Consumers Health Forum OF Australia

SUBMISSION

CONSULTATION: PROPOSED CRITERIA FOR APPENDIX M OF THE POISONS STANDARD TO SUPPORT RESCHEDULING OF SUBSTANCES FROM SCHEDULE 4 (PRESCRIPTION ONLY) TO SCHEDULE 3 (PHARMACIST ONLY)

Consumers Health Forum of Australia 2019 *Consultation: Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only)*

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Introduction

Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF appreciates the opportunity to provide input into your consultation on the proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only).

The CHF is generally supportive of improving the availability of medicines to consumers providing that the risks are appropriately mitigated and efforts taken to inform consumers of both the risks and benefits. Doing so makes additional safe and effective healthcare options available to consumers; empowering them to make decisions that improve their health status.

At the heart of CHF's policy agenda is patient-centred care. Our responses to the TGA's consultation questions have been formed with a patient-centred approach in mind.

Response to proposed Appendix M Criteria

Broadly speaking, the CHF support the suggested requirements and criteria for Appendix M medicines but believe that the suggestions must be reframed as clear, mandatory requirements rather than potential options.

For example, we observe that applicants for rescheduling to Appendix M will be "expected" to canvass operations and implications with "relevant professional bodies and other stakeholders" (Page 5). We believe this should be a requirement for all applicants not just an expectation. Additionally we believe that this canvassing should specifically include consumers as a stakeholder group who must be consulted. We would recommend the TGA produces guidance detailing which stakeholders need to be consulted.

In regard to Group 1 criteria, we would query how the TGA proposes to monitor regulation via the States and Territories to ensure that appropriate measures are being implemented, followed and enforced across the board. Typically this sort of multi-jurisdiction monitoring has proven difficult in the past so additional detail should be provided by the TGA on their intended processes.

We would advocate for the listed criteria in Group 1 to be refined as minimum requirements rather than optional suggestions. In relation to the provision of patient education by the pharmacist (Criteria 1), the statement "This may be required to be provided as oral and/or written advice" should be replaced with "This will be required to be provided as both oral and written advice". We believe it important that healthcare professionals both speak with consumers to ensure they understand the medicines they are taking (oral advice) and provide

resources they can refer to after should further questions arise (written advice). Simply doing only one of these things, for example handing over a CMI document without speaking to a patient or vice versa, is in our view insufficient for ensuring consumers are appropriately informed about the potential risks of medicine. To do both is better quality use of medicines practice and also takes into account variation in patient health literacy.

Similarly, we support the requirement for specific training to be completed in order for a Pharmacist to dispense an Appendix M medicine (Criteria 2). We observe there is some potential inconsistency in the consultation paper about the status of this training. In some areas it is referred to as "required" (e.g. Page 7) while in other it is "optional" (e.g. Page 6). We would argue that such training must be a mandated requirement in order to make sure the risks of Appendix M medicines are appropriately mitigated.

Additionally we argue that records indicating which pharmacists have completed this training must be kept. Rather than the current framing of it being "anticipated" that records "would" be retained, we would urge that records "must" be kept. Ideally such records would be kept and monitored by the TGA as the regulator rather than industry sponsors or other health bodies. Delegating this to other parties could be viewed as the TGA abrogating their responsibilities as a regulator. Given recent events in Australia showing failures in sectors that are self-regulating, we believe consumers would not support the TGA entirely absolving these responsibilities to industry groups. This is not to say that those same issues necessarily exist within this industry, but that the general attitude amongst consumers is that government regulators should take direct action to protect consumers.

We support the provision for additional conditions being imposed as required (Criteria 3) but note that an articulation of some examples of what such conditions could be and examples of cases where additional provisions are required would be beneficial.

In regard to the Group 2 criteria, we support the proposal for item-specific professional practise standards being developed (Criteria 4). However we believe that community expectation would be for active government protection, and that the TGA should play an active role in the development and monitoring of such standards to ensure they appropriately mitigate the risks of Appendix M medicines and are being complied with by health professionals.

