Complaint to TGA: Recoverthol, Rejoove, Hangover Relief, Hey! King Premium Hangover Relief

See also complaint submitted 30 July 2018, BioRevive® Hydrodol® Hangover Relief Products, AC-MW9QQH4F/2018

This is a complaint about another three listed "hangover remedies" that are currently being promoted to the public. There is also a fourth sponsor (D & X Pty Ltd) with multiple products listed, one of which is advertised.

I submit that this is a "critical" complaint because these products undermine accepted public health messages about responsible drinking and are likely to lead to harm or injury if the claims are relied upon.

See also the appended article commissioned by "The Conversation", "Science or snake oil: Do hangover cures work?".

These products should be delisted from the ARTG.

Publications:

- https://www.rejoove.co/
- https://www.facebook.com/RejooveAUS/
- https://www.amcal.com.au/rejoove-hangover-relief-8-tablets-p-9348204000992
- Etc.
- https://recoverthol.com.au/
- https://www.facebook.com/recoverthol/
- https://www.youtube.com/watch?v=LdqNP4a2OrM
- https://twitter.com/recoverthol?lang=en
- http://www.dailymail.co.uk/news/article-5515141/Brisbane-pharmacist-think-shesdeveloped-ultimate-cure.html
- Etc.
- https://www.bodyarmour.com.au
- http://www.dandx.com.au/Hangover-Relief.htmlEtc.

Date/Edition: 7/08/2018

Products:

- ARTG: 296905, Rejoove, Clever Health
- ARTG: 291026, Recoverthol, Plus Daily Ltd
- ARTG: 289237, Hey! KING STANDARD, D & X Pty Ltd
- ARTG: 288722, Hey! King Premium, D & X Pty Ltd
- ARTG: 300798, Hangover Relief Exclusive, D & X Pty Ltd
- ARTG: 301646, Hangover Relief, Body Armour Pty Ltd
- ARTG: 304293, Hangover Relief, Body Armour Pty Ltd
- ARTG: 306807, Hangover Relief Boon, D & X Pty Ltd
- ARTG: 30079, Hangover Relief Exclusive, D & X Pty Ltd

Dr Ken Harvey MBBS, FRCPA, AM

Associate Professor

Department of Epidemiology and Preventive Medicine School of Public Health and Preventive Medicine

Monash University Alfred Campus 553 St Kilda Rd Melbourne VIC 3004

Complaint to TGA: Recoverthol, Rejoove, Hangover Relief, Hey! King Premium Hangover Relief

Mobile: +61 419181910

Email: <u>kenneth.harvey@monash.edu</u>
WWW: <u>www.medreach.com.au</u>

7 August 2018

Science or snake oil: Do hangover cures work?

Authors

- 1. Ken Harvey Associate Professor, School of Public Health and Preventive Medicine, Monash University
- 2. Paulina Stehlik Senior research fellow, Bond University



Hangover products advertised in Australia.

The recent article in 'The Conversation', "<u>Drink, drank, drunk</u>" prompted us to review the <u>2015</u> <u>article on hangovers</u> which concluded, "there is no cure".

Since that article was published, eight "hangover" products have been listed on the Australian Register of Therapeutic Goods (ARTG). Three are currently marketed (<u>Recoverthol</u>, <u>Rejoove</u> and <u>Hydrodol</u>. Another, (<u>Body Armour™ Hangover Relief</u>) is "coming soon". The marketing status of four others listed by D & X Pty Ltd is uncertain. These new products make strong claims:

- 1. Recoverthol is "Australian formulated and tested". "Avoid hangover symptoms, just snap and pour 1 vial into your first drink". "Party with protection".
- 2. Hydrodol provides, "Natural hangover relief".
- 3. Rejoove "has been scientifically formulated and tested to provide symptomatic relief of a hangover". "Approved by the Therapeutic Goods Administration (TGA)".
- 4. Body Armour Hangover Relief is, "Australia's best & scientifically proven Hangover Relief".

The four products promoted contain a total of 70 ingredients. The smallest number of ingredients per product was 3, the average 18 and the most 34.

