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OTC Medicines Regulatory Process Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

10 October 2014

OTC.Medicines@tga.gov.au

To whom it may concern,

Consultation: OTC Medicine Monograph: Mebendazole

ASMI is pleased for the opportunity to comment on the new OTC Medicine Monograph (OMM) for Mebendazole.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI provides the detail of our comment in a tabulated format.

We trust our comments are helpful and we look forward to the outcomes of the consultation. Please contact me should you have any need for clarification of our comments.

Yours sincerely

A handwritten signature in black ink, reading 'Catherine Gwynne', with a fluid, cursive style.

Catherine Gwynne
Regulatory and Technical Manager – OTC Medicines

Consultation Response - OTC medicine monograph: Mebendazole

Due Date: 10 October 2014

Chapter/ title/subtitle	Page no (original draft)	Paragraph/line	Comment	Proposal
Directions for use	6 & 7 of 9	Labelling generally	<p>ASMI assume and seek confirmation that applicants can use 'words to the effect'.</p> <p>We note that the pack sizes for these monograph products are typically small.</p> <p>The Directions for use, contraindications, and wording for worms other than threadworm, the additional required instructions and then optional measures to reduce/prevent infection, amounts to a sizable body of text.</p> <p>The <i>Requirements for OTC new medicines N2 applications (using OTC medicine monographs)</i> states that "Medicine labelling must comply with the following:</p> <p>Labelling requirements <u>as specified</u> in the applicable OTC Medicine Monograph (eg. directions, warnings)."</p> <p>This might be interpreted that wording must be as specified. Where ASMI would assume that similar to RASML 'words to the effect' could be used.</p>	Confirm ability to use 'Words to the effect'

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Directions for use	6 of 9	Pregnancy Warning	Suggest that 'or may become pregnant' in the pregnancy warning statement may be unnecessarily restrictive for a single dose product. For example it might include all premenopausal women.	If you are pregnant or may become trying to become pregnant, check with your doctor or pharmacist before taking this medicine.
Directions for use	6 of 9	Roundworm, Hookworm, Whipworm statement	<p>Members expressed concern at the practicality of fitting all the wording with respect to Roundworm, hookworm and whipworm on the label as size is limited.</p> <p>Members also noted that some of this wording is contrary to the current entry in ARGOM App 5.</p> <p>If the indications on the product labels include use for other, less commonly occurring types of worms (in addition to use for threadworms), <u>the labels should not include directions for use</u> of mebendazole for the treatment of worms other than threadworms. However, the directions for use on the labels could include a statement such as:</p> <ul style="list-style-type: none"> <i>Roundworm, hookworm and whipworm rarely occur in the general Australian population. If suspected, medical advice should be sought.</i> <p>Sponsors may include dosage instructions for treatment of worms other than threadworms <u>in a product information document</u>. The recommended dosage of mebendazole for treatment of worms other than threadworms in adults and children aged 2 years and over is 100 mg twice a day for three days. Where this information is included in the Product Information (PI) and a Consumer Medicine Information (CMI) document</p>	<p>Please confirm ability to use 'Words to the effect'.</p> <p>Please confirm if TGA's position on provision on the label of recommended dosage for treatment of worms other than threadworm has changed.</p>

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			<p>and/or package insert is supplied, the CMI and/or package insert should include a statement such as:</p> <ul style="list-style-type: none"> <i>Medical advice should be sought before use of the product for worms other than threadworms.</i> 	
Additional Instructions	6 of 9	2 nd bullet point	<p>The statement -</p> <p><i>Before treating for threadworm, evidence of infestation should be present.</i></p> <p>- as written may cause some confusion as further down it is stated "Treat all other household members at the same time, even if others have no symptoms, because the worms spread very easily".</p> <p>It is also known that some people do not show symptoms. It is more important to provide details on the sign and symptoms and if threadworm infestation is suspected to treat. Hence, within the context of the other bullet points this statement may not be relevant.</p>	<p>Suggest amend this statement to</p> <p><i>Before treating, signs of threadworm, evidence of infestation should be present.</i></p> <p>This proposal leads into the next statements – signs and symptoms.</p> <p>It also addresses the next comment on the term ‘infestation’.</p>

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Additonal instructions	6 of 9		A member of the family having worms can be confronting to consumers. The term 'infestation' while technically correct, adds unnecessarily to the concern.	Please confirm ability to use 'Words to the effect'
	7 of 9	1 st bullet point	<p>Again for purposes of achieving maximum information for the consumer – some wording might be streamlined.</p> <p>e.g. "Wash hands after using the toilet and before eating."</p> <p>Might be reduced to</p> <p>"Maintain good personal and hand hygiene."</p>	Please confirm ability to use 'Words to the affect'