We support the record keeping and information sharing (Criteria 5) proposed, however we believe that the listed criteria should be the minimum records that must be kept as part of the data. We believe there is a need for further consultation with professional and professional standard setting bodies in relation to this criteria particularly relating to our views that records should, at a minimum, include patient questionnaires, records of interview, all material/information used to support the pharmacists decision in making supply of an Appendix M medicine and evidence of compliance with Appendix M criteria. We would also like to see an articulation for what the minimum "specific period" such records must be kept for. At a minimum it should be slightly longer than the medicine having a biological interaction and effect on the health of the consumers receiving the medication.

We also support the integration of MyHealthRecord into this system to improve the efficiency of data management and sharing provided consumer consent, privacy and data security considerations are taken into account. This will improve the information available to the health professional when considering dispensing Appendix M or other higher risk medicines and reduce the burden on consumers of having to manually manage their data. Broadly we would support, with consumer consent and privacy and security considerations accounted for, the inclusion into MyHealthRecord of all high risk medications a consumer may be prescribed by a GP or provided by a Pharmacist.

We support the proposed criteria which provides scope to specify additional limitations on the duration, quantity and frequency of supply (Criteria 6). However we note a potential inconsistency between Criteria 5 and Criteria 6. While Criteria 5 states that real-time data collection will typically not be required, Criteria 6 articulates a range of restrictions on the provision of Appendix M medicines that would require real-time data collection to be effectively enforced. On balance we believe that real-time data collection and sharing will be required to effectively monitor the provision of Appendix M medicines and appropriately mitigate the risks of these medicines. As with previous points, we would argue that as the regulator the TGA should maintain an active role in this data collection and monitoring.

Finally, we support the need for formal diagnosis and periodic review of the condition by a medical practitioner (Criteria 7), noting that we support the explicit requirement for both to occur, not the optional requirement of one or the other as the current phrasing implies in the consultation paper.

Response to accompanying guidance

We believe that the “Samples of proposed patient information and advisory material” should be consumer tested for effectiveness as part of or before the application process to rescheduling to Appendix M. This is to ensure that the material appropriately and effectively convey the necessary information to consumers in a way that is useful and understandable.

Similarly evidence of consultation and collaboration with professional colleges and associations should be made an explicit requirement rather than something that “should also be included”. This is to ensure that the health professionals who will be dispensing the Appendix M medicines have ensured the materials provided to them are appropriate and effective.

Response to monitoring, evaluation, compliance and enforcement

We support the suggestion to include Appendix M training as part of Pharmacy CPD for general compliance. However we do not support it simply being a possibility rather than a confirmed method to ensure compliance. We would argue that having possible methods of compliance is insufficient at this stage of the discussion and that specific ones need to be articulated and confirmed.

We note with concern that there is no mechanism articulated by which the TGA, as the regulator, will monitor the provision of Appendix M medicines to ensure that compliance is being achieved. While we support mechanisms for the Pharmacy Board and state and territory regulators to do this, we believe that the TGA should also play a role to directly ensure compliance is being achieved.

Similarly we would argue that a pathway should be specified for additional parties, including consumers and other health professionals, to be able report perceived non-compliance with Appendix M requirements.

Lastly, we would like to see an articulation of the proposed penalties for non-compliance with the Appendix M requirements. Without ensuring there are adequate penalties for non-compliance there will be little purpose in any efforts to regulate the supply of Appendix M medicines to consumers.

Additional Considerations

In addition to the above, there are some additional items that we believe need to be addressed in the Appendix M provisions.

First is how Appendix M will interact with regulations on the advertising of therapeutic goods. Given Appendix M medicines will arguably have a higher amount of risk compared to other S3 medicines, we would argue that advertising regulations for Appendix M medicines should be more akin to those for S4 medicines than S3 medicines

Secondly, we believe guidance should be issued as to how and where Appendix M medicines are stored and distributed in a pharmacy shop. Specifically we believe that they will most likely need to be kept “behind the counter” out of direct reach or eyesight of consumers as with other higher risk medicines. This is to ensure that consumers are appropriately informed about the risks associated with the medicine before they are able to physically procure it.

Finally, we would like clarification on the processes that will be used to manage the provision of Appendix M medicine in in pharmacies where some of the pharmacists have completed the additional training for compliance purposes but others have not. How does the TGA intend to ensure that in these pharmacies only the health professionals who have completed the training will be dispensing the Appendix M medicine?