MS Health submission to the consultation on the Scheduling Policy Framework and Advertising of pharmacist-only medicines (Schedule 3 substances)

April 2017

Introduction

In March 2017, the Therapeutic Goods Administration released a consultation paper focussed upon the scheduling and advertising of pharmacist-only (Schedule 3) medicines. MS Health welcomes the opportunity to provide comment on the topics raised in the consultation paper, *Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances).*

About Us

Marie Stopes International

Marie Stopes International is a global organisation providing personalised contraception and safe abortion services to women and girls. Our local teams of professionals are passionate about the work they do in communities across 37 countries.

The high quality services we provide give a woman the power to choose if and when she has children so that she's free to pursue her plans and dreams for herself and her family.

MS Health

MS Health is a not-for-profit pharmaceutical company that supplies sexual and reproductive health medicines. MS Health supplies two Schedule 4 medical abortion products and a Schedule 3 contraception product in Australia. We are part of the Marie Stopes International partnership, delivering a global mission of *children by choice, not chance*. Surplus generated by MS Health is reinvested into the work that Marie Stopes International conducts in Australia and overseas.

Table 1: Summary of Topics Requesting Input - Business Improvements

Number	Topic of Input	Suggestion	MS Health Comment
Business Improvement Measures 1	**Structure and content of the committee's advice**	a. A clearer explanation of the cascading principle and how it is applied should be included in the SPF.	a. No comment as of April 2017.
		b. The structure and the content of the Committee's advice, and the delegate's reasons should be revised to ensure they are meeting the needs of stakeholders. Particular consideration should be given to explaining how the advice and reasons relate to the scheduling factors, and how the information that applicants have submitted has been reflected in the decision-making process.	b. No comment as of April 2017.
Business Improvement Measures 2	**Public summary of the scheduling submission and other communication processes**	a. A summary for public dissemination should be provided by scheduling applicants, and this would be published as part of the public consultation process. This could be included in the application template. If an appropriate summary is not provided by the applicant, the default option could be that the entire (de-identified) application would be published for public consultation.	a. MS Health is in agreement that a publicly available summary would be beneficial as it is likely to facilitate informed public consultation and may increase public consultation.
		b. A mechanism should be developed to alert stakeholders of items	b. MS Health is in agreement that an alert mechanism would be beneficial.
		c. Develop communication milestones and application tracking to improve communication between the Secretariat and applicants.	c. MS Health is in agreement that communication milestones and tracking systems should be introduced.

Table 1 continued: Summary of Topics Requesting Input - Business Improvements

Number	Topic of Input	Suggestion	MS Health Comment
Business Improvement Measures 3	**Greater emphasis on benefits as well as risks**	When updating the SPF guidance for submissions, consider how greater emphasis can be placed on potential benefits as well as risks of proposed rescheduling of substances.	MS Health is in agreement that balanced and accurate information on benefits and risks should be included.
Business Improvement Measure 4	**Guidance on legal nature of scheduling and scheduling decisions**	Include an explanation of the legislative nature of scheduling decisions and why they are not appealable in the SPF.	MS Health is in agreement that it would be beneficial to include an explanation of the legislative nature of scheduling decisions.
Business Improvement Measures 5	**Decision transparency and information sharing.**	a. Include an explanation in the SPF of jurisdictional requirements for decisions to enhance stakeholder understanding. b. Identify an early alert mechanism to ensure the initial applicant, the jurisdictions, and stakeholder groups have the maximum time available for activities associated with a decision. c. Develop a mechanism to allow early information sharing between the APVMA and the Secretariat to better screen and manage agricultural and veterinary chemicals applications.	a. MS Health is in agreement that it would be beneficial to include an explanation of jurisdictional requirements for decisions. b. MS Health is in agreement that an alert mechanism to notify the applicant, jurisdictions and stakeholder groups would be beneficial. c. No comment as of April 2017.

