Animal Medicines Australia

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Safe Work Australia
GPO Box 641
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Lodgement: SWA GHS Consultation Portal

Dear Sir/Madam

Proposal to adopt GHS 7th edition under the model WHS laws

Animal Medicines Australia (AMA) is pleased to provide comments and recommendations on elements of the proposal that particularly impact the animal medicines industry, supply chains and users.

The areas for focus of this submission are transition and labels.

Transition or co-existence?

Australia implemented the 3rd revised edition of the GHS (GHS3) under the Model Work Health and Safety laws on 1 January 2012, with a 5 year transition.

Australia participates in the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals and the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals.

Australia currently proposes adoption of the 7th revised edition of the GHS (GHS7), also noting that the 8th revised edition of the GHS will be available in 2019 and the 9th edition in 2021.

The GHS document will no doubt continue to evolve long into the future with revised editions.

AMA notes that GHS7 text (p.6) includes:

> "Harmonisation will also have benefits in terms of facilitating international trade, by promoting greater consistency in the national requirements for chemical hazard classification and communication that companies engaged in international trade must meet." *(underlining added)*

GHS3 (p.3) sets out the purpose of the GHS in more detail:

About Animal Medicines Australia

AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

AMA works closely with its members, a variety of organisations, and governments to promote an evidence-based approach to public policy. Additionally, AMA advocates for the responsible and judicious use of all veterinary medicines to improve and protect animal health and welfare.

"Thus the reasons for setting the objective of harmonisation were many. It is anticipated that, when implemented, the GHS will:

(a) enhance the protection of human health by providing an internationally comprehensible system for hazard communication;

(b) provide a recognised framework for those countries without an existing system;

(c) reduce the need for testing and evaluation; and

(d) facilitate international trade in chemicals whose hazard have been properly assessed and identified on an international basis." *(underling added)*

AMA contends that Australia will only meet its trade commitments (import and export), and achieve benefits, if it provides for co-existence of available editions of the GHS. Australia adopted ADG3 in 2012 – trading partners who have already adopted ADG4, ADG5, ADG6 or ADG7 and provide chemicals or products to Australia may be at risk of being in technical non-compliance.

Transition times equally provide challenges for the local animal medicines industry, its supply chains, and users. Safe Work Australia will recognise and appreciate the vagaries and unpredictability of weather and market conditions that can affect Australian agricultural and livestock production.

Products may be used seasonally or cyclically. They may be veterinary medicine products or chemicals with extended shelf life characteristics that may be carried over to provide available treatments for pests, diseases, conditions, treatments during an outbreak. Products may also be produced at specific times or in particular batch sizes to achieve necessary economies of scale. Similarly, for labels.

Providing for co-existence of published GHS editions would have trade and industry cost saving benefits where withdrawal, relabelling or label destruction at the end of a prescribed transition period can be avoided.

AMA would be pleased to work with Safe Work Australia to further develop this proposal.

Reponses to consultation questions

1. **Noting international movement to adopt GHS 7, when do you think Australia should adopt GHS 7?**

   It had been intended that Australia would move in concert with its major trading partners, noting that an objective of harmonisation is trade facilitation.

2. **As the EU transition to GHS 7 finishes in October 2020, should Australia's transition period to GHS 7 begin before October 2020, to ensure that products coming from the EU are accepted in Australia?**

   Given the objectives of harmonisation, Australia should be in a position to have trade to GHS7 compliant shipments at the time of adoption by trading partners. There will be early adopters and those who follow.

3. **Noting that the GHS is being continually updated (GHS 8 will be published this year, and GHS 9 in 2021), how long should the transition period to GHS 7 be? For example, 12 months, 2 years or longer?**

   See further comments under AMA's response to question 4.

4. **What transition arrangements should be applied to minimise the impacts from moving to GHS 7? Some examples are provided below:**

There is need to re-think Australia's approach to adoption of future GHS editions. A flawed approach will be millstone to government, industry and the user community – with lots of activity, increased costs, and reduced focus on the outcomes we collectively need to achieve.

