ATTACHMENT 2

ANSWERS TO THE QUESTIONS RAISED IN THE CONSULTATION PAPER

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General questions on the proposed regulatory changes for the prominence of the active ingredients on medicine labels

Q. What do you think will be the impact of increasing the prominence and standardising the location of the active ingredient on the medicine label?
A. If implemented as proposed, the impact will be significant (as discussed in previous parts of our response).

Q. What do you think about the proposed warnings for paracetamol and ibuprofen containing products?
A. Ego does not manufacture products containing paracetamol or ibuprofen. Ego therefore has no comment to make in relation to this question.

Q. Are there any other concerns you have with the size or position of brand names and active ingredient?
A. Ego's concerns with the proposed changes are discussed in previous parts of our response.

Q. If the active ingredient name is clear, directly below the brand name and in a large font, what are the additional benefits that you see by making it the same size as the brand name?
What is the smallest size font that you consider readable?
A. The "benefits" of the proposed changes have not been established. Ego's concerns with the proposed changes are discussed in previous parts of our response. Ego contends that there are other ways of achieving due prominence apart from increasing the font size.

General question on the proposed regulatory changes for look-alike sound-alike names and look-alike packaging

Q. Do you think the proposed changes to address LASA names and LA packaging will improve medicine safety? Why/why not?
A. Ego's concerns with the proposed changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General questions on the proposed regulatory changes for look-alike medicine branding

Q. What benefits, if any, do you think the proposed changes to address look-alike medicine branding will have for consumer safety?
A. Ego's concerns with the proposed changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

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Q. Do you understand the proposed changes?
A. As discussed in our response, the Consultation Paper has confusingly amalgamated separate issues and has co-mingled prescription and non-prescription risks. This has resulted in a lack of clarity which made interpretation difficult. This lack of clarity has compromised the consultation process.

Q. If you can read the labels and warnings clearly, will these changes reduce the potential for harm?
A. [it is unclear why this question has been included in this section] Ego's concerns with the proposed LASA changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General question on the proposed regulatory changes for Standardised Information Format: Medicine Information Box

Q. 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?
A. Ego's concerns with the proposed changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Are there other ways that the presentation of information could be improved?
A. Ego has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

Q. Do you think the proposed requirements for products with more than three active ingredients (directions and warnings and allergy information), is sufficient for these products? Please propose an alternative if you don't agree with current recommendation.
A. Ego's concerns with the proposed changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. The alternatives put forward by Ego all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

General question on the proposed regulatory changes for dispensing label space

Q. Do you support a designated space for the dispensing label on prescription medicines? Why/why not?
A. This item has been identified as applying to prescription medicines only. Ego offers no comment in relation to this part of the Consultation paper.

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General question on the proposed regulatory changes for blister strip labelling

Q. Do you think the proposed information for blister strips is sufficient?
A. Blister strips are not used for the packaging of Ego products. Ego therefore has no comment to make in relation to this part of the Consultation paper.

Q. What other changes would you like to see for this type of packaging?
A. Blister strips are not used for the packaging of Ego products. Ego therefore has no comment to make in relation to this part of the Consultation paper.

General question on the proposed regulatory changes for small container labelling

Q. To what extent do you support the proposed changes for small container labels? Please provide details.
A. Ego's concerns with the proposed changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you have any further suggestions for how labelling of small containers could be improved?
A. Ego has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed regulatory changes for pack insert requirements

Q. Do you support the proposed changes for pack inserts? Why/why not?
A. Ego's concerns with the proposed changes are discussed in previous parts of our response. In the absence of evidence, no assessment can be made as to the effectiveness of the proposed changes. No change to the current requirements should be made unless based on evidence from consumer testing in the context of the entire label.

Q. Do you have any further suggestions regarding pack inserts?
A. Ego has put forward a range of alternatives. These all come with an important caveat: none of the proposed alternatives have been tested as the consultation timeframe was insufficient to undertake that task.

General question on the proposed establishment of a labels and packaging advisory committee

Q. To what extent do you think that a Labels and Packaging Advisory Committee will assist the TGA to manage consumer health risks associated with medicine labels and packaging?
A. Ego's position on this topic is discussed in previous parts of our response.

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