Vitamin B3 (Nicotinamide) was listed in all four products. *Silybum marianum* (Milk thistle), *Pueraria lobata* (Kudzu root), Vitamin B1 (Thiamine), B2 (Riboflavin) B6 (Pyridoxine), B12 (Cyanocobalamin) and an amino acid (cysteine) were found in three products. *Hovenia dulcis* (Japanese Raisin Tree), Vitamin C (ascorbic acid) and Vitamin B5 (calcium pantothenate) were listed in two products.

The <u>reason</u> given for including vitamins and amino acids in hangover products is that the liver only stores limited volumes of enzymes that break down alcohol such as aldehyde dehydrogenase (ALDH). It's claimed that providing additional enzyme co-factors reduces toxic by-products and hangover symptoms.

Science or snake oil: Do hangover cures work?

Regardless of the attractiveness of this hypothesis, a current search of the scientific literature found no evidence from clinical trials that supplementation with vitamins and amino acids reduces hangover symptoms.

What about herbal ingredients? *Silybum marianum* (Milk thistle) is <u>said</u> to be "traditionally used... protecting your liver from toxin and environmental pollution related damage".

Pueraria lobata (Kudzu root) is another traditional hangover remedy. It's <u>said</u> "to enhance acetaldehyde removal".

Hovenia dulcis (Japanese Raisin Tree) is <u>said</u> to be "among the premier anti-hangover herbal medicines in China. There is ample scientific evidence showing it to lower alcohol concentrations in the blood, restoring the liver's activity... and reducing the effect of a hangover".

We investigated the evidence for these claims. We found two systematic reviews (2005) and (2017) that looked at hangover cures. None of the ingredients used in hangover cures marked in Australia were mentioned in these reviews.

Pueraria lobata (Kudzu root) <u>has been reported</u> to inhibit aldehyde dehydrogenase and elevate acetaldehyde levels (the opposite of what is claimed above). There is <u>concern</u> that its use in hangover remedies, may predispose subjects to an increased risk of acetaldehyde-related neoplasm and pathology.

We found one randomised controlled trial that explored the effect of *Hovenia dulcis* in alleviating hangover symptoms. Among 14 items hangover symptoms evaluated, headache, dizziness and weakness were improved in the intervention group compared to the controls (P< 0.05). The limitations of this study included a small sample size, no female subjects, only Korean Soju was tested, and a relatively short study period (12 h). These results need replication with a larger number of mixed sex and age subjects and a variety of alcohol preparations.

Australian products containing *Hovenia dulcis* do not appear to use the standardised extract used in the above small trial and the amount contained (according to their ARTG entries) varies, Rejoove 75 mg (2 tablets recommended); Body Armour Hangover Relief 30 mg/mL (100 ml recommended). In our opinion, the limited scientific evidence about this ingredient does not support the strong advertising claims made.

The TGA accepts "<u>traditional evidence</u>" (use for over 75 years) for indications and claims of <u>listed medicines</u>. Indeed, the <u>controversial Therapeutic Goods (Permissible Indications) Determination No.1 of 2018</u> specifically allows "Decrease/ reduce/ relieve symptoms associated with occasional overindulgence" albeit with the caveat, "Product presentation must not imply or refer to excess consumption of alcohol".

A complaint to the TGA alleged that advertisements such as the following breach the above provision.

Science or snake oil: Do hangover cures work?



Hydrodol Instagram jpg. Internet

What about the other products promoted? We argue they all breach the objects of the Therapeutic Goods Advertising Code 2015. These state that the marketing and advertising of therapeutic goods to consumers should be socially responsible and not mislead or deceive. These products should be de-listed from the ARTG.

We also support <u>Choice and others</u> in calling for an educational statement to be placed on all products invoking traditional claims. For example, "This product is based on traditional beliefs, not modern scientific evidence."

In conclusion, the advice given in 2015 remains unchanged. There is still no proven cure for a hangover. But it can be prevented by drinking in moderation.

7 August 2018