the opportunity to review the Over-the-Counter (OTC) Medicines Business Process Reform consultation paper.

Managing the risk of avoidable harm associated with the use of OTC medicines through safety, quality and efficacy standards is imperative. We are happy to expand on any of the issues raised in this paper.

NPS provides the following responses to the proposed regulatory changes by the TGA.

Regulatory change	Comment
Risk categorisation framework	<p>The comprehension of the risk categorisation framework would be improved with further definition of 'consequence' and 'likelihood'. The shades of difference between 'unlikely' and 'possible' could also be given more scientific and objective definitions. This would improve the understanding of risk and evaluated safety of the medicine.</p> <p>How the outcomes of the risk categorisation framework are going to be effectively communicated to consumers to enable them to make informed choices needs further explanation.</p> <p>Within the risk categorisation framework there is opportunity to consider factors which may be relevant to the medicine and impact on consumer safety which are not considered when the medicine is evaluated in isolation. Examples of this may be where the medicine significantly interacts with other medications or medical conditions. Information such as this would need to be considered during evaluation so consumers are able to make an informed choice.</p>
Evaluation process	<p>We understand the rationale in compressing approval times; however we would like to highlight the consequence of this not risking the integrity of the evaluation process.</p>
OTC medicine monographs	<p>We would like to understand how compliance of OTC monographs would be assessed in the marketplace.</p>