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Advancing Responsible Self-Care

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Sent by email to: TGA Scientific Ops Management TGA.Scientific@health.gov.au

Dear Sir/Madam,

Updates to medicine labelling rules – Public consultation on proposed changes to TGO 91 and TGO 92 to support medicine safety

Thank you for the opportunity to provide comment on the TGA consultation on labelling rules on proposed changes to TGO 91 and TGO 92 to support medicine safety.

Consumer Healthcare Products Australia (CHP Australia) is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care. Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

CHP Australia would like to provide comments in relation to Part 3 – Improving information on listed medicines about large solid oral dosage forms intended to be swallowed whole.

For non-prescription medicines, the labelling is the most important source of information for consumers. It allows consumers to select appropriate medicines and use them safely. It is therefore in the interests of the community for non-prescription medicine labelling to be well designed and effective in meeting consumer needs.

In principle, CHP Australia members support initiatives to improve patient safety and we acknowledge that some listed as well as registered medicines are formulated as large dosage forms. There is a spectrum of risk and setting appropriate thresholds is of critical importance. Even with the presence of warning statements, unfortunately it will be impossible to completely eliminate choking risk from swallowing tablets or capsules due to accidents and human factors that are difficult to control.

We believe that warning statements on large dosage forms should be proportionate to demonstrated risk, meet consumer needs, and not provoke fear and anxiety in people who take

these medicines as this can in itself increase the risk of choking sensation / dysphagia[1]. Warning statements on labels should be properly researched, tested and applied where the level of risk is greatest so as not to dilute messaging and confuse consumers. The new requirements should also not be burdensome for industry to introduce.

The principles of best practice regulation require that an impact analysis of any proposals to introduce new legal requirements should be conducted. CHP Australia believes that the TGA may be underestimating the degree of industry impact of these proposals on listed medicines. The proposals are described as intending to address a high priority need (hence the introduction before sunsetting of TGO 92), yet the proposed changes will capture the labels of an estimated 30-45% of listed medicines (depending on individual sponsor company portfolios). This is indicative that the requirements are not proportionate to risk, as there is no evidence that the risk of choking is associated with such a high proportion of listed medicines. Appendix F table 3 lists only a subset of products that carry the highest risk, yet the proposal goes far beyond these higher risk products and extends the new requirements to products where the risk is low or possibly even theoretical.

We are not aware of any comparable regulator in the world that requires or is proposing to introduce label statements for large dosage forms. As a first in the world initiative it is important that care is taken so that the thresholds and warnings are appropriate and based on evidence.

We provide the TGA with the following general comments as well as responding to the consultation questions.

Industry impact

In response to the 2023 targeted consultation, CHP Australia provided in-principle support for addressing some safety matters before the sunsetting of TGO 92, for 'large solid oral dosage forms intended to be swallowed whole'. The 2023 paper provided no detail but it referenced the FDA Guidance and TGO 101, leading many in the industry to believe that there would be some alignment with this guidance, and that the impact would be confined to products where there is the greatest risk. We were therefore logically anticipating that the greatest risk would apply to the highest percentile of tablet and capsule sizes. This consultation paper is not reflective of the 2023 targeted consultation. It impacts a disproportionately high number of listed medicines as well as products that are not intended to be swallowed whole. Industry has been genuinely surprised at the foreseeable impact, which makes it difficult to fully support the proposals in this consultation paper.

The TGA should ensure that industry has sufficient time to work through any changes that result from the updated TGO 92. Sponsors will need to carefully examine their product portfolios to determine and assess impacted products. We are very concerned that sponsors will be required to update labelling for a large number of products before the sunsetting of TGO 92, and then be required again to change labels when TGO 92 is revised after sunsetting. A hypothetical two-year transition for the 'pre-sunsetting' changes will end towards the end of 2026, and by that stage TGO 92 will have expired and be in its transitional phase to the new Order. This may impose a burden on industry, both financially and in terms of business and human resources.