Under a *GHS edition co-existence model,* existing GHS editions would be recognised for the purpose Work Health and Safety laws. From time to time older editions could be retired – for instance, it may be possible to retire the 1st and 2nd revised editions at the outset.

AMA would welcome further dialogue on this proposal.

Notwithstanding, for the purposes of this consultation, AMA makes the following comments and recommendations.

AMA notes and generally supports the elements described in Question 4c) of the Consultation Paper

> "A transition which applies only to new products or where there is a significant change from GHS 3 to GHS 7 with labels and SDS for existing products being acceptable (regardless of which GHS is used) until the end of the 5 year review cycle for the SDS. For example, a significant change would include updating a product's classification in the hazard classes not included in GHS 3, for example non-flammable aerosols or pyrophoric gases, or updates to ensure it contains correct, current information as required in the regulations. It would not include changes to precautionary statements where the meaning has not changed, consistent with the flexibility provisions in GHS 7. A significant change would not include changes such as updated precautionary statements where the meaning has not changed."

There is additional need to address:

- the period of time for manufacturers to update their labels

  (AMA recommends an additional 2 years); and

- product warehoused, in supply chains and with users

  (AMA recommends that an end period not be specified – this recognises the manner in which animal medicines are dealt with and the extended self-life of some products)

5. **What guidance and/or support can Safe Work Australia provide to ensure you are ready for these changes? For example, online tools, guidance or fact sheets.**

   For AMA's industry sector key information will be a gap analysis of GHS3 and GHS7 with clear advice on transition arrangements. Web based materials would be welcomed.

6. **Beyond a reasonable transition timeframe, are there any other barriers to adopting GHS 7?**

   Rethink Australia's approach adoption of GHS editions with a co-existence framework.

7. **Australia's current implementation for Category 2 eye irritants and the exclusion of sub-category 2B is not consistent with the GHS text, or the implementation of the GHS applied by other countries. For consistency with international implementations and the GHS text, it is proposed to clarify this and adopt Category 2, with sub-categorisation into category 2A and 2B being optional. Optional sub-categorisation is consistent with the approach adopted for all other hazard categories, where sub-categorisation is possible.**

   Noted.

8. **Are there benefits to including ingredient proportions on labels? Given this information is already included in safety data sheets, would there be any negative consequence if this information was not mandatory on a label?**

   AMA notes that this information is included on the safety data sheet. We do not see additional benefits from duplicating this information on the label.

   The GHS is intended to deliver a harmonised scheme – variations with trading partners adds additional costs and complexities. Where Australia seeks different approaches, these should be progressed through the appropriate participation in the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals and the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals.

9. **Does the requirement to disclose ingredient proportions on the label lead to additional costs for your business?**

   AMA has not had the time to adequately survey its members on costs but the anecdotal information is that deviations with Australia's trading partners in the implementation of the GHS lead to additional costs. Similar issues are experienced locally.

   Additional costs could include separate label inventories, artwork, increased small production runs, integration issues within manufacturing sites and other factors, difficulties with small labels that have labelling requirements under multiple regulatory regimes. These represent increased costa and activity without creating health and safety outcomes.

   AMA would strongly support changes to the Model Work Health and Safety Regulations to address this issue.

10. **Would you support removing this requirement?**

    Yes

GHS and Animal Medicines

AMA notes that changes to sectors, including veterinary chemicals, are specifically excluded from the scope of this consultation, however AMA also notes that the only reference to veterinary in GHS7 is the following:

> *"At other stages of the life cycle for these same chemicals, the GHS may not be applied at all. For example, at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS (it should be noted that the risks to subjects associsated with the medical use of human or veterinary pharamceuticals are generally addressed in package inserts and are not part of the harmonisation process)."*[1]

[1] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), seventh revised edition, page 6

AMA is committed to schemes that provide for appropriate information to be available through the supply chains and to users. As has been contended in the past, expert risk assessment undertaken by a regulator during registration and approvals is appropriate for these highly regulated defined-use products. We just flag this at this stage as something we would like to discuss with Safe Work Australia in the future.

I trust this information is of assistance. If I can provide additional information please do not hesitate to contact me.

Yours Sincerely

Unsigned for electronic lodgement

Ben Stapley
Executive Director