Submission

Consultation: Changes to permissible ingredients - Low-negligible risk

11 October 2019

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BACKGROUND

About the NHAA

The NHAA is the peak professional association for the naturopathy and Western herbal medicine profession in Australia. Established in 1920, it is also the oldest professional association of complementary therapists in the country. The NHAA represents around 2,000 practitioners and is a member of the World Naturopathic Federation (WNF) which represents practitioners globally.

Our members provide primary care services to people suffering both acute and chronic disease. We use a combination of therapies, including diet, exercise, stress management, supplementation and herbal medicine formulations to deliver holistic treatments. We work alongside other health professionals to support conventional treatment. We play an important role in public health, including the quality use of medicines by Australian consumers.

The primary aims of the NHAA are to:

- Promote, protect and encourage the learning, knowledge and service delivery of naturopathic and Western herbal medicine
- Disseminate such knowledge through available media and networks
- Encourage the highest ideals of professional and ethical standards
- Promote naturopathic and Western herbal medicine as safe and effective public healthcare
- Engage with legislative tools and their representatives as they relate to the practice of naturopathic and Western herbal medicine in Australia

The vision of the NHAA is:

- Practitioners and the practice of naturopathic medicine and Western Herbal medicine are fully integrated into the primary healthcare system in Australia
- The NHAA is recognised as the peak body for naturopathic and Western Herbal medicine
- Naturopathic and Western Herbal medicine is accessible to all
- The integrity of the profession of naturopathic and Western Herbal medicine is maintained
- The standards and quality of education of the professions continue to be promoted
- Career opportunities and research pathways for naturopathic and Western Herbal medicine professionals are developed and maintained
- The integration of traditional knowledge and evolving science is continued

The NHAA publishes the quarterly *Australian Journal of Herbal & Naturopathic Medicine (AJHNM)*. The AJHNM publishes material on all aspects of medical herbalism and naturopathic practice including philosophy, phytochemistry, pharmacology and clinical application of medicinal plants. The NHAA also holds annual seminars throughout Australia, with the Herbal and Naturopathic International Conference held biennially (recently in March 2019 the *11th Herbal & Naturopathic International Conference* kicked off the NHAA's 100th year Celebrations). Since its inception, the NHAA and its members have been at the forefront of naturopathic and Western Herbal medicine and have been influential in areas ranging from education and practice to ethical, regulatory and industry standards.

Proposed changes to the Permissible Ingredients Determination - low-negligible risk

Withania somnifera

TGA proposes the label claim: 'Consult a health care professional prior to use if you are pregnant or breastfeeding.' The NHAA does not support the inclusion of the proposed label claim/warning statement.

The rationale provided for TGA's proposal is based on:

1. Seven traditional texts and ethnobotanical surveys, five references are positive for the *Withania somnifera* suggesting its use to aid conception, pregnancy and lactation, to treat infertility and menstrual irregularities whilst the remaining two suggest *Withania somnifera* may be abortifacient.
2. A statement from ACCM that there is insufficient anecdotal and clinical evidence to establish that *Withania somnifera* is safe in pregnancy or as an abortifacient

Regarding the evidence the NHAA would like to submit the following considerations:

1. The evidence selected for review is primarily tradition in nature, at the exclusion of the typically applicable experimental models used to establish risk to maternal and foetal health, such as animal toxicity studies.
2. Of the evidence selected by the TGA, the majority suggested that WS is safe in pregnancy and lactation.
3. One of the sources which refers to an abortifacient effect is a book by dated 1982 however, as noted Mills and Bone (2005; p631) the definition of abortifacient was very broad at the time and included emmenagogue and ecbolic.
4. Mahmood is narrative on the diversity of medicinal plants used in the Gujrawala District in Pakistan and does not discuss toxicity
5. Moteetee (2016) is a study an ethnobotanical survey of hundreds of plants in an area. It does not describe the interview methods or the search method performed. It concludes that 87 plants were used for several reproductive problems, and lists WS as one example for removing contents of conception. It does not weight WS as more dangerous than any of the other plants mentioned in the survey.
6. In a rat study not included in the TGA's evidence provided, Prabu and Panchapakesan (2014) found "no evidence of maternal or foetal toxicity …. *Withania somnifera* root extract caused no changes ($p < 0.05$) in body weight of parental females, number of corpora lutea, implantations, viable foetuses, external, skeletal and visceral malformations. They concluded: "Under the conditions of the study, the no-observed-effect level of *Withania somnifera* root extract for maternal and developmental toxicity was concluded to be at least 2000 mg/kg/day."
7. The 2018 review by Azgomi on female and male reproductive health found positive effects on both reproductive systems. The search strategy included *in vivo* and *in vitro* models and included pregnancy in the search terms. No negative findings regarding pregnancy were reported.
8. A search of the Database of Adverse Event Notifications (DAEN) of all medicines containing *Withania somnifera* found no reported gynaecological events.

Whilst the NHAA appreciates due caution be applied in pregnancy and lactation, in this instance, the label warning statement appears to contradict the traditional indications and animal research which not only demonstrate lack of harm but potentially proffering of a benefit use mentioned while favouring a far smaller number potentially unclear references to a potentially negative impact to lead to the warning statement.

Furthermore, as the women taking it are likely to become pregnant, it's quite possible they could be taking Withania before they know they are pregnant. So consultation 'prior to' would not be possible and may result in undue distress in pregnancy women.

The NHAA maintains that the evidence cited in support of the proposed concerns about *Withania somnifera* are inadequate, and not supported by available scientific data. Therefore, the NHAA does not support the inclusion of the proposed label claim/warning statement of 'Consult a health care professional prior to use if you are pregnant or breastfeeding'.

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Board Director NHAA

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