Complementary Medicines Australia submission:

Permitted Indications Determination

Submission (2) of a multi-part submission:

Maternal health and infancy.

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1. Infant 0-6 month evidence qualifier

The draft list of permitted indications list excludes the group:

- **infants under the age of 6 months.**

CMA understands the general concern around this group of goods, and that there may have been problems internationally demonstrating some level of risk. We believe the concern falls into the category around directions for use and applicability to the individual circumstances in a vulnerable group, rather than suitability of the medicine itself. By not including the qualifier, the TGA is proposing to remove this group from listed medicines. However, there is the necessity to consider all the listed medicines that would currently fall into this category, whether some useful goods that do not present an appreciable risk are inadvertently captured, and if there is another appropriate mechanism to mitigate risk in this category.

There are topical preparations, such as nappy rash creams and other healing skin creams that are listed medicines, that are low risk and suitable for continuation of use in this age range.

In terms of oral medicines, there are preparations that are suitable for supply as listed medicines generally for a range of ages, including infants 0-6 months. For example, a children's vitamin D liquid might be indicated for children up to the age of 12, and paediatricians, GPs and other HCPs often recommend the use of vitamin D in younger infants. There may be situations when a medical professional sees a malnourished baby, or the mothers diet is poor and the GP or HCP recommends nutritional supplementation. By excluding infants under 6 months it creates potential for a conflicting message where it contradicts HCP advice. If such products are excluded from listed medicines, they may not fmeet the requirements of the listed assessed pathway to hold an intermediate indication and a certain level of evidence. Necessary medicines will be made unavailable for this population, which introduces other health risks. However, CMA would agree that in this age range, administration should only be under the guidance of a health care professional. Therefore, we propose that the evidence qualifier for infants under the age of 6 months **is included** in the permitted indication list, but that it has an attached restriction:

- **Oral medicines must contain within the directions for use a statement to the effect that the medicine must only be used under the direction of a health care professional in infants 0-6 months.**

2. Newly Proposed Warning Statements

The draft list of permitted indications includes new label advisory statements included in Table 1 and Table 2 of this section. Each statement is linked to certain indications.

Table 1. Pregnancy: Specific requirement applying to use of the indication (1)

Label statement: Not to be taken in first trimester of pregnancy unless under medical advice
1. Maintain/support healthy pregnancy
2. Helps prepare the body for labour
3. Helps enhance/promote maternal health
4. Maintain/support maternal health
5. Decrease/reduce/relieve morning sickness
6. Helps enhance/promote preconception health
7. Maintain/support preconception health
8. Maintain/support placenta health/growth
9. Helps enhance/promote maternal postnatal health
10. Helps prepare the body for pregnancy

The warning statement above will capture all pregnancy-related health products. It implies there is something inherently unsafe about the use of the medicine in the first trimester. CMA does not agree with or believe that the use of above warning statement is justified for the following reasons.

1. When a sponsor lists a medicine, they must certify under s.26A(2)(b) of the Therapeutic Goods Act that the medicine is safe for the purposes for which it is to be used; and under s.26A(2)(f) that the medicine complies with all prescribed quality or

safety criteria that are applicable to the medicine. A review of the reasons provided for cancellation of medicines in the last five years from the TGA website reveals that there were no maternal health products cancelled for incorrect certifications under s.26A(2)(b) or (f), indicating that the proposed increase in regulation is unlikely to be in response to a regulatory problem that has been occurring.

2. Indications 6 and 7 refer to preconception health. As the warning statement implies there may be something inherently unsafe about the product, and as it isn't known for many weeks whether pregnancy has occurred, the inclusion of the warning statement will invoke fear and distress. Assuming the preconception product is performing an important function preconceptionally, as some nutrients are known to, the advisory statement implies that women should not be taking these nutrients, which are widely recommended to be taken before and during pregnancy. This is a confusing message, in conflict with best clinical practice and public health messages about preconception and pregnancy health, and is more likely to produce a negative health outcome than to prevent one.

3. Specifically, the warning statement implies there could be inherent harm from taking the supplement in the first trimester. There is a long standing principle behind the use of listed medicines that they are generally safe for use in the general population, including pregnant women, and the CMA is not aware that the use of listed medicines in pregnancy has been associated with challenges to maternal health. No evidence has been presented to demonstrate that harm has been caused to infants or pregnant women due to use of supplements in the first trimester, and there is widely recognised evidence demonstrating the benefit. It is also unclear how a medical practitioner who is aware of the importance of nutrients such as folate, could determine that a product is unsafe in the absence of such evidence. Ingredients that could theoretically cause harm such as high doses of iron are limited by the Poisons Standard or other listing restrictions.

4. If there is concern around particular items such as Vitamin A and B2, the only items that are included in the prescribing medicines in pregnancy database, it is a consideration as to whether an ingredient specifically requires risk mitigation, and is not applicable to pregnancy indications generally.

5. Creating concern in women about the safety of a supplement is very likely to deter women from taking such prenatal supplements in the first trimester even when seeing a medical practitioner. The first trimester is the critical effective window of taking particular nutrients, notably folate and iodine. It is more likely that pregnant women are low in vitamins and minerals and that this may have negative outcomes on the baby. Supplements should not replace a balanced diet however in some cases supplementation may be the most practical and effective way of obtaining required nutrients. Negative outcomes associated with overconsumption is unlikely with normal, responsible use as there is a large safety margin for most vitamins and minerals.

6. Folate supplements and pregnancy multivitamins and minerals are listed medicines with a high degree of regulatory familiarity and no evidence of harm to the population. In the absence of any measurable, identified problem, it appears that the negative consequences of including such a warning statement on a product outweighs the benefits of including it.