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[1] Doruk C, Mocchetti C, Rives H, Christos P, Rameau A. Correlations between anxiety and/or depression diagnoses and dysphagia severity. Laryngoscope 2024 May;134(5):2115-2120. doi: 10.1002/lary.31164. Epub 2023 Nov 9. https://pubmed.ncbi.nlm.nih.gov/37942834/

We are aware that when the FDA Guidance[2] was introduced and TGO 101 included associated best practice recommendations, some sponsors took action to re-size their products, for example changing from a one-a-day formulation to two-a-day formulation. Some sponsors may elect to do this in response to this update to TGO 92 and make their products below the thresholds, however this is a lengthy and costly exercise which involves:

- Developing plans to re-size and assess costs and budget
- Product development
- Re-tooling and cost of upgrades to equipment
- Testing of re-sized products to ensure they meet specifications
- Stability testing

We urge the TGA to undertake a financial impact analysis on potential costs prior to deciding on the final outcome and to support an appropriate transition.

Some sponsors may seek to change packaging to clear containers to reduce the demands on available label space of the proposed warnings, in which case stability testing will be required, along with the associated time and cost.

All of this takes time and financial provisioning, and transitional arrangements will be very important in allowing sponsors to determine the most appropriate approach.

For sponsors who do not wish to re-size products, they will need to undertake labelling updates. These will also be costly and will need to be budgeted given the number of products affected. Issues that sponsors will encounter include:

- Listed medicines can contain multiple active ingredients and other information, as well as barcodes, country of origin information and other mandatory information. There is limited label space on many product labels, especially primary pack / container wrap-around labels, making it very challenging to introduce a graphic. There has been insufficient time for sponsors to produce mock-ups to test whether the graphic and warning statements can be accommodated on labelling.
- There are certain product types that will definitely not be able to meet the proposed labelling requirements. In particular some listed medicines in packaging where the label is small. These may include products such as [redacted] that have small label dimensions. These types of products will find it difficult to fit an actual sized image, plus associated warning statements in addition to all of the existing label information.
- For all products undergoing labelling changes, the costs of re-designing and producing new labels will be significant.
- There will be write-offs of existing labelling, and a high probability for further write offs of this new labelling with the sunsetting of TGO 92, depending on transitional arrangements.

CHP Australia believes that warning statements for large dosage forms may be appropriate in some cases, however we do not believe that these should be applied to the number of products that appear to be affected (i.e. up to 45% of product portfolios). They should be reserved for

[2] FDA Guidance: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules Guidance for Industry https://www.fda.gov/media/87344/download

products where the risk is highest. The extent of the impact of this TGA proposal is due to the TGA's proposed thresholds that go beyond those of the FDA's Guidance.

[redacted]

As a contract manufacturer, they will be guided by the sponsor's actions in relation to the updates, but these figures provide evidence that the changes will be highly significant in terms of cost and resources.

Any changes to labelling, but particularly those introduced shortly before sunsetting, should be proportionate to risk, and informed by comprehensive data demonstrating a clear need. For changes required pre-sunsetting, the TGA should be respectful of cost and burden to the impacted industry. We are concerned that there has been inadequate analysis and impact assessment, which are generally principles applied in best practice regulation.

As such, this proposal represents more than a pre-sunsetting minor update, going beyond the scope proposed in the 2023 targeted consultation. We believe it would be more appropriate for these proposals to be part of the TGO 92 sunsetting consultation, with more work being done in the intervening period to assess what might be the most appropriate risk-based thresholds.

Research conducted by TGA

CHP Australia acknowledges the work that the TGA has done in collating adverse event reports. However, the way this information has been used to determine the proposed thresholds that define 'large dosage forms' lacks rigour and detail.

The proposed thresholds have been set at the point of impacting approximately 45% of CHP Australia member company (sponsors') portfolios, indicating that the thresholds may not be aligned with actual risk. The FDA guidance[3] has been cited as one of the foundations for these proposals, yet the thresholds go beyond the FDA's recommendations, particularly regarding tablet width / diameter.