Table 1 continued: Summary of Topics Requesting Input - Business Improvements

Number	Topic of Input	Suggestion	MS Health Comment
Business Improvement Measures 6	**Improving the clarity of the SPF**	1. Amend section 3.2 to provide the delegate with greater discretion when deciding to refer (or to not refer) particular substances to the relevant advisory committee(s) for advice, particularly for a. rescheduling considerations of "second in class" medicinal substances (where the committee has already considered and the delegate already determined that a substance in the same pharmacological / medicinal class be rescheduled, based on similar considerations); b. a number of Schedule 5 and Schedule 6 chemicals scheduling applications; c. straightforward considerations of scheduling of a particular substance used in an agrochemical or veterinary medicine that has been subject to a recent evaluation by the Australian Pesticides and Veterinary Medicines Authority (APVMA); d. and consideration of Appendix E, F and K entries of the SUSMP. 2. Clarification that Appendix E and F requirements do not apply to workplace chemicals where they are subject to the requirements of the Globally Harmonised System for the classification and labelling of chemicals (GHS, discussed further below).5 3. Decisions to include a substance in Appendix K can be a delegate-only decision and not require referral to the Advisory Committee for Medicines Scheduling. 4. Amendment to the description of the Cascading Principle and the details for inclusion in Appendix B.	No comments as of April 2017.

Table 2: Summary of Topics Requesting Input - Policy Recommendations

Note: Policy Recommendations 1 and 2 are not for comment.

Number	Topic of Input	Suggestion	MS Health Comment
Policy Recommendation 3	**Public consultation on interim decisions**	Amend the Therapeutic Goods Regulations to allow general public consultation and receipt of submissions from any interested parties on the interim decision and remove the prescriptive requirements on time available for submissions.	MS Health is in agreement that any interested parties should be able to submit a public comment following the interim decision.
Policy Recommendation 4	**Consider a chemicals scheduling delegate within APVMA**	In consultation with the Agriculture and Water Resources portfolio, explore options to establish a delegate in the APVMA to streamline scheduling applications for relevant (agricultural and veterinary) chemicals, with due consideration to the management of the process and ensuring that the specific roles and responsibilities of each delegate are clearly defined.	No comment as of April 2017.
Policy Recommendation 5	**New controls for certain medicines that have been down-scheduled to pharmacist only classification (S 3)**	Create a new Appendix in the Poisons Standard (SUSMP) to enable additional controls or requirements for certain Schedule 3 substances to be specified, in particular for substances that have been down-scheduled from Schedule 4 (prescription only). This new appendix will function in a similar manner to Appendix D, which specifies additional controls for particular Schedule 4 or 8 substances.	MS Health is in agreement that the creation of a new Appendix in the Poisons Standard (SUSMP) to enable additional controls or requirements for certain Schedule 3 substances could be beneficial. However, MS Health notes that the evaluation process for inclusion of medicines in this new Appendix would need to carefully consider the risks and benefits of the product in question, and to consider how additional controls may limit access to Schedule 3 substances included in this new Appendix.

Table 3: Summary of Topics Requesting Input - Ongoing Improvements

Number	Topic of Input	Suggestion	MS Health Comment
Ongoing Improvements 1	**Applicants presenting to the advisory committees**	A pilot exercise to assess the value of applicants presenting directly to the advisory committees should be undertaken.	MS Health does not believe that this recommendation is necessary.
Ongoing Improvements 2	**Improved guidance on risk and benefit**	Prepare worked examples of the risk: benefit tree for recent scheduling considerations and assess the utility of this approach for scheduling applications.	MS Health is in agreement that provision of risk: benefit tree examples would be beneficial for scheduling applicants.
Ongoing Improvements 3	**Proactive identification of substances for rescheduling**	Implement a system for proactively identifying substances for rescheduling, similar to schemes in place in some comparable international jurisdictions.	MS Health is in agreement that implementing a system to proactively identify substances for rescheduling would be beneficial for increasing access to the identified medicines in Australia.
Ongoing improvements 4	**Down-scheduling - alignment with OTC product submission and market incentives**	a. Develop a mechanism to better align applications to reschedule an active substance from Schedule 4 to Schedule 3 with the marketing authorisation applications for newly rescheduled Schedule 3 medicines. b. Consider options for market incentives for down-scheduling, for example similar to the UK system, and whether development of a similar mechanism for the Australian context would be in the interests of public health.	a. MS Health is in agreement that a better mechanism to align applications to down schedule from Schedule 4 to Schedule 3 would be beneficial to facilitate the application process and potentially decrease waiting periods. b. MS Health is in agreement that considering market incentives for down-scheduling and potentially developing a similar mechanism for Australia could be beneficial as it may increase access to medicines.

