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TGA Labelling and Packaging Review
Therapeutic Goods Administration
PO Box 100
Woden ACT, 2606

TGA Medicine Labelling and Packaging Review – Consultation Paper (version 1.0, May 2012)

Fresenius Kabi Australia Pty Limited welcomes the opportunity to provide feedback on the proposed regulatory changes to medicine labels and labelling requirements.

Please find below responses to some of the questions raised in the consultation paper that affect our business.

Prominence of active ingredients on medicine labels

- **What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?**

  Response:
  It is appreciated that the increase in prominence and standardisation of location has been recommended to improve differentiation between branding and the active ingredient. However, there is concern that such changes may in fact cause more confusion to consumers. With multiple names appearing with equal prominence on the front panel, it is not unforeseeable that consumers will experience difficulty in distinguishing between the brand name and the active ingredient.

  Of particular concern are those instances where the tradename of the product already incorporates the active ingredient (i.e. Paclitaxel Kabi, where the active ingredient is paclitaxel). In such cases, with the proposed changes, it may be difficult for a consumer to understand where the tradename ends and where the active ingredient begins.

  Are there any other concerns you have with the size or position of brand names and active ingredient?

  Response:
  There are significant concerns regarding the practicality of the proposed changes. In the case of products supplied by Fresenius Kabi, some products currently contain up to 20 active ingredients, are presented in multiple pack sizes and, due to manufacturing constraints, carry single panel labels. Given the limited real estate available on such labels, proposals 1.2 and 1.3 present significant issues in regard to compliance.

Furthermore, where many of the active ingredients are in equal quantity, it would be difficult to differentiate the "most abundant" ingredients as suggested in these proposed changes.

Standardised Information Format: the Medicine Information Box

- **To what extent do you think a standardised format for information on the labels of over-the counter and complementary medicines will improve access to information for these medicines?**

  Response:
  Fresenius Kabi supports the inclusion of a standardised Medicine Information box to assist consumers in determining the suitability of a medicine. Such uniformity would significantly improve the readability medicine labels in Australia.

Dispensing label space

- **Do you support a designated space for the dispensing label on prescription medicines? Why/why not?**

  Response:
  The above proposal is appropriate for carton labels where there is adequate space for a dispensing sticker. However, reasonable consideration should be extended to those products that would not be directly dispensed to a patient (i.e. hospital line parenterally administered products). In these cases, where products are solely administered by a health care professional, an exemption to this proposal is suggested.

  Similarly, for products that are supplied in small presentations (i.e. 1 mL and 3 mL ampoules) where it is not practicable, an exemption to the requirement to include such space is proposed.

Small containers

- **To what extent do you support the proposed changes for small container labels? Please provide details**

  Response
  Fresenius Kabi supports the changes for small container labels. However, given the limited real estate available on some labels, the inclusion of all requirements outlined in point 7.2 of the TGA's consultation paper would be difficult. Together with the proposal to also include dispensing label space, compliance to these changes would be exceedingly problematic.

- **Do you have any further suggestions for how labelling of small containers could be improved?**

  Response:
  Fresenius Kabi currently supplies products in 1 mL and 3 mL ampoules. As is expected, such small labels present significant issues in relation to space. It would be highly appreciated if consideration could be apportioned to reducing the current letter height from 1.5 mm to >1 mm for such ampoules.

In closing, Fresenius Kabi recognises and supports the initiative to improve the quality and readability of medicine labels supplied in Australia. However, any changes should not be so onerous as to unnecessarily restrict the products brought to the Australian market. It is recommended that the TGA provide allowance for the case-by-case consideration of label space as a restriction to compliance. Where there is a barrier to compliance posed by space limitations, proposals by sponsors for alternative methods of conformity (together with appropriate justification) would be duly assessed by the TGA.

Fresenius Kabi trust that they are of assistance and look forward to further collaboration to develop mutually agreeable changes to labelling requirements in Australia.

Regards,
Fresenius Kabi Australia Pty Limited