[3] FDA Guidance: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules Guidance for Industry https://www.fda.gov/media/87344/download

The TGA's report has not adequately explained why >9 mm has been chosen as the threshold that forms the data analysis. Round tablets of this diameter make up a very small proportion of the adverse events described (9 reports of 161 reports for total tablet dosage forms, or 5.6%). In addition, there has been no analysis of how many of these reports applied to tablets > 10 mm, or >11 mm, or >12 mm, i.e. at which point do the safety reports increase significantly. There is no analysis of how many adverse events reflect incorrect product use and little information on patient characteristics. We do not believe that round tablets are represented in any of the listed medicine products that are most involved in choking related hazards.

The proposed threshold for capsules is problematic because it does not consider the slight variation in capsule sizes as well as tolerances, meaning that sponsors will not reliably be able to use 00 capsules from manufacturers, and with some batches the finished product may be larger than the threshold.

For a proposal with such significant impact, no thought has been given to the financial and logistical impact on sponsors and manufacturers. There has been no impact analysis.

These gaps should be addressed and there should be increased transparency regarding how the targeted consultation (which mentioned the FDA Guidance and TGO 101) has been translated into dosage form thresholds that will result in approximately 45% of listed medicine portfolios requiring labelling updates, that in most cases will be very difficult to achieve on many labels.

Impact on a disproportionate number of listed medicines

The scope of this consultation, as identified in the targeted consultation held in 2023 and as outlined in the consultation paper, is intended to address higher priority safety issues before the sunsetting of TGO 92. Products affected by this consultation will be required to update labels before sunsetting and are likely to also be affected by changes to TGO 92 after sunsetting, meaning multiple label changes in quick succession.

CHP Australia members who are sponsors with listed medicine portfolios have indicated that [redacted]. It is clear that the changes in Part 3 will have a significant impact on industry. The proposals appear to be disproportionate to demonstrated or proven risk and the impact is much greater than the intended scope of this consultation, which is to address higher priority safety issues before sunsetting of the Order.

Given the large volumes of these medicines supplied through pharmacies, grocery and health food retailers, we would expect to see a much higher number of adverse event reports both to the TGA and to sponsors, across a much wider range of listed medicines, i.e. if 30-45% of listed medicines were the direct cause of serious and non-serious choking. The TGA's consultation paper (Appendix F table 5) shows tablet size data for 161 reports for tablets (69 serious AEs and 92 non-serious AEs) and 50 reports for capsules (24 serious and 26 non-serious). Even accounting for other reports where no tablet size data was provided, these reports are low in number compared to the very large volumes of these products sold. Ideally it would have been useful to know whether the causative factors for these choking episodes have been accurately characterised, to determine to what extent these adverse event numbers may have been reduced by the presence of an image and warning statement.

The consultation paper indicates that the highest numbers of choking related adverse events (10 or more) have been reported with:

- Glucosamine / chondroitin
- Fish oil / krill oil / omega 3
- Calcium with vitamin D
- Multivitamin / minerals

CHP Australia is concerned that as written, the 'large dosage form' labelling statements will be required on a much greater range of products impacting large segments of the market. Products that have been the subject of very few or even no choking related adverse events will be required to carry an image and labelling statements. This capture of a large number of products outside the higher risk medicines mentioned in the consultation is not aligned with the principles of risk-based regulation.

We therefore urge the TGA to reconsider the proposed thresholds for the inclusion of label warning statements and adjust the thresholds to apply to products that carry the highest risk of choking related adverse events, rather than having labelling statements applying to a very large proportion of listed medicines that have not been the subject of choking related adverse events.

Risk proportionate approach to threshold for label statements

The TGA should take a risk-based approach to the requirement to include an image and warning statement on the labels of large dosage forms.

The dosage unit threshold sizes proposed by the TGA are set too low and CHP Australia believes that higher cut-offs are needed. TGO 101, which commenced in March 2019, contains 'best practice recommendations' on the size of discrete dosage forms, which are based on the FDA Guidance.[4] This non-mandatory guidance states that the largest dimension of tablets should not exceed 22 mm and that capsules should not exceed 00 size. There are no separate length / width dimensions. Additionally, the recommendations do not apply to other oral dosage forms such as chewable tablets, tablets for suspension / solution, orally disintegrating tablets, and gums. The guidance also does not apply to dietary supplements in the US.

TGO 101 also describes other variables that impact choking risk, such as size, shape, use of coating materials and the intended patient population. It is concerning how the proposals in this consultation do not consider anything other than the physical dimensions of the dosage forms, and the proposed thresholds are also much tighter.