Table 4: Summary of Topics Requesting Input - Advertising

Number	Topic of Input	Suggestion	MS Health Comment
Consideration 1	**Advertising Criteria**	Criteria for allowing advertising of medicines containing Schedule 3 substances under the TGA Advertising Framework.	MS Health is in agreement that criteria should be set and proposes that the criteria for allowing advertising of Schedule 3 substances should include but not necessarily be limited to: - Risks and/or safety considerations of the medicine; - Benefits of the medicine, including potential public health benefit; - Availability of pharmacist education, resources and guidance on the medicine; - Likelihood that advertising would lead to inappropriate use of the medicine, including off-label / unapproved indications; - Availability of the Consumer Medicine Information (CMI); - Level of patient information required for correct use; - Desire of consumers/patients to manage their own medication; and - Experience(s) with advertising the medicine in other similar markets.
Consideration 2	**Appendix H**	Possible retention of some form of "list" similar to Appendix H. We seek feedback on the alternatives of whether this would be a positive list (substances considered and permitted to be advertised, status quo) or a negative list (list of substances not permitted to be advertised to consumers, with anything off the list authorised to be advertised by default) from this public consultation.	MS Health is in agreement that it would be beneficial to retain some form of "list" similar to Appendix H. MS Health expresses a preference for a positive list that would include a list of substances that are permitted to be advertised to consumers, with anything off the list not authorised to be advertised.

Table 4 continued: Summary of Topics Requesting Input - Advertising

Number	Topic of Input	Suggestion	MS Health Comment
Consideration 3	**Advertising Restrictions**	Any restrictions or requirements that should be applied to advertisements or other form of information provided for medicines containing these substances, e.g. mandatory and repeated mention that the product should be selected with the advice of a pharmacist, requirement to describe possible adverse events, requirement to emphasise that the particular OTC products containing the substance in question are only for short-term use.	MS Health is in agreement that restrictions or requirements should be applied to advertisements or other information for Schedule 3 substances that are able to be advertised to the general public. MS Health proposes that the following restrictions or requirements be applied: - Include 'speak to your pharmacist' or 'seek advice from your pharmacist' or similar; - Include balanced, accurate, current information which is consistent with the Product Information (PI) and/or Consumer Medicine Information (CMI) and that does not mislead either indirectly or directly; - Take particular care with comparative statements, ensuring that they are factual, fair, substantiated and referenced; - Do not use disparaging comparative statements; - Do not use hanging comparatives; - Does not mention off-label / unapproved indication(s); and - Include a link or immediate access to the Consumer Medicine Information (CMI).

Table 4 continued: Summary of Topics Requesting Input - Advertising

Number	Topic of Input	Suggestion	MS Health Comment
Consideration 4	**Pre-approval Process**	An exploration of what regulatory enforcement/compliance powers would be required in the event that restrictions for the advertising of Schedule 3 substances were changed, noting that the Government has agreed that advertising pre-approval processes should be removed once appropriate compliance and enforcement powers are in place (MMDR Recommendation 55).	MS Health is in agreement that an exploration of what regulatory enforcement / compliance powers would be required in the event that the Schedule 3 advertising restrictions are changed. MS Health proposes that the prescription arrangements (Medicines Australia Code of Conduct and Appeals Committees and/or TGA or ACCC hearings) be considered, with the potential to establish a committee and process akin to the Medicines Australia set-up with a Schedule 3 pharmaceutical industry body or other relevant entity.
Consideration 5	**Additional Requirements**	Relationship with possible additional requirements for pharmacist education and provision of information by patients (e.g. to declare that they do not have certain pre-existing conditions for which the OTC medicine would be contra-indicated) at the point of sale, for particular medicines that have been down scheduled from Schedule 4 to Schedule 3.	MS Health strongly believes that pharmacists should have ready access to education, resources and guidelines for all Schedule 3 medicines. MS Health recommends that all public advertisements for Schedule 3 substances include 'speak to your pharmacist' or 'seek advice from your pharmacist' or similar wording. MS Health is open to other considerations to ensure appropriate use of medicines and that patients provide relevant information regarding Schedule 3 substances.
Consideration 6	**Approval**	Consideration of a potential mechanism to allow sponsors to seek approval to advertise to the public products containing Schedule 3 substances as part of a market authorisation application for the medicine(s) in question.	No comment as of April 2017.