7. In the consultation for permitted indications, the TGA has not provided consultation or a balanced regulatory impact analysis regarding the inclusion of this warning statement or other changes in relation to maternal and infant heath products, which constitutes a large regulatory impact.

Table 2. Pregnancy: Specific requirement applying to use of the indication (2)

Label statement: If you are concerned about the health of yourself or your baby, please consult with your healthcare practitioner (or words to that effect)
1. Maintain/support healthy pregnancy
2. Helps enhance/promote maternal health
3. Maintain/support maternal health
4. Decrease/reduce/relieve morning sickness
5. Maintain/support placenta health/growth
6. Helps prepare the body for labour
7. Helps enhance/promote maternal postnatal health
8. Maintain/support breast milk production/lactation
9. Enhance/improve/promote/increase breast milk production
10. Decrease/reduce/relieve excessive breast milk flow
11. Lactifuge/reduce breast milk production

The warning statement 'If you are concerned about the health of yourself or your baby, please consult with your healthcare practitioner' will capture all pregnancy and maternal health related health products. CMA notes it appears as general public health message, but does not agree that the application of above statement is necessary for application to maternal and infant health listed medicines for the following reasons.

1. The warning statement appears to be expressing information that is already well known and understood by the population. A reasonable person with pregnancy/infant health concerns would not delay medical advice because they are taking a supplement for general pregnancy and breastfeeding health.

2. All pregnant women in Australia will be under the care of one or more health care professionals on a very regular basis. It is clearly understood by every reasonable person that if concerned about their maternal or foetal health at any moment in time, that they should seek the care of their maternal care providers. Postpartum mothers and infants are provided regular prenatal and postnatal care including health checkups by maternal and child health nurses as well as other health providers. As they are already under regular, accessible, familiar medical care, it is unnecessary to advise that they need to seek medical care for concerns, and use of the statement is not necessary for the safe or appropriate use of the goods.

3. With the exception of morning sickness, all indications are for the support or enhancement of health or the modulation up or down of a physiological process. They are not indications for the relief of symptoms or conditions, therefore they are not being taken because a woman or her child is experiencing concerning or unusual symptoms. Therefore the warning statement is not applicable to the indications.

4. In relation to morning sickness, it is a common and well understood condition that does not affect the health of the mother or baby, except in rare cases where it is severe, in which case women are generally hospitalised. The symptoms of severe morning sickness or hyperemesis gravidarum are so pronounced that no person would be attempting to self-medicate or avoiding adequate medical care.

5. In the consultation period, the TGA has not provided consultation on this group or a balanced regulatory analysis of the inclusion of this warning statement that does not perform a necessary regulatory function, or the overall effect of the new restrictions on maternal health products as a whole.

Summary – Warning Statements

In all regulation, there must be a balance between appropriate regulation to mitigate genuine, identified risks, generally a problem that represents some magnitude or significance, and not

over-regulating or introducing other risks. Although there is a protective intention to the inclusion of these warning statements, we believe that the warning statements will not only be unnecessary and perhaps considered distressing (for the first) or generally redundant (for the second) by the general public in context of the products that are being presented, and there may be a greater risk introduced than prevented. There is no evidence of harm, the possibility of introducing risks, impact upon a wide category of goods, and no accompanying regulatory analysis on the totality of changes to the maternal health category. There has not been consultation discussing these items, and considering the regulatory impacts to individuals and businesses, a regulatory impact statement has not been conducted.

3. Foetal development indications

Many listed medicines refer to the developing foetus as part of maternal health products. The draft list of permitted indications list excludes this group by not including a population evidence qualifier for this group.

Lack of such a qualifier will decrease transparency and information to consumers about the effects of certain goods. It will have large regulatory impact on many hundreds of medicines, with the effect that any good with such an indication would require to be upregulated to the listed assessed pathway, despite the fact they conform to the eligibility of low risk indications and the low risk principles outlined by the Medicine and Medical Devices Regulation review. As with other items outlined in this submission, specific consultation on the proposal has not occurred despite the effective result in increased regulation. There are many indications included in the list of permitted indications for which it has been and would continue to be appropriate to include this time of population evidence qualifier.

Therefore, CMA is requesting the addition of:

- **In developing foetuses/infants**

However, CMA recognises that there could be concerns regarding the attachment of the qualifier to indications that would not be suitable for this population. If this is the case, then in place of this evidence qualifier, pre-qualified permitted indications could be included in the list for health support indications only.

Pre-qualified health support/maintenance indications to add instead of qualifier:

- supports normal/healthy foetal growth
- supports normal/healthy growth/development of the foetal/infant brain
- supports normal/healthy growth/development of foetal/infant nervous system
- supports healthy development of foetal/infant cognitive function
- supports normal/healthy development of foetal/infant eyesight
- supports normal/healthy development of foetal/infant vision
- supports normal/healthy development of foetal/infant motor skills
- supports normal/healthy development of foetal/infant hearing

4. Healthy Labour Indication

We note that the indication 'Helps maintain/support a healthy labour' has been removed with the note 'modified to make more general' and there is the continued inclusion of 'help the body prepare for labour'. We submit that both indications should continue to be included in the list, as they refer to different time periods and processes. The former may refer to the process/time of labour, where the latter refers to the time period prior to labour. For example, *Rubus idaeus* (raspberry leaf) is typically used for the whole of the third trimester, but not during labour. Other nutrients and herbs can be used supportively during labour itself. Therefore these indications are used differently; both need to be maintained on the list to represent the use of complementary medicines before and during labour.