Proposed tablet dimensions threshold

Appendix F of the consultation paper (Table 5) indicates that the majority of serious and non-serious choking related adverse events for tablets have been reported for tablets with length >22 mm and width >9 mm, with no adverse events for tablet length > 22 mm and width < 9 mm. The greatest level of risk appears to apply when tablets exceed both 22 mm and 9 mm dimensions. Width of tablets < 9 mm appears to be of comparatively lower risk.

The TGA in Appendix F states that 86% of reports for tablets involved dosage units that were either >22 mm in length and / or >9 mm wide, but that of these, only 6% involved round tablets with a diameter >9mm. This indicates that the highest level of risk applies to tablets that are both long, and wide. The evidence in the consultation paper indicates that round tablets of > 9 mm

[4] FDA Guidance: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules Guidance for Industry https://www.fda.gov/media/87344/download

diameter present a lower level of risk (approx. 9 /211, or 4.3% of cases overall) and there are many commonly used OTC and prescription medicine tablets that are round tablets > 9 mm diameter and overall, the TGA considers that these medicines are of lower risk with respect to choking.

In Appendix F, table 3, the TGA has listed the products with the highest number of choking related cases. Generally these are the highest strength fish oils, the larger glucosamine / chondroitin, calcium carbonate / colecalciferol, krill oils and multivitamin/mineral products, where the size of these dosage forms is larger than 22 mm x 9 mm. The TGA had not provided evidence that round tablets with a diameter of > 9 mm are represented in this product list. The selection of > 9 mm width / diameter appears rather arbitrary and not based on solid evidence such as an analysis of choking cases at different sizes and shapes, e.g. 9 mm, 10 mm, 11 mm. More research is needed on the association between tablet size and oesophageal transit, to determine the appropriate threshold.

CHP Australia is of the view that the threshold should be changed, to focus on the highest risk tablet dimensions. We do not support the need for labelling requirements to apply to round tablets > 9 mm diameter, however we would support changing this threshold to > 11 mm diameter which is consistent with the FDA guidance information on round tablets, which indicates that 11 mm diameter tablets have a longer oesophageal transit time, indicating that at this point, the risk may be increased.

CHP Australia believes that the threshold should be changed to:

[redacted]

These tablets which are likely to present a higher level of risk, should be required to include a statement such as 'Large [dosage form]' and a real size image of the tablet on the label, as well as a 'swallow with liquid' statement or words to that effect.

Proposed capsule threshold

CHP Australia does not agree with the proposed threshold for capsules and we question whether the TGA intended for the labelling requirements to apply for 00 capsules. As written, the proposed threshold dimensions mean that many 00 sized capsules will require the label statements and image, and there is no evidence of 00 size capsules being of such high risk as to warrant large dosage form label statements. Size 00 capsules are very commonly used across listed medicines as well as OTC and prescription medicines and probably make up the largest proportion of capsules sold.

Our members have checked the specifications for 00 capsules used for their products, and these show that 00 size capsules can be up to 23.4 mm length with a tolerance of up to ± 0.5mm, according to one commonly used supplier for the product range of a member company[5]. The TGA's proposals do not specify whether the 23.3 mm threshold proposal is an average or a maximum and as written, some 00 size capsules will require the label statements and some will

[5] Personal communication with a CHP Australia member company. We are willing to provide the TGA with a copy of the specifications.

not, and it will vary from batch to batch. This is very difficult if not impossible for sponsors to work with and indicates that the proposed threshold requires adjustment.

[redacted] specifications for standard hard gelatin caps indicate these may be 23.3 ± 0.3 mm, therefore the 00 capsule acceptance criteria are wider than the TGA's proposed threshold, meaning that from batch to batch of capsules there will be variation that can put some of the capsules above the TGA's threshold. This also applies to another capsule supplier, which specifies a capsule length of 23.4 ± 0.3 mm on their website[7]. In addition, there are various types of capsules. For example, some 00 sized capsules designed to securely contain liquids and semi-solids can be 23.8 mm ± 0.3 mm[8].

