The Submission of the Department of Industry, Innovation, Science, Research and Tertiary Education to the *Therapeutic Goods Administration Medicine Labelling and Packaging Review*.

1. The Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE) appreciates the opportunity to provide a submission to the *Therapeutic Goods Administration (TGA) Medicine Labelling and Packaging Review.*

2. DIISRTE works with its stakeholders to help accelerate productivity growth and secure Australia's prosperity in a competitive global economy.

3. DIISTRE supports the aims of the TGA safety policy of ensuring clarity in the identification of active ingredients to consumers and health professionals. The Department also supports the safety policy of preventing consumer confusion caused by products that have the same or different active ingredient(s).

4. Where there is high evidence of a risk to safety, for example in relation to certain prescription medicines, the proposed approaches may be appropriate.

5. DIISRTE has concerns that the implementation of the review could have significant unnecessary adverse impacts on consumers and industry. This is due to the unnecessarily prescriptive nature of some of the proposed implementation measures in a global business environment. For instance the costs to importers of medicines of alteration of the exact position, font size, colour and case of font with respect to active ingredients on medicine labels in the prescribed manner may be prohibitive when considered in the light of the size of the Australian market for the therapeutic product.

6. The proposals could have unnecessary adverse impacts on consumer health and industry. This is because of their impact on the business viability of some therapeutic products, resulting in reduced consumer access to medicines that meet quality and efficacy criteria.

7. We note the Government's approach to better regulation where proposed regulation is to achieve the policy objective 'in a manner that minimises costs for business and the community'[1].

8. DIISRTE suggests a possible approach for implementing TGA safety policy that could be achieved with less adverse impacts on consumers and industry. DIISRTE proposes that a less prescriptive approach to implementation may be able to be applied more generally.

[1] http://www.finance.gov.au/obpr/proposal/handbook/docs/Best-Practice-Regulation-Handbook.pdf accessed on 17 August 2012.

Potential unnecessary impacts of proposed prescriptive approach

9. A prescriptive approach may have adverse consequences for industry, particularly importers of low margin products who have little effective control over labelling in the country of manufacture. Higher costs due to increased regulatory burden are typically passed on to consumers. If it becomes uneconomic to introduce or continue to have such products in the Australian market, this may result in adverse health outcomes, as consumers will not have access to such products.

10. Also, as companies invest in brands rather than company names, they may exit the market due to their inability to leverage existing investment or due to the risk that further such investment could be wasted. Examples are in paragraph 17.

11. There is some risk to consumers in altering the business environment so that there are fewer multiple suppliers. Single supplied medicines may leave companies in a position to charge what the market can bear, rather than charging on the basis of costs. Also, if there is even a temporary issue with the supply of medicines there may be no ready alternative. These issues could adversely impact on timely access to affordable medicines for Australians.

Prominence of active ingredients on medicine labels

12. The TGA's proposed approach as set out in the consultation paper prescribes the position, font size, colour and case with respect to active ingredients on medicine labels.

13. The Australian proportion of the global market for pharmaceuticals is generally less than two per cent for medicines. Medicines are generally suppled on a global basis. Unique Australian packaging and labelling requirements may require expensive and specific packaging for Australia thereby reducing the business case for continuing to supply them to our small market. Consequently unique Australian packaging and labelling requirements should be based on evidence rather than a possible risk in order to ensure that products are not unnecessarily uneconomic to supply. Similarly, unique Australian packaging and labelling requirements may reduce the business case for the export of Australian therapeutic products.

14. A possible alternative to the proposed approach that may be appropriate is to indicate that the active ingredient must be readable and prominent on the packet and be at least an amount (say 40 per cent) larger than the size of product name and/or that the minimum text size is a certain size (say 10pt). This approach could assist in increasing the prominence of active ingredients on medicine labels without necessarily requiring unique Australian packaging.

15. Overseas jurisdictions such as the US, Ireland and UK have required that non-prescription medicines containing paracetamol or ibuprofen be identified[2][3][4]. As this is the case in major markets, making the required changes for the Australian market is unlikely to be a substantial burden for industry. However, even closer alignment of requirements in these jurisdictions may be beneficial to both consumers and industry. For instance it may be

[2] Statutory Instrument: S.I, 150 of 2001. Medicinal Products (Control of Paracetamol) Regulation, 2001 Dublin: Stationary Office; 2001.
[3] Statutory Instrument 1997 No.2045: The Medicines (Sales or Supply) (Miscellaneous Provisions) Amendment (No.2) Regulation 1997 London: Stationary Office; 1997.
[4] King, J.P et al (2011) Developing Consumer-Centred, Non-prescription Drug Labelling. Am J Prev Med , Volume 40,Pages 593-598.

beneficial if the additional warning statement was similar to what is required in these jurisdictions.

Examples of problems with look alike and sound alike medicine brands

16. In relation to 'look-alike' packaging changes it is proposed that there be specific prohibitions on certain types of branding. Rules such as 'Products that are listed on the ARTG cannot be marketed under the same name as a registered medicine' are logical to avoid consumer confusion. However, some of the other proposed approaches should be based on specific evidence arising from consumer research in order to avoid unnecessary adverse impacts on consumer health and industry.

17. Many businesses have heavily invested in brands, not necessarily in the company name (e.g. Panadol™ rather than GSK). If businesses are unable to sufficiently differentiate products based on their existing investment, they may exit the market. This may be due to the inability to leverage off of this investment or because of the risk that there may be similar major changes to branding on labels in the future.

18. An approach might be to allow all brand names and packaging that are sufficiently differentiated to consumers (as evidenced in specific consumer testing) to be used where presence of an additional active ingredient or the different active ingredient is clear. For example Nurofen™ is used as a brand name for ibuprofen, whereas Nurofen™ Plus has an additional ingredient (codeine). It is not clear whether the different products with different colour packets are confusing to consumers, however all such products appear to be banned under the proposed changes.

Blister strip labelling

19. If there is a requirement for unique Australian packaging or labelling it could reduce unnecessary adverse consequences by implementing the changes in a flexible manner.

20. For instance it is not clear if there is to be a requirement for the blister packs to have the information printed on the foil or whether a sticker can be used. Requiring the information to be printed on the foil may have unnecessary adverse consequences for industry, particularly importers of low margin products such as some complementary medicines or over the counter products who have little effective control over labelling in the country of manufacture. The application of a sticker may be a low cost way of achieving the desired health outcome.

Submission status

21. This submission has been approved by the acting head of the Innovation Division and we have no objection to it being released publicly.