Using the proposed thresholds for capsules, sponsors will not be able to confidently use 00 capsules and rely on this for compliance to TGO 92. This is not well thought through and impossible for sponsors to work with.

For most listed medicines the company finished product specifications for individual medicines are expressed in terms of capsule size rather than dimensions in mm, e.g. 00 size capsule. The TGA threshold should also be referenced by capsule size rather than dimensions for consistency with specifications, to ensure that sponsors can be certain that they comply with TGO 92 if they use size 00, and that this takes account of tolerances. CHP Australia believes that capsules in sizes greater than 00 should be subject to the additional labelling warning statements, and that the threshold for capsules should be expressed as 'greater than 00'.

There are some longer 00 capsules that are referred to as '00E' or '00EL' and the guidance can be worded in such a way as to be clear that size 00E or 00EL capsules are subject to the labelling requirements for large dosage forms, as these are typically longer than standard size 00 capsules, i.e. 25.3 ± 0.3 mm.

The TGO 92 capsule size threshold should be expressed as greater than 00 size, to ensure that sponsors have certainty that if they use 00 size capsules the labelling statements will not be required. Otherwise, if the TGO 92 expresses capsule size thresholds as 23.3 mm, it is foreseeable that in a compliance audit or testing situation, some sponsors may find themselves non-compliant with the Labelling Order if using 00 capsules that are within manufacturers' specifications.

Alternatively, the TGO 92 capsule threshold should refer to a length of 'greater than 24.1 mm' to ensure that all 00 capsules will be compliant with the requirements regardless of supplier and accounting for batch to batch variation within the specified tolerances.

CHP Australia believes that expressing the threshold for capsules as either 'greater than size 00' or 'greater than 24.1 mm' will have no adverse impact on consumer safety and that it probably reflects the TGA's intention for size 00 capsules to not require the proposed labelling statements.

[6] [redacted]

[redacted]

[redacted]

Softgel capsules

[redacted] Given the volumes of product sold, we suggest that it is likely to be the largest soft gel capsules are causing most adverse events (see Appendix F, table 3).

This, together with the data on the impact on the number of products supplied overall, indicates that the TGA's proposed thresholds are too low for soft gel capsules and should be increased so that only the higher risk products will require labelling statements.

CHP Australia believes that more work should be done to ensure an appropriate cut off for soft gel capsules.

Chewable / dissolvable tablets

CHP Australia does not agree with the TGA's proposed labelling requirements for lozenges, chewable tablets, and dissolvable tablets, that tablets that are above the proposed threshold will be required to include the labelling statements, unless a statement such as 'Do not swallow whole' is included.

The TGA consultation on this issue is ambiguous and confusing. The Part 3 requirements state '*We recommend that listed medicines in the above dosage forms should include instructions in the directions for use 'Do not swallow whole' (see Appendix G for guidance).* Appendix G (proposed guidance) then states that for these medicines, the label should include the statement '*Do not swallow whole*'. The paper is not clear how the TGA will apply the requirement and whether this will be a mandatory requirement or a recommendation.

The FDA Guidance and TGO 101 best practice have no requirements for these tablets and the FDA Guidance clearly states *This guidance is not intended to apply to other oral dosage forms (e.g. chewable tablets, oral tablets for suspension / solution, orally disintegrating tablets, sublingual tablets, troches, gum*[9].

The TGA consultation paper describes the proposal as being introduced because '*consumers could attempt to swallow them whole'*. We believe that this is probably infrequent and due to misuse of the product i.e. not properly following instructions. There is no evidence of widespread consumer risk. [redacted]

Sponsors try to make the directions for use as clear and concise as possible. The front of pack of these dosage forms clearly states 'chewable tablets' or 'lozenges' as applicable. Instructions for use state 'chew or suck'. Some chewable tablets and lozenges are square in shape – clearly not designed or described as being for swallowing whole. Dissolvable tablets instruct the user to

[9] FDA Guidance: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules Guidance for Industry https://www.fda.gov/media/87344/download

[10] Personal communication

'dissolve in a glass of water'. There has been no identified problem or consumer confusion or risk identified with labels for these types of products as they currently are.

New label statements should not be mandated on products unless there is unequivocal evidence of significant risk to consumers. We note also that these dosage forms and dimensions are also used in prescription and non-prescription medicines that are chewable or dissolve in the mouth - and if there was really a significant problem it would be evident.

Consumer impact

CHP Australia would have liked to see some consumer research, especially relating to the impact of the proposed wording of the warning statement, i.e. 'Warning – Large [dosage form]'. We believe this is an important issue that has not been adequately addressed in the consultation paper. Labelling statements should be evidence based.

A 'warning' label conveys a very high level of risk. We have concerns that as written, it provides no 'call to action' for the consumer but will instead only serve to make the consumer more anxious, and increasing anxiety around pill taking can make it even harder to swallow the tablets/capsules[11]. We are concerned that the warning as proposed offers no solution or advice but may be counterproductive, causing a fear response. Including an actual size image of large dosage forms may be useful for consumers, however this does not need to be accompanied by a fear inducing warning. If any wording is needed, it should be limited to 'Large [dosage form]' – i.e. providing factual information without trying to alarm consumers, or 'Caution – Large [dosage form]' which employs softer language urging that care should be taken and is less likely to alarm people.

CHP Australia supports including a statement advising consumers to 'swallow with water' or 'swallow with liquid' in the directions for use. We request that the TGA allows some flexibility in the language used.

CHP Australia supports the TGA's proposal to provide educational material for consumers on safer swallowing techniques and some sponsors may also wish to provide this type of educational material.

From US research cited by the TGA, as well as data from DAEN in Appendix F, adults aged 65 years and over appear to be at greatest risk and some in this age group have medical conditions that make it even more difficult to swallow. Education would be useful for this cohort. While many older people self-select medicines, many are also advised to take calcium and other supplements by their doctor and are likely to consume them especially if they have been taking them for a prolonged period of time. Provision of education on swallowing techniques may assist people in this age group. In addition, we are aware that many people try to take tablets without liquid. Any educational campaigns should also address this, and also offer advice on talking to their healthcare professional to recommend alternative products if they are finding their tablets / capsules too big to take safely.

We trust that provision of consumer education materials either on websites or on display in pharmacies will assist in minimising choking incidents.

[11] Adams, R., Crisp, D.A. & Thomas, J. The Psychological Impacts of Pill Dysphagia: A Mixed Methods Study. Dysphagia (2024). https://doi.org/10.1007/s00455-024-10703-4 https://link.springer.com/article/10.1007/s00455-024-10703-4

Summary of CHP Australia position

CHP Australia is of the view that the proposals in the consultation are not proportionate to risk, largely because the proposed thresholds for tablet and capsule dimensions are set too low. As written, approximately 45% of listed medicines in member companies' portfolios will be subject to additional labelling requirement. We do not believe that the case reports support this degree of intervention. Given the large volumes of products supplied, we would have expected greater numbers of adverse events if 45% of listed medicines were a risk for choking.

We therefore request:

- Changes to the proposed thresholds for tablets and capsules, including soft gel capsules – so that the highest risk products will require the labelling changes.

  CHP Australia's suggested thresholds are that labelling statements should apply:

  [redacted]

- Clarification around chewable tablets, lozenges, dissolvable tablets to ensure that the guidance is clear regarding the acceptable wording of the directions for use.
- That the word 'Warning' is not required as part of the label statement as this may cause alarm to consumers, and may unintentionally cause anxiety, which can impact the ability to swallow tablets/capsules.
- If the word 'warning' or 'caution' is required, this should be able to be grouped with other warning statements, rather than positioned next to the image.

The TGA has also not considered the business impact of changing a large number of labels just prior to sunsetting of TGO 92. It is likely that many sponsors will need to consider:

- Changing product dimensions, which will lead to significant costs for re-tooling, equipment changes, formulation changes, stability
- Changing label dimensions, with costs of new labels and packaging, as well as write-offs
- Changing container types, with costs of stability, and new labelling

Some products such as small labels, stick packs, roll wraps, pocket packs will be unable to fit an image and label statements.

The TGA has not conducted an impact analysis to understand cost to industry, nor is there evidence of consumer research on the proposed label statements and how these will affect consumers.

We are very concerned about the available time to work through the changes to labelling. It is foreseeable that sponsors will be required to update labelling for a large number of products before the sunsetting of TGO 92, and then be required again to change labels when TGO 92 is revised again after sunsetting. We request that the TGA carefully considers transitional arrangements and the feasibility of a stratified approach, to minimise immediate impact.

CHP Australia cares about the safety of consumers who use listed medicines. We would like to see an evidence based and risk-based approach to the issue of choking hazard with these products, and ensure that thresholds are set at the appropriate dimensions and that labelling statements are consumer focused as well as feasible for industry to implement within a timeframe that does not add a significant cost and resource burden.

Please feel free to contact me if you have any further queries.

[redacted]

12. Do you agree that the proposed dosage unit size thresholds for the labelling requirements are set at the right size? Please explain your answer. If you do not think the proposed size thresholds are set at the right size, do you think they should be smaller or larger than what we have proposed? Please ensure you read Appendix F and provide evidence to support your proposal.

CHP Australia does not agree with the proposed dosage thresholds for the labelling requirements.

As outlined in our written response, the thresholds for tablets and capsules is set very low, and this will result in significant changes to labelling for approximately 45% of sponsors' listed medicines portfolios.

We do not believe that the adverse event figures described in Appendix 5 are indicative of safety concerns for almost half of listed medicines.

CHP Australia believes that the threshold should be changed to:

Oral tablets and oral dosage forms where:

- The length or largest dimension is greater than 22 mm or
- The width, widest dimension or diameter is greater than 11 mm, including round tablets with a greater diameter than 11 mm

These tablets which are likely to present a higher level of risk, should be required to include a statement such as 'Large [dosage form]' and a real size image of the tablet on the label, as well as a 'swallow with liquid' statement or words to that effect.

For capsules, the TGA's proposed threshold is very low to the extent that sponsors will not be able to confidently use size 00 capsules and be within the threshold, due to the slight variation in 00 sized capsules across different suppliers, as well as tolerances.

We therefore believe that for capsules, the threshold should be changed to:

- Greater than size 00, or 24.1 mm

The TGA should also undertake more research on soft gel capsules to ensure a risk-based threshold that is aligned to the greatest degree of risk.

Please see our full written response for details.

13. Is the word 'Warning' needed as part of the proposed label statement to alert consumers that a dosage unit is large and presents a risk? Please explain your answer. Please ensure you read Appendix F and submit evidence to support your proposal.

CHP Australia does not agree that the word 'Warning' is needed as part of the proposed label statement. The words 'Large [dosage form]' are sufficient to raise awareness for people, along with an understanding of the actual size of the dosage form.

The word 'Warning' raises alarm, and anxiety, that can be counterproductive for people who take the medicines. Anxiety and fear can make people more likely to have difficulty taking the medicine. It may also cause people to start cutting tablets, which for some tablets may increase

risk of discomfort with sharp edges. It may cause people to empty capsules, with unknown or unpredictable impact.

Generally, warning statements also advise the consumer what to do, e.g. 'stop taking and see your healthcare professional'. In the case of the proposed warning, the labelling cannot tell people not to take a medicine, or advise them to talk to their doctor, or cut the tablets or empty the capsules. All the label can and should do is to raise awareness so that the consumer can decide whether or not to buy and consume the product or whether to find an alternative. Some consumers might think that the 'Warning' means that the dose is very high, or that they will have an adverse outcome due to the dosage form and this will not be the case for the vast majority of consumers.

For these reasons, we do not agree with the word 'Warning' as part of the label statement. Where a label statement is required, we are of the view that the actual size image and the statement 'Large [dosage form] are sufficient to raise consumer awareness without inducing fear and distress and misunderstanding about the safety of the product. However, the words 'Caution – Large [dosage form] could be considered instead of 'Warning' as the language is softer, advising consumers to be careful. CHP Australia would accept the word 'Caution'.

If the words 'Warning' or 'caution' are introduced then we request that the statement be allowed to be grouped together with other warning and cautionary statements, rather than located next to the image. This flexibility may assist in trying to fit all of the information on limited label space.

Please see our full written response for details.

14. Please tell us if you have any other comments about the proposed required warning statement.

The requirement to include the warning statement next to the image of the dosage form may be challenging for small labels. The TGA should provide some flexibility regarding location where this challenge exists. There should be no requirement to co-locate the image with the warning statement, and we believe that any warning statement should be able to be grouped with other warning and cautionary statements on the label.

15. For large oral dosage forms, should alternatives to the directions 'Swallow with water' be allowed if they have a similar meaning? For example: 'Take with fluid'. Please explain your answer. If you think similar directions should be allowed, do you think there should be a list of acceptable directions that sponsors can choose from to display on the label? Please see Appendix F for further discussion about this.

CHP Australia believes that the statements 'Swallow with water', 'Take with water', 'Take with liquid' are all acceptable and that sponsors should have flexibility regarding which words are included on the label.

Sponsors must provide sufficient information to enable the consumer to use the product safely however we do not believe that the TGA should not impose a prescriptive list of acceptable directions for use. Flexibility should be allowed, e.g. words to the effect of 'Swallow with water' or 'Take with liquid'.

There are many different dosage forms potentially covered by this Order, and chewable tablets, tablets for dissolution/dispersion, lozenges etc. require different directions for use which

sponsors should be able to use to provide clear directions of use for consumers. These should be differentiated from the other large oral dosage forms as they are used differently and the above TGA suggested wording does not apply in these cases.

16. For large dosage forms, would dimensions of the dosage unit in millimetres (mm) in place of an 'actual size' image on the label be enough to inform consumers about size if dosage units can't be seen through the packaging? Please explain your answer. Please refer to Appendix F for further discussion about this.

CHP Australia does not believe that dimensions in millimetres should be provided in place of an actual sized image, if dosage units cannot be seen through the packaging.

We believe that images provide accurate and clear information for consumers. Many consumers who have low numerical literacy will not be able to understand the dimensions in mm or visualise the size of the dosage form, but an actual size image is very clear for people regardless of their language and numerical skills.

The issue with images however is the space required on the label. For this reason the TGA should only require images and warning statements on the highest risk products and also be aware that for some products (as mentioned in our written response) it will be impossible to fit the image and warnings. Will section 14 exemptions be available in these cases? There should be some separate provisions for smaller labels.

17. Do you think the proposed guidance in Appendix G to support the proposed new requirements for large dosage forms is clear and easy to understand? Please explain your answer.

As discussed in our written response provided to the TGA, we do not agree on the thresholds proposed, or the requirement to include the word 'Warning' on the label statement.

We agree with the provision to allow shorter names for dosage forms.

In the section on image of large dosage forms, the TGA's requirement for how to display the actual sized image is problematic for non-symmetrical dosage forms. In effect, two images will be required, i.e. a font and side view, resulting in a very large part of the label having to be devoted to this image and accompanying warning statement. The purpose of the image is to give consumers a visual cue that the dosage form is large, and this can be achieved by showing an image of the largest dimension. Detailed diagrams are not needed to get this message across. It is foreseeable that two images could easily take up two lots of up to 9 cm^2 (i.e. 18 cm^2) of valuable label space and we query whether this is physical achievable. There are limits on usable label space considering the need for all of the mandatory information, in minimum font size, plus full-sized barcodes required for retail scanning. Duplicate images will be very difficult to achieve.

The section on 'Directions for use that preclude swallowing whole for certain dosage forms' is very unclear in relation to TGO 92, with the statement '*It is recommended that listed medicines in the above dosage forms should include instructions in the directions for use: 'Do not swallow whole'*. The TGO 92 requirements must be very clear on sponsor obligations. Most dosage forms in this category have clear directions for use so that consumers can use the product safely. The TGO 92 and the guidance should be very clear that there will be no requirement to include 'Do not swallow whole' for these dosage forms.

CHP Australia believes that the guidance will be intended for industry rather than consumers. When decisions on wording and threshold have been made, the TGA can release the draft guidance for targeted consultation

18. Please tell us if you have any other comments about the proposed new labelling requirements for large solid oral dosage forms intended to be swallowed whole